IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN, Petitioner, v. IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	CASE NO. CVCV065114 **CERTIFIED AGENCY RECORD**

The undersigned, as counsel for the Iowa Department of Health and Human Services, certify that the documents accompanying this certificate are true and correct copies of the agency record regarding the contested case concerning the Department's denial of Olsen's application for a medical cannabidiol registration card.

The agency record contains the following documents:

Respectfully submitted,

BRENNA BIRD
ATTORNEY GENERAL OF IOWA

/s/ Laura Steffensmeier
LAURA STEFFENSMEIER
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
Telephone: (515) 281-6690
Facsimile: (515) 281-4209
E-mail: laura.steffensmeier@ag.iowa.gov

/s/ William E. Sales III
WILLIAM E. SALES III
Assistant Attorney General
1305 E. Walnut Street, 2nd Flr.
Des Moines, Iowa 50319
Telephone: (515) 242-6264
Facsimile: (515) 281-4209
E-mail: william.sales@ag.iowa.gov
ATTORNEYS FOR THE IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

Original filed via EDMS this 20th day of March, 2023.

January 20, 2022

Iowa Department of Public Health
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319-0075
Certified Mail Return Receipt: 7015 0920 0002 1767 5776

Department of Public Health:

On November 7,2020, the department denied my application for a medical cannabidiol registration card. The letter denying the application is attached to this letter.

Carl Olsen hereby appeals the denial a medical cannabidiol registration in accordance with 641 Iowa Administrative Code – Chapter 154, Section 7.

Please forward this request within five working days to the department of inspections and appeals.

Thank you!

Carl Olsen
130 E Aurora Ave
Des Moines, Iowa 50313-3654
515-343-9933
carl@carl-olsen.com

January 7, 2022

Mr. Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313

Dear Mr. Olsen,

Your application for an Iowa medical cannabidiol registration card was received by the Department on November 24, 2021. A complete patient application requires the submission of a healthcare practitioner certification form, pursuant to Iowa Code Chapter 124E.4.1.c, below:

1. Issuance to a patient. Subject to subsection 6, the department may issue a medical cannabidiol registration card to a patient who:
   c. *Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.*

Because you did not submit a written certification from your health care practitioner, the Department is unable to approve your application, and it has been denied. Your credit card was automatically processed for the application fee when you submitted your application. Your payment is in the process of being refunded to you.

You maintain the right to appeal this decision. The process for appeal of this denial is outlined in 641 IAC 154.7, below:

- *If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.*

Sincerely,

Owen Parker, MPH
Chief, Bureau of Medical Cannabidiol
Iowa Department of Public Health

Cc: Joseph Husak

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN, Petitioner vs. **IOWA DEPARTMENT OF PUBLIC HEALTH ,** Defendant.	Case No. CVCV062566 **ORIGINAL NOTICE**

TO THE ABOVE-NAMED DEFENDANT:

YOU ARE HEREBY NOTIFIED that there is now on file in the office of the Clerk of Court a *First Amended Petition for Declaratory Judgment* the above-entitled action, a copy of which is attached hereto. The Plaintiff's attorney is Colin C. Murphy with Gourley, Rehkemper & Lindholm, PLC, 440 Fairway Drive, Suite 210, West Des Moines, Iowa 50266.

YOU ARE FURTHER NOTIFIED that unless, within twenty (20) days after service of this *Original Notice* upon you, you serve, and within a reasonable time thereafter file a motion or answer, in the Iowa District Court for Polk County, at the Courthouse in Des Moines, Iowa judgment by default will be rendered against you for the relief demanded in the Petition.

If you require the assistance of auxiliary aids or services to participate in court because of disability, immediately call your district ADA coordinator. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942.)

NOTE: The Attorney(s) who is/are expected to represent the Respondent should be promptly advised by Respondent of the service of this Notice.

E-FILED 2023 MAR 20 10:52 AM POLK - CLERK OF DISTRICT COURT
E-FILED 2022 JAN 18 9:30 AM POLK - CLERK OF DISTRICT COURT

Iowa Judicial Branch

Case No. **CVCV062566**
County **Polk**

Case Title CARL OLSEN V STATE OF IOWA

You must file your Appearance and Answer on the Iowa Judicial Branch eFile System, unless the attached Petition and Original Notice contains a hearing date for your appearance, or unless the court has excused you from filing electronically (*see* Iowa Court Rule 16.302).

Register for the eFile System at www.iowacourts.state.ia.us/Efile to file and view documents in your case and to receive notices from the court.

For general rules and information on electronic filing, refer to the Iowa Rules of Electronic Procedure in chapter 16 of the Iowa Court Rules at www.legis.iowa.gov/docs/ACO/CourtRulesChapter/16.pdf.

Court filings are public documents and may contain personal information that should always be kept confidential. For the rules on protecting personal information, refer to Division VI of chapter 16 of the Iowa Court Rules and to the Iowa Judicial Branch website at www.iowacourts.gov/for-the-public/representing-yourself/protect-personal-information/.

Scheduled Hearing:

If you need assistance to participate in court due to a disability, call the disability access coordinator at **(515) 286-3394** . Persons who are hearing or speech impaired may call Relay Iowa TTY (1-800-735-2942). For more information, see www.iowacourts.gov/for-the-public/ada/. **Disability access coordinators cannot provide legal advice.**

Date Issued **01/18/2022 09:30:59 AM**

District Clerk of Court or/by Clerk's Designee of Polk *County*
/s/ Christy Wagner

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN, Petitioner, vs. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	No. ***CVCV062566*** ***FIRST AMENDED PETITION FOR DECLARATORY JUDGMENT***

COMES NOW Petitioner Carl Olsen, through counsel, Colin Murphy, and for the First Amened Petition for Declaratory Judgment states:

PARTIES

1. Petitioner, Carl Olsen, ("**Olsen**"), is a resident of Polk County, Iowa.

2. Respondent is the Iowa Department of Public Health ("**Department**").

JURISDICTION AND VENUE

3. The court has jurisdiction over this matter pursuant to Iowa Code § 602.6101 (2021).

4. Venue is proper pursuant to Iowa Code § 616.3(2) (2021) because this matter arises in Polk County.

DECLARATORY RELIEF

5. This declaratory action is based on Olsen's constitutional right to the free exercise of religion under both the First Amendment and article 1, section 3 of the Iowa Constitution to purchase medical cannabidiol products from licensed Iowa dispensaries under Iowa Code chapter 124E, possess and use the same and enjoy any affirmative defenses available, including those in chapters 124 and 453B.

FACTUAL ALLEGATIONS

6. In 2014, the State enacts Iowa Code Chapter 124D (2014), 2014 Iowa Acts Chapter 1125. This act provides an exemption for non-psychoactive cannabinoids found in the plant *Cannabis sativa L.* or *Cannabis indica* or any other preparation that is essentially free from plant material and has a tetrahydrocannabinol ("THC") level of no more than three percent. *See* Iowa Code § 124D.2(1) (2014). These marijuana extracts are to be obtained from an out-of-state source. *See id.* § 124D.6(1)(b) (2014).

7. In 2017, the State repeals chapter 124D by enacting Iowa Code Chapter 124E. 2017 Iowa Acts Chapter 162. This act provides for the manufacture, distribution, retail sales of the marijuana extracts in Iowa. *See* Iowa Code § 124E.2(6) (2017). These marijuana extracts are to be obtained from an out-of-state source, if not available in Iowa. *See id.* § 124E.12 (2017). Retail sales begin on December 1, 2018.

8. In 2020, the State removes the three percent cap on THC. Iowa Code § 124E.2(6) (2020). The law now allows 4.5 grams of THC every 90 days. *See id.* § 124E.9(14). The limit can be increased by a health care practitioner. *Id.* § 124E.9(15)(b).

9. Olsen is a member of the Ethiopian Zion Coptic Church.

10. The sacramental, non-drug use of cannabis in bona fide religious worship is one of Olsen's sincerely held religious beliefs.

11. Olsen stopped using cannabis as a sacrament following the decision in *Employment Div. v. Smith*, 494 U.S. 872, 110 S. Ct. 1595, 108 L. Ed. 2d 876 (1990), and wishes now to resume his religious practice in a manner consistent with the secular use of cannabis extracts permitted under chapters 124, 124E and 453B.

12. On November 24, 2021, Olsen submitted an application fee in the amount of $100 and filed an application for a registration card with the Department pursuant to Iowa Code section 124E.4(1)(3).

13. On January 7, 2022, the Department denied Olsen's application for a registration card. *See* Ex. 2.

14. Olsen will appeal the Department's decision.

LIMITED RELIGIOUS EXEMPTION

15. Olsen hereby incorporates the previous allegations as though they were fully set forth herein.

16. The First Amendment provides: "[c]ongress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . . ." U.S. Const. amend. I.

17. The First Amendment is applicable to the states through the Due Process clause of the Fourteenth Amendment.

18. The Iowa Constitution similarly provides: "[t]he general assembly shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . . ." Iowa Const. art. 1, § 3.

19. The Free Exercise Clauses prohibit a state from enforcing a regulatory law that is neither neutral nor generally applicable. *See Mitchell County v. Zimmerman*, 810 N.W.2d 1 (Iowa 2012) (noting a regulatory law may lack sufficient generally applicability when it contains exceptions that undermine its purpose).

20. Iowa Code chapter 124 is not neutral toward religion because it contains a religious exemption for peyote. *See* Iowa Code § 124.204(8) (2021) ("[n]othing in [Chapter 124] shall apply to peyote when used in bona fide religious ceremonies of the

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Native American Church.") The peyote exemption was enacted in 1967, which immediately followed the federal religious exemption created by administrative regulation in 1966 and carried over into the federal Controlled Substance Act of 1970. *See* 54 Fed. Reg. 4679 (1966); 21 C.F.R. § 166.3(c)(3) (1968); currently codified at 21 C.F.R. § 1307.31.

21. Iowa Code chapters 124 and 453B are no longer generally applicable with respect to marijuana as a result of the secular exemption carved out for medical cannabidiol in chapter 124E.

22. Olsen's sincerely held religious belief in the sacramental use of cannabis is at least equal to the secular use of cannabis extract permitted under chapters 124, 124E and 453B.

WHEREFORE, Olsen respectfully requests this Court to enter a judgment that declares:

(1) The Department shall consider Olsen's religious use of cannabis as a qualifying condition under Iowa Code section 124E.2(2) and, thereafter, respond to Olsen's application for a registration card.

Respectfully submitted,

By: /s/ Colin Murphy AT0005567
GOURLEY REHKEMPER LINDHOLM, P.L.C.
440 Fairway, Suite 210
West Des Moines, Iowa 50266
T: (515) 226-0500
F: (515) 244-2914
E-mail: ccmurphy@grllaw.com

ATTORNEY FOR PETITIONER

Original filed.

Copy to counsel via EDMS.

January 7, 2022

Mr. Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313

Dear Mr. Olsen,

Your application for an Iowa medical cannabidiol registration card was received by the Department on November 24, 2021. A complete patient application requires the submission of a healthcare practitioner certification form, pursuant to Iowa Code Chapter 124E.4.1.c, below:

1. Issuance to a patient. Subject to subsection 6, the department may issue a medical cannabidiol registration card to a patient who:
   c. *Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.*

Because you did not submit a written certification from your health care practitioner, the Department is unable to approve your application, and it has been denied. Your credit card was automatically processed for the application fee when you submitted your application. Your payment is in the process of being refunded to you.

You maintain the right to appeal this decision. The process for appeal of this denial is outlined in 641 IAC 154.7, below:

- *If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.*

Sincerely,

Owen Parker, MPH
Chief, Bureau of Medical Cannabidiol
Iowa Department of Public Health

Cc: Joseph Husak

EXHIBIT
tabbies
2

IOWA DEPARTMENT OF
INSPECTIONS & APPEALS

ADMINISTRATIVE HEARINGS DIVISION
Wallace State Office Building, Third Floor
502 East 9th Street
Des Moines, IA 50319-0083
(515) 281-6468

KIM REYNOLDS
GOVERNOR

ADAM GREGG
LT. GOVERNOR

RODNEY A. ROBERTS, DIRECTOR

TRANSMITTAL FORM

Transmitting Agency

Agency Name	*Phone Number*	*Email Address*
Iowa Department of Public Health	515-418-7574	Owen.Parker@idph.iowa.gov
Address 321 E 12th St	*City, State, Zip* Des Moines Iowa 50319	
Transmitting Officer, Title Owen Parker, Bureau Chief, Medical Cannabidiol	*Agency File/Docket/Reference Numbers(s)*	*Date Received by Agency* 1/20/22

Appellant

Name	*Phone Number*	*Email Address (if known)*
Carl Olsen	515-343-9933	carl@carl-olsen.com
Address 130 E Aurora Ave	*City, State, Zip* Des Moines, Iowa 50313-3654	

Jurisdictional and Other Authority Involved in Case

Iowa Code Section(s)	*Iowa Administrative Rule(s) or Federal Regulation(s)*
Iowa Code 124E	641 IAC 154.7

Statement of the Issues Involved and Reference to Particular Sections of Statues and Rules Involved

Special Requests (Include any special features or requirements such as a required petition or answer, specialized expertise needed by administrative law judge, mandatory time limits or notice requirements that apply to case, requests regarding preferred potential hearing dates or dates to avoid, and requests for in-person or telephone-conference-call hearings. Attach additional pages if necessary.)

Attorney for Appellant (If any)

Name	*Phone Number*	*Email Address (if known)*
Colin Murphy	(515) 226-0500	ccmurphy@grllaw.com
Address 440 Fairway, Suite 210	*City, State, Zip* West Des Moines, Iowa 50266	

Send Copies to (Other Agency Contacts, Attorney General's Office, Other Parties, etc. Attach additional pages if necessary)

List Name, Title, and Mailing or Email Address for each Contact

Laura Steffensmeier, AAG: Laura.Steffensmeier@ag.iowa.gov

Heather Adams, AAG: Heather.adams@iowa.gov

Sarah Reisetter, Deputy Director: Sarah.reisetter@idph.iowa.gov

Owen Parker, Chief, Burea of Medical Cannabidiol: Owen.parker@idph.iowa.gov

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building, Third Floor
Des Moines, IA 50319

Carl Olsen, Appellant, v. Iowa Department of Public Health, Respondent.	Case No. 22IDPH0002 NOTICE OF IN-PERSON HEARING

Pursuant to section 17A.12 of the Iowa Code, a hearing shall be conducted in this proceeding by telephone conference call before the administrative law judge (ALJ) and at the date and time designated below:

DATE: March 15, 2022
TIME: 9:00 a.m. Central Time
PLACE: Administrative Hearings Division, Wallace State Office Building, 502 E. 9th Street, Third Floor, Des Moines, IA 50319
ALJ: Carla Hamborg (Email: carla.hamborg@dia.iowa.gov; Phone: 515-281-7183)

In lieu of an in-person hearing, the hearing may be held by telephone with the consent of all parties pursuant to rule 641-173.8. A request for a telephone hearing shall be made to the assigned administrative law judge.

Important additional instructions for participating in this hearing are on the next page of this Notice. Failure to appear and participate in the hearing may result in the entry of a default judgment.

The hearing shall be conducted under the authority of and pursuant to the following statutes and administrative rules involved in the proceeding:

IOWA CODE SECTION(S): 124E
IOWA ADMINISTRATIVE RULE(S): 641-154.7

The following matters have been asserted and will be decided in the proceeding:

- Whether the Department correctly rejected Carl Olsen's application for an Iowa medical cannabidiol registration card.

Issued this January 31, 2022.

cc: Carl Olsen, Appellant, 130 E Aurora Ave, Des Moines, IA 50313-3654
carl@carl-olsen.com (By Email and Mail)
Colin Murphy, Attorney for Appellant, 440 Fairway, Suite 210, West Des Moines, IA 50266 ccmurphy@grllaw.com (By Email and Mail)
Laura Steffensmeier, AAG laura.steffensmeier@ag.iowa.gov (By AEDMS)
Heather Adams, AAG heather.adams@iowa.gov (By Email)

Sarah Reisetter, IDPH sarah.reisetter@idph.iowa.gov (By Email)
Owen Parker, IDPH owen.parker@idph@iowa.gov (By Email)

INSTRUCTIONS TO PARTICIPATE IN THE HEARING:

Exhibits: If you wish to have documents or other exhibits considered by the administrative law judge in the hearing, you must do the following unless otherwise ordered by the administrative law judge:

- Deliver, mail, fax or email the documents or other exhibits **to the administrative law judge** at the following location **at least 7 days before the hearing**:

  Division of Administrative Hearings
  Wallace State Office Building, Third Floor
  Des Moines, IA 50319
  Fax: (515) 281-4477
  E-Mail: adminhearings@dia.iowa.gov

- Deliver, mail, fax or email the documents or other exhibits **to all other parties to the case.**
- Please mark any materials you submit with your full name and case number of your case. The case number is found on the first page of this notice on the top right-hand corner of the document.

Witnesses: If you wish to have any witnesses (other than yourself) present testimony at the hearing, you must do the following unless otherwise ordered by the administrative law judge:

- Mail, fax, or email a list of the names of each witness to the administrative law judge and the other parties **at least 7 days before the hearing**.
- Make sure that your witnesses understand that they must be available at the date and time of the hearing. **If your witnesses are not available and present at the time of the hearing, they will not be able to testify unless granted permission to testify by telephone.**

Legal Representation: You are not required to have an attorney and may represent yourself in this proceeding. But you should seriously consider obtaining legal advice or representation. You may qualify for free legal assistance from Iowa Legal Aid. To apply, call Iowa Legal Aid at **1-800-532-1275** or visit **www.iowalegaid.org**. More information about obtaining legal representation is also available on the Administrative Hearings Division website at **http://dia.iowa.gov/ahd**.

More Information: Additional information about this proceeding, including a directory of administrative law judge phone numbers and links to the applicable statutes and administrative rules, is available online at **http://dia.iowa.gov/ahd**. Parties with questions may also contact the Division at (515) 281-6468 or by email at **adminhearings@dia.iowa.gov**.

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building – Third Floor
Des Moines, Iowa 50319

Carl Olsen	)	
	)	Docket No. 22IDPH0002
Appellant,	)	
	)	
v.	)	**Order Rescheduling**
	)	**Telephone Hearing**
Iowa Department of Public Health	)	
	)	
Respondent,	)	

This is an appeal from a decision of the Iowa Department of Public Health to deny the Appellant's application for an Iowa medical cannabidiol registration card. An in-person hearing is scheduled for March 15, 2022. Prior to the hearing, the Appellant moved to continue the hearing pending a decision in a related district court action. The Appellant also requested that the hearing be conducted by telephone.

The Respondent does not resist the motion. Accordingly, the motion is granted. The hearing is re-scheduled for **9:00 a.m. on Tuesday, April 19, 2022.**

At the date and time of the hearing, all parties must call the toll-free number **1-866-770-6601. The system will ask if you are the organizer. You are not the organizer – Do not press 2.** You will be placed on hold until the judge enters the conference call.

Dated this 9th day of March, 2022.

Carla J. Hamborg
Administrative Law Judge

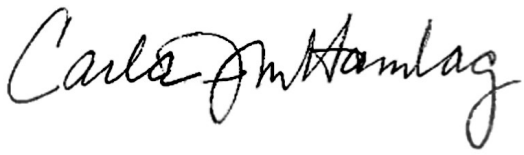
cc: Carl Olsen (by Mail and Email)
Colin Murphy, Attorney for Appellant (by Mail and Email)
Laura Steffensmeier, AAG (By AEDMS)
Heather Adams, AAG (By Email)
Sarah Reisetter, IDPH (By Email)
Owen Parker, IDPH (By Email)

Case Title: CARL OLSEN V. IOWA DEPARTMENT OF PUBLIC HEALTH

Case Number: 22IDPH0002

Type: Order

IT IS SO ORDERED.



Carla Hamborg, Administrative Law Judge

ELECTRONICALLY FILED 2022 APR 04 2:37 PM ADMIN HEARING E-FILING SYSTEM
E-FILED 2023 MAR 20 10:52 AM POLK - CLERK OF DISTRICT COURT

Iowa Department of Inspections and Appeals
Division of Administrative Hearings

CARL OLSEN, Appellant, v. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	)	DIA Docket No. 22IDPH002 **IOWA DEPARTMENT OF PUBLIC HEALTH'S WITNESS AND EXHIBIT LIST**

COMES NOW, the Iowa Department of Public Health, by and through the undersigned, and submits the following Witness List and Exhibit List for the contested case hearing.

Witness List

1. Owen Parker

Exhibit List

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

/s/ Heather Adams
HEATHER ADAMS
Assistant Attorney General
1305 East Walnut Street, 2nd Fl.
Des Moines, Iowa 50319
Ph: (515) 281-3441
Email: Heather.Adams@ag.iowa.gov

/s/ Laura Steffensmeier
LAURA STEFFENSMEIER
Assistant Attorney General
1305 East Walnut Street, 2nd Fl.
Des Moines, Iowa 50319
Ph: (515) 281-6690
Email: Laura.Steffensmeier@ag.iowa.gov

ATTORNEYS FOR IOWA
DEPARTMENT OF PUBLIC HEALTH

Filed electronically via AEDMS.

Copy to:

Colin Murphy
ATTORNEY FOR APPELLANT
ccmurphy@grllaw.com

Proof of Service

The undersigned certifies that the foregoing instrument was served upon Attorney for Appellant by delivery in the following manner on the 4th day of April, 2022.

___ U.S. Mail	___FAX
___ Hand Delivery	___Overnight
___ Federal Express	___Other
_X_ Electronically	

Signature: */s/ Laura Steffensmeier*

CHAPTER 124E

MEDICAL CANNABIDIOL ACT

Referred to in §124.401, 204.17, 730.5

124E.1 Short title.

This chapter shall be known and may be cited as the "*Medical Cannabidiol Act*".

2017 Acts, ch 162, §4, 25

124E.2 Definitions.

As used in this chapter:

1. "*Bordering state*" means the same as defined in section 331.910.
2. "*Debilitating medical condition*" means any of the following:

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. AIDS or HIV as defined in section 141A.1.

e. Crohn's disease.

f. Amyotrophic lateral sclerosis.

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. Chronic pain.

j. Severe, intractable autism with self-injurious or aggressive behaviors.

k. Post-traumatic stress disorder.

3. "*Department*" means the department of public health.
4. "*Disqualifying felony offense*" means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).
5. "*Employee*" means a natural person who is employed in this state for wages by an employer.

EXHIBIT 1

IDPH - 001

6. *"Employer"* means a person who in this state employs for wages an employee.

7. *"Health care practitioner"* means an individual licensed under chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, a physician assistant licensed under chapter 148C, an advanced registered nurse practitioner licensed under chapter 152, or an advanced practice registered nurse under chapter 152E, who is a patient's primary care provider or a podiatrist licensed pursuant to chapter 149.

8. *"Laboratory"* means the state hygienic laboratory at the university of Iowa in Iowa City or any other independent medical cannabidiol testing facility accredited to standard ISO/IEC 17025 by an international organization for standards-approved accrediting body, with a controlled substance registration certificate from the United States drug enforcement administration and a certificate of registration from the board of pharmacy. For the purposes of this chapter, an independent laboratory is a laboratory operated by an entity that has no equity ownership in a medical cannabidiol manufacturer.

9. *"Marijuana"* means any derivative of marijuana including but not limited to medical cannabidiol.

10. *"Medical cannabidiol"* means any pharmaceutical grade cannabinoid found in the plant Cannabis sativa L. or Cannabis indica or any other preparation thereof that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule.

11. *"Primary caregiver"* means a person who is a resident of this state or a bordering state as defined in section 331.910, 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 cannabidiol pursuant to the provisions of this chapter.

12. *"Total tetrahydrocannabinol"* means eighty-seven and seven-tenths percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

13. *"Untreatable pain"* 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.

14. *"Written certification"* means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

2017 Acts, ch 162, §5, 25; 2020 Acts, ch 1116, §2 – 5
Referred to in §96.5, 124.401

124E.3 Health care practitioner certification — duties.

1. Prior to a patient's submission of an application for a medical cannabidiol registration card pursuant to section 124E.4, a health care practitioner shall do all of the following:

a. 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 under this chapter, and if so determined, provide the patient with a written certification of that diagnosis.

b. Provide explanatory information as provided by the department to the patient about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

2. Subsequently, the health care practitioner shall do the following:

a. 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.

b. Otherwise comply with all requirements established by the department pursuant to rule.

3. A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this section.

2017 Acts, ch 162, §6, 25
Referred to in §124E.11

124E.4 Medical cannabidiol registration card.

1. *Issuance to patient.* Subject to subsection 6, the department may issue a medical cannabidiol registration card to a patient who:

a. Is at least eighteen years of age.

b. Is a permanent resident of this state.

c. Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.

d. Submits an application to the department, on a form created by the department, that contains all of the following:

(1) The patient's full name, Iowa residence address, date of birth, and telephone number.

(2) A copy of the patient's valid photo identification.

(3) Full name, address, and telephone number of the patient's health care practitioner.

(4) Full name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) Any other information required by rule.

e. Submits a medical cannabidiol registration card fee of one hundred dollars to the department. If the patient attests to receiving social security disability benefits, supplemental security insurance payments, or being enrolled in the medical assistance program, the fee shall be twenty-five dollars.

2. *Patient card contents.* A medical cannabidiol registration card issued to a patient by the department pursuant to subsection 1 shall contain, at a minimum, all of the following:

a. The patient's full name, Iowa residence address, and date of birth.

b. The date of issuance and expiration date of the medical cannabidiol registration card.

c. Any other information required by rule.

3. *Issuance to primary caregiver.* For a patient in a primary caregiver's care, subject to subsection 6, the department may issue a medical cannabidiol registration card to the primary caregiver who:

a. Submits 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.

b. Submits an application to the department, on a form created by the department, that contains all of the following:

(1) The primary caregiver's full name, residence address, date of birth, and telephone number.

(2) The patient's full name.

(3) A copy of the primary caregiver's valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) Any other information required by rule.

c. Submits a medical cannabidiol registration card fee of twenty-five dollars to the department.

4. *Primary caregiver card contents.* A medical cannabidiol registration card issued by the department to a primary caregiver pursuant to subsection 3 shall contain, at a minimum, all of the following:

a. The primary caregiver's full name, residence address, and date of birth.

b. The date of issuance and expiration date of the registration card.

c. The medical cannabidiol registration card number of each patient in the primary caregiver's care. If the patient in the primary caregiver's care is under the age of eighteen, the full name of the patient's parent or legal guardian.

d. Any other information required by rule.

5. *Expiration date of card.* A medical cannabidiol registration card issued pursuant to this section shall expire one year after the date of issuance and may be renewed.

6. *Federally approved clinical trials.* The department shall not approve the issuance of a medical cannabidiol registration card pursuant to this section for a patient who is enrolled in

a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

2017 Acts, ch 162, §7, 25; 2019 Acts, ch 24, §17, 18; 2020 Acts, ch 1116, §6 – 16
Referred to in §124E.3, 124E.11

124E.5 Medical cannabidiol board — duties.

1. *a.* A medical cannabidiol board is created consisting of eight practitioners representing the fields of neurology, pain management, gastroenterology, oncology, psychiatry, pediatrics, family medicine, and pharmacy, and one representative from law enforcement.

b. The practitioners shall be licensed in this state and nationally board-certified in their area of specialty and knowledgeable about the use of medical cannabidiol.

c. Applicants for membership on the board shall submit a membership application to the department and the governor shall appoint members from the applicant pool.

d. For purposes of this subsection, *"representative from law enforcement"* means a regularly employed member of a police force of a city or county, including a sheriff, or of the state patrol, in this state, who is responsible for the prevention and detection of crime and the enforcement of the criminal laws of this state.

2. The medical cannabidiol board shall convene at least twice per year.

3. The duties of the medical cannabidiol board shall include but not be limited to the following:

a. Accepting and reviewing petitions to add medical conditions, medical treatments, or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under this chapter.

b. Making recommendations relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under this chapter would be medically beneficial.

c. Working with the department regarding the requirements for the licensure of medical cannabidiol manufacturers and medical cannabidiol dispensaries, including licensure procedures.

d. Advising the department regarding the location of medical cannabidiol manufacturers and medical cannabidiol dispensaries throughout the state.

e. Making recommendations relating to the form and quantity of allowable medical uses of cannabidiol.

4. Recommendations made by the medical cannabidiol board pursuant to subsection 3, paragraphs *"b"* and *"e"*, shall be made to the board of medicine for consideration, and if approved, shall be adopted by the board of medicine by rule.

5. On or before January 1 of each year, beginning January 1, 2018, the medical cannabidiol board shall submit a report detailing the activities of the board.

6. The general assembly shall have the sole authority to revise the definition of medical cannabidiol for purposes of this chapter.

2017 Acts, ch 162, §8, 25; 2020 Acts, ch 1116, §17

124E.6 Medical cannabidiol manufacturer licensure.

1. *a.* The department shall issue a request for proposals to select and license by December 1, 2017, up to two medical cannabidiol manufacturers to manufacture and to possess, cultivate, harvest, transport, package, process, or supply medical cannabidiol within this state consistent with the provisions of this chapter. The department shall license new medical cannabidiol manufacturers or relicense the existing medical cannabidiol manufacturers by December 1 of each year.

b. Information submitted during the application process shall be confidential until a medical cannabidiol manufacturer is licensed by the department unless otherwise protected from disclosure under state or federal law.

2. As a condition for licensure, a medical cannabidiol manufacturer must agree to begin supplying medical cannabidiol to medical cannabidiol dispensaries in this state no later than December 1, 2018.

3. The department shall consider the following factors in determining whether to select and license a medical cannabidiol manufacturer:

a. The technical expertise of the medical cannabidiol manufacturer regarding medical cannabidiol.

b. The qualifications of the medical cannabidiol manufacturer's employees.

c. The long-term financial stability of the medical cannabidiol manufacturer.

d. The ability to provide appropriate security measures on the premises of the medical cannabidiol manufacturer.

e. Whether the medical cannabidiol manufacturer has demonstrated an ability to meet certain medical cannabidiol production needs for medical use regarding the range of recommended dosages for each debilitating medical condition, the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the debilitating medical conditions, and the form of the medical cannabidiol in the manner determined by the department pursuant to rule.

f. The medical cannabidiol manufacturer's projection of and ongoing assessment of fees on patients with debilitating medical conditions.

4. A medical cannabidiol manufacturer shall contract with a laboratory to perform spot-check testing of the medical cannabidiol produced by the medical cannabidiol manufacturer as provided in section 124E.7. The department shall require that the laboratory report testing results to the medical cannabidiol manufacturer and the department as determined by the department by rule. If a medical cannabidiol manufacturer contracts with a laboratory other than the state hygienic laboratory at the university of Iowa in Iowa City, the department shall approve the laboratory to perform testing pursuant to this chapter.

5. Each entity submitting an application for licensure as a medical cannabidiol manufacturer shall pay a nonrefundable application fee of seven thousand five hundred dollars to the department.

2017 Acts, ch 162, §9, 25; 2020 Acts, ch 1116, §18

124E.7 Medical cannabidiol manufacturers.

1. A medical cannabidiol manufacturer shall contract with a laboratory to perform spot-check testing of the medical cannabidiol produced by the medical cannabidiol manufacturer as to content, contamination, and consistency. The cost of all laboratory testing shall be paid by the medical cannabidiol manufacturer.

2. The operating documents of a medical cannabidiol manufacturer shall include all of the following:

a. Procedures for the oversight of the medical cannabidiol manufacturer and procedures to ensure accurate recordkeeping.

b. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol.

3. A medical cannabidiol manufacturer shall implement security requirements, including requirements for protection of each location by a fully operational security alarm system, facility access controls, perimeter intrusion detection systems, and a personnel identification system.

4. A medical cannabidiol manufacturer shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

5. A medical cannabidiol manufacturer shall not permit any person to consume medical cannabidiol on the property of the medical cannabidiol manufacturer.

6. A medical cannabidiol manufacturer is subject to reasonable inspection by the department.

7. A medical cannabidiol manufacturer shall not employ a person who is under eighteen years of age or who has been convicted of a disqualifying felony offense. An employee of a medical cannabidiol manufacturer shall be subject to a background investigation conducted by the division of criminal investigation of the department of public safety and a national criminal history background check pursuant to section 124E.19.

8. A medical cannabidiol manufacturer owner shall not have been convicted of a

disqualifying felony offense and shall be subject to a background investigation conducted by the division of criminal investigation of the department of public safety and a national criminal history background check pursuant to section 124E.19.

9. A medical cannabidiol manufacturer shall not operate at the same physical location as a medical cannabidiol dispensary.

10. A medical cannabidiol manufacturer shall not operate in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, or supplying, within one thousand feet of a public or private school existing before the date of the medical cannabidiol manufacturer's licensure by the department.

11. A medical cannabidiol manufacturer shall comply with reasonable restrictions set by the department relating to signage, marketing, display, and advertising of medical cannabidiol.

12. *a.* A medical cannabidiol manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries pursuant to this chapter.

b. All manufacturing, cultivating, harvesting, packaging, and processing of medical cannabidiol shall take place in an enclosed, locked facility at a physical address provided to the department during the licensure process.

c. A medical cannabidiol manufacturer shall not manufacture edible medical cannabidiol products.

2017 Acts, ch 162, §10, 25; 2018 Acts, ch 1165, §122, 126; 2020 Acts, ch 1116, §19
Referred to in §124E.6

124E.8 Medical cannabidiol dispensary licensure.

1. *a.* The department shall issue a request for proposals to select and license by April 1, 2018, up to five medical cannabidiol dispensaries to dispense medical cannabidiol within this state consistent with the provisions of this chapter. The department shall license new medical cannabidiol dispensaries or relicense the existing medical cannabidiol dispensaries by December 1 of each year.

b. Information submitted during the application process shall be confidential until a medical cannabidiol dispensary is licensed by the department unless otherwise protected from disclosure under state or federal law.

2. As a condition for licensure, a medical cannabidiol dispensary must agree to begin supplying medical cannabidiol to patients by December 1, 2018.

3. The department shall consider the following factors in determining whether to select and license a medical cannabidiol dispensary:

a. The technical expertise of the medical cannabidiol dispensary regarding medical cannabidiol.

b. The qualifications of the medical cannabidiol dispensary's employees.

c. The long-term financial stability of the medical cannabidiol dispensary.

d. The ability to provide appropriate security measures on the premises of the medical cannabidiol dispensary.

e. The medical cannabidiol dispensary's projection and ongoing assessment of fees for the purchase of medical cannabidiol on patients with debilitating medical conditions.

4. Each entity submitting an application for licensure as a medical cannabidiol dispensary shall pay a nonrefundable application fee of five thousand dollars to the department.

2017 Acts, ch 162, §11, 25

124E.9 Medical cannabidiol dispensaries.

1. *a.* The medical cannabidiol dispensaries shall be located based on geographical need throughout the state to improve patient access.

b. A medical cannabidiol dispensary may dispense medical cannabidiol pursuant to the provisions of this chapter but shall not dispense any medical cannabidiol in a form or quantity other than the form or quantity allowed by the department pursuant to rule.

2. The operating documents of a medical cannabidiol dispensary shall include all of the following:

a. Procedures for the oversight of the medical cannabidiol dispensary and procedures to ensure accurate recordkeeping.

b. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol.

3. A medical cannabidiol dispensary shall implement security requirements, including requirements for protection by a fully operational security alarm system, facility access controls, perimeter intrusion detection systems, and a personnel identification system.

4. A medical cannabidiol dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

5. A medical cannabidiol dispensary shall not permit any person to consume medical cannabidiol on the property of the medical cannabidiol dispensary.

6. A medical cannabidiol dispensary is subject to reasonable inspection by the department.

7. A medical cannabidiol dispensary shall not employ a person who is under eighteen years of age or who has been convicted of a disqualifying felony offense. An employee of a medical cannabidiol dispensary shall be subject to a background investigation conducted by the division of criminal investigation of the department of public safety and a national criminal history background check pursuant to section 124E.19.

8. A medical cannabidiol dispensary owner shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the division of criminal investigation of the department of public safety and a national criminal history background check pursuant to section 124E.19.

9. A medical cannabidiol dispensary shall not operate at the same physical location as a medical cannabidiol manufacturer.

10. A medical cannabidiol dispensary shall not operate in any location within one thousand feet of a public or private school existing before the date of the medical cannabidiol dispensary's licensure by the department.

11. A medical cannabidiol dispensary shall comply with reasonable restrictions set by the department relating to signage, marketing, display, and advertising of medical cannabidiol.

12. Prior to dispensing of any medical cannabidiol, a medical cannabidiol dispensary shall do all of the following:

a. Verify that the medical cannabidiol dispensary has received a valid medical cannabidiol registration card from a patient or a patient's primary caregiver, if applicable.

b. Assign a tracking number to any medical cannabidiol dispensed from the medical cannabidiol dispensary.

c. Properly package medical cannabidiol in compliance with federal law regarding child resistant packaging and exemptions for packaging for elderly patients, and label medical cannabidiol with a list of all active ingredients and individually identifying information.

13. A medical cannabidiol dispensary shall employ a pharmacist or pharmacy technician licensed or registered pursuant to chapter 155A for the purpose of making dosing recommendations.

14. A medical cannabidiol dispensary shall not dispense more than a combined total of four and one-half grams of total tetrahydrocannabinol to a patient and the patient's primary caregiver in a ninety-day period, except as provided in subsection 15.

15. A medical cannabidiol dispensary may dispense more than a combined total of four and one-half grams of total tetrahydrocannabinol to a patient and the patient's primary caregiver in a ninety-day period if any of the following apply:

a. The health care practitioner who certified the patient to receive a medical cannabidiol registration card certifies that patient's debilitating medical condition is a terminal illness with a life expectancy of less than one year. A certification issued pursuant to this paragraph shall include a total tetrahydrocannabinol cap deemed appropriate by the patient's health care practitioner.

b. The health care practitioner who certified the patient to receive a medical cannabidiol registration card certifies that the patient has participated in the medical cannabidiol program and that the health care practitioner has determined that four and one-half grams of total

tetrahydrocannabinol in a ninety-day period is insufficient to treat the patient's debilitating medical condition. A certification issued pursuant to this paragraph shall include a total tetrahydrocannabinol cap deemed appropriate by the patient's health care practitioner.

2017 Acts, ch 162, §12, 25; 2018 Acts, ch 1165, §123, 126; 2020 Acts, ch 1116, §20; 2020 Acts, ch 1121, §62, 70

124E.10 Fees.

All fees collected by the department under this chapter shall be retained by the department for operation of the medical cannabidiol registration card program and the medical cannabidiol manufacturer and medical cannabidiol dispensary licensing programs. The moneys retained by the department shall be considered repayment receipts as defined in section 8.2 and shall be used for any of the department's duties under this chapter, including but not limited to the addition of full-time equivalent positions for program services and investigations. Notwithstanding section 8.33, moneys retained by the department pursuant to this section shall not revert to the general fund of the state but shall remain available for expenditure only for the purposes specified in this section.

2017 Acts, ch 162, §13, 25; 2018 Acts, ch 1165, §124, 126

124E.11 Department duties — rules.

1. *a.* The department shall maintain a confidential file of the names of each patient to or for whom the department issues a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under section 124E.4.

b. Individual names contained in the file shall be confidential and shall not be subject to disclosure, except as provided in subparagraph (1).

(1) Information in the confidential file maintained pursuant to paragraph *"a"* may be released on an individual basis to the following persons under the following circumstances:

(a) To authorized employees or agents of the department as necessary to perform the duties of the department pursuant to this chapter.

(b) To authorized employees of law enforcement agencies of a state or political subdivision thereof, but only for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to this chapter.

(c) To authorized employees of a medical cannabidiol dispensary, but only for the purposes of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to this chapter and that a person has not purchased total tetrahydrocannabinol in excess of the amount authorized by this chapter.

(d) To any other authorized persons recognized by the department by rule, but only for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to this chapter.

(e) To a health care practitioner for the purpose of determining whether a patient seeking a written certification pursuant to section 124E.3 has already received a written certification from another health care practitioner.

(2) Release of information pursuant to subparagraph (1) shall be consistent with the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

2. The department shall adopt rules pursuant to chapter 17A to administer this chapter which shall include but not be limited to rules to do all of the following:

a. Govern the manner in which the department shall consider applications for new and renewal medical cannabidiol registration cards.

b. Ensure that the medical cannabidiol registration card program operates on a self-sustaining basis.

c. Establish the form and quantity of medical cannabidiol allowed to be dispensed to a patient or primary caregiver pursuant to this chapter as appropriate to serve the medical needs of patients with debilitating medical conditions, subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

d. Establish requirements for the licensure of medical cannabidiol manufacturers

and medical cannabidiol dispensaries and set forth procedures for medical cannabidiol manufacturers and medical cannabidiol dispensaries to obtain licenses.

e. Develop a dispensing system for medical cannabidiol within this state that provides for all of the following:

(1) Medical cannabidiol dispensaries within this state housed on secured grounds and operated by licensed medical cannabidiol dispensaries.

(2) The dispensing of medical cannabidiol to patients and their primary caregivers to occur at locations designated by the department.

f. Establish and collect annual fees from medical cannabidiol manufacturers and medical cannabidiol dispensaries to cover the costs associated with regulating and inspecting medical cannabidiol manufacturers and medical cannabidiol dispensaries.

g. Specify and implement procedures that address public safety including security procedures and product quality including measures to ensure contaminant-free cultivation of medical cannabidiol, safety, and labeling.

h. Establish and implement a real-time, statewide medical cannabidiol registry management sale tracking system that is available to medical cannabidiol dispensaries on a twenty-four-hour-a-day, seven-day-a-week basis for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to this chapter and for tracking the date of the sale and quantity of medical cannabidiol purchased by a patient or a primary caregiver.

i. Establish and implement a medical cannabidiol inventory and delivery tracking system to track medical cannabidiol from production by a medical cannabidiol manufacturer through dispensing at a medical cannabidiol dispensary.

2017 Acts, ch 162, §14, 25; 2020 Acts, ch 1116, §21, 22

124E.12 Use of medical cannabidiol — affirmative defenses.

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.

2. A medical cannabidiol manufacturer, including any authorized agent or employee thereof, shall not be subject to prosecution for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, or supplying medical cannabidiol pursuant to this chapter.

3. A medical cannabidiol dispensary, including any authorized agent or employee thereof, shall not be subject to prosecution for dispensing medical cannabidiol pursuant to this chapter.

4. *a.* In a prosecution for the unlawful possession of marijuana under the laws of this state for the possession of medical cannabidiol, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the patient has been diagnosed with a debilitating medical condition, used or possessed medical cannabidiol pursuant to a certification by a health care practitioner as authorized under this chapter, and, for a patient eighteen years of age or older, is in possession of a valid medical cannabidiol registration card issued pursuant to this chapter.

b. In a prosecution for the unlawful possession of marijuana under the laws of this state for the possession of medical cannabidiol, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the person possessed medical cannabidiol because the person is a primary caregiver of a patient who has been diagnosed with a debilitating medical condition and is in possession of a valid medical cannabidiol registration card issued pursuant to this chapter, and where the primary caregiver's possession of the medical cannabidiol is on behalf of the patient and for the patient's use only as authorized under this chapter.

c. If a patient or primary caregiver is charged with the unlawful possession of marijuana under the laws of this state for the possession of medical cannabidiol, including but not limited to chapters 124 and 453B, and is not in possession of the person's medical cannabidiol

registration card, any charge or charges filed against the person for the possession of medical cannabidiol shall be dismissed by the court if the person produces to the court prior to or at the person's trial a medical cannabidiol registration card issued to that person and valid at the time the person was charged.

5. An agency of this state or a political subdivision thereof, including any law enforcement agency, shall not remove or initiate proceedings to remove a patient under the age of eighteen from the home of a parent based solely upon the parent's or patient's possession or use of medical cannabidiol as authorized under this chapter.

6. The department and 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.

7. Notwithstanding any law to the contrary, the department, the governor, or any employee of any state agency shall not be held civilly or criminally liable for any injury, loss of property, personal injury, or death caused by any act or omission while acting within the scope of office or employment as authorized under this chapter.

8. An attorney shall not be subject to disciplinary action by the Iowa supreme court or attorney disciplinary board for providing legal assistance to a patient, primary caregiver, or others based upon a patient's or primary caregiver's possession or use of medical cannabidiol as authorized under this chapter.

9. Possession of a medical cannabidiol registration card or an application for a medical cannabidiol registration card by a person entitled to possess or apply for a medical cannabidiol registration card shall not constitute probable cause or reasonable suspicion, and shall not be used to support a search of the person or property of the person possessing or applying for the medical cannabidiol registration card, or otherwise subject the person or property of the person to inspection by any governmental agency.

2017 Acts, ch 162, §15, 25; 2020 Acts, ch 1116, §23; 2021 Acts, ch 80, §63
Subsection 6 amended

124E.13 Medical cannabidiol source.

Medical cannabidiol provided exclusively pursuant to a written certification of a health care practitioner, if not legally available in this state or from any other bordering state, shall be obtained from an out-of-state source.

2017 Acts, ch 162, §16, 25

124E.14 Out-of-state medical cannabidiol dispensaries.

The department of public health shall utilize a request for proposals process to select and license by December 1, 2017, up to two out-of-state medical cannabidiol dispensaries from a bordering state to sell and dispense medical cannabidiol to a patient or primary caregiver in possession of a valid medical cannabidiol registration card issued under this chapter.

2017 Acts, ch 162, §17, 25

124E.15 Iowa patients and primary caregivers registering in the state of Minnesota.

A patient or a primary caregiver with a valid medical cannabidiol registration card issued pursuant to this chapter may register in the state of Minnesota as a visiting qualified patient or primary caregiver and may register with one or more medical cannabis manufacturers registered under the laws of Minnesota.

2017 Acts, ch 162, §18, 25

124E.16 Penalties.

1. A person who knowingly or intentionally possesses or uses medical cannabidiol in violation of the requirements of this chapter is subject to the penalties provided under chapters 124 and 453B.

2. A medical cannabidiol manufacturer or a medical cannabidiol dispensary shall be

assessed a civil penalty of up to one thousand dollars per violation for any violation of this chapter in addition to any other applicable penalties.

2017 Acts, ch 162, §19, 25

124E.17 Use of medical cannabidiol — smoking prohibited.

A patient shall not consume medical cannabidiol possessed or used as authorized under this chapter by smoking medical cannabidiol.

2017 Acts, ch 162, §20, 25

124E.18 Reciprocity.

A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allows an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to this chapter, except that an out-of-state patient in this state shall not obtain medical cannabidiol from a medical cannabidiol dispensary in this state.

2017 Acts, ch 162, §21, 25

124E.19 Background investigations.

1. The division of criminal investigation of the department of public safety shall conduct thorough background investigations for the purposes of licensing medical cannabidiol manufacturers and medical cannabidiol dispensaries under this chapter. The results of any background investigation conducted pursuant to this section shall be presented to the department.

a. An applicant for a medical cannabidiol manufacturer license or a medical cannabidiol dispensary license and their owners, investors, and employees shall submit all required information on a form prescribed by the department of public safety.

b. The department shall charge an applicant for a medical cannabidiol manufacturer license or a medical cannabidiol dispensary license a fee determined by the department of public safety and adopted by the department by rule to defray the costs associated with background investigations conducted pursuant to the requirements of this section. The fee shall be in addition to any other fees charged by the department. The fee may be retained by the department of public safety and shall be considered repayment receipts as defined in section 8.2.

2. The department shall require an applicant for a medical cannabidiol manufacturer license or a medical cannabidiol dispensary license, their owners and investors, and applicants for employment at a medical cannabidiol manufacturer or medical cannabidiol dispensary to submit fingerprints and other required identifying information to the department on a form prescribed by the department of public safety. The department shall submit the fingerprint cards and other identifying information to the division of criminal investigation of the department of public safety for submission to the federal bureau of investigation for the purpose of conducting a national criminal history record check. The department may require employees and contractors involved in carrying out a background investigation to submit fingerprints and other identifying information for the same purpose.

3. The department may enter into a chapter 28E agreement with the department of public safety to meet the requirements of this section.

4. An applicant for a medical cannabidiol manufacturer license or a medical cannabidiol dispensary license shall submit information and fees required by this section at the time of application.

5. The results of background investigations conducted pursuant to this section shall not be considered public records under chapter 22.

2018 Acts, ch 1165, §125, 126

Referred to in §124E.7, 124E.9

124E.20 Observational effectiveness study.

The department may conduct an observational effectiveness study in cooperation with patients and health care practitioners and pursuant to rules of the department in order

to study the effectiveness of medical cannabidiol in the treatment of debilitating medical conditions.

2020 Acts, ch 1116, §24

124E.21 Employer regulation of marijuana use.

1. Nothing in this chapter shall require an employer to permit or accommodate the use, consumption, possession, transfer, display, transportation, distribution, sale, or growing of marijuana in the workplace.

2. Nothing in this chapter shall prohibit an employer from implementing policies restricting the use of marijuana by employees for the purpose of promoting workplace health and safety.

3. Nothing in this chapter shall prohibit an employer from including in a contract with an employee a provision prohibiting the use of marijuana.

4. Nothing in this chapter shall prohibit an employer from establishing and enforcing a zero-tolerance drug policy or a drug-free workplace by use of a drug testing policy in accordance with section 730.5 or any other procedures provided by federal statutes, federal regulations, or orders issued pursuant to federal law.

2020 Acts, ch 1116, §25

124E.22 Regulation of marijuana use by government medical assistance programs, private health insurers, and other entities.

Nothing in this chapter shall require a government medical assistance program, private health insurer, workers' compensation carrier, or self-insured employer providing workers' compensation benefits to reimburse a person for costs associated with the medical use of marijuana.

2020 Acts, ch 1116, §26

124E.23 Regulation of marijuana use on property.

Nothing in this chapter shall require a person that owns, occupies, or controls a property to allow the use, consumption, possession, transfer, display, transportation, distribution, sale, or growing of marijuana on or in that property.

2020 Acts, ch 1116, §27

124E.24 Limitation of liability.

Nothing in this chapter shall create any claim, cause of action, sanction, or penalty, for discrimination or under any other theory of liability, under chapter 216 or any other provision of law, based on an act, omission, policy, or contractual provision permissible under this chapter including but not limited to refusing to hire, discharging, disciplining, discriminating, retaliating, or otherwise taking any adverse employment action against a person with respect to hiring, tenure, or any terms, conditions, or privileges of employment.

2020 Acts, ch 1116, §28

124E.25 Cannabis-derived products — exemption.

This chapter shall not apply to any cannabis-derived investigational product or cannabis-derived product approved as a prescription drug medication by the United States food and drug administration.

2020 Acts, ch 1116, §29

124E.26 Applicability.

The provisions of this chapter apply notwithstanding any other provision of law to the contrary.

2020 Acts, ch 1116, §30

CHAPTER 154
MEDICAL CANNABIDIOL PROGRAM

641—154.1(124E) Definitions. For the purposes of these rules, the following definitions shall apply:

"*Acceptance criteria*" means the specified limits placed on characteristics of an item or method that are used to determine data quality.

"*Accreditation*" means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

"*Accredited nonpublic school*" means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

"*Action level*" means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

"*Aliquot*" means a portion of a sample that is used in an analysis.

"*Analyte*" means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

"*Analytical batch*" means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

"*Analytical method*" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

"*Audit*" means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

"*Background investigation*" means a thorough review of an entity, an owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

"*Batch*" means a specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

"*Batch number*" means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is harvested. The batch number shall contain the manufacturer's number and a sequence to allow for inventory and traceability.

"*Biosecurity*" means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

"*Bordering state*" means the same as defined in Iowa Code section 331.910.

"*Cannabinoid*" means a chemical compound that is unique to and derived from cannabis.

"*Cannabis*" means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

"*CAS number*" means a unique numerical identifier assigned to every chemical substance described in the open literature by Chemical Abstracts Service.

"*CBD*" means cannabidiol, Chemical Abstracts Service number 13956-29-1.

"*CBDA*" means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

"*CBG*" means cannabigerol, Chemical Abstracts Service number 25654-31-3.

"*CBN*" means cannabinol, Chemical Abstracts Service number 521-35-7.

"*Certificate of analysis*" means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

"*Certification*" means a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.

"*Certified*" means that a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department's requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

"*Certified reference material*" means a reference material prepared by a certifying body.

"*Crop input*" means any substance applied to or used in the cultivation and growth of a cannabis plant. "Crop input" includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

"*Data-quality assessment*" means a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the intended use of the data.

"*Date of expiration*" means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

"*Date of issuance*" means the date of issuance of the medical cannabidiol registration card by the department.

"*Debilitating medical condition*" means any of the following:

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. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.
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. Chronic pain.
10. Severe, intractable autism with self-injurious or aggressive behaviors.
11. Post-traumatic stress disorder.
12. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

"*Department*" means the Iowa department of public health.

"*Director*" means the director of the Iowa department of public health.

"*Dispensary*" means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. "Dispensary" includes the employees and agents of the dispensary.

"*Dispensary facility*" means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

"*Dispense*" or "*dispensing*" means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

"*Disqualifying felony offense*" means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

"*Edible medical cannabidiol products*" means food items containing medical cannabidiol. "Edible medical cannabidiol products" does not include pills, tinctures, oils, or other forms of medical

cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.

"*Field duplicate sample*" means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

"*Form and quantity*" means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

"*Frequency*" means the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

"*Health care practitioner*" means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, a physician assistant licensed under Iowa Code chapter 148C, an advanced registered nurse practitioner licensed under Iowa Code chapter 152, or an advanced practice registered nurse under Iowa Code chapter 152E, who is a patient's primary care provider or a podiatrist licensed pursuant to Iowa Code chapter 149.

"*Increment*" or "*sample increment*" means a smaller sample that, together with other increments, makes up the primary sample.

"*Inspection*" means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

"*International Electrotechnical Commission*" or "*IEC*" means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

"*International Organization for Standardization*" or "*ISO*" means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

"*Investor*" means a person making a cash investment of at least 5 percent interest in an applicant or licensed manufacturer or dispensary with the expectation of receiving financial returns.

"*Laboratory*" means the state hygienic laboratory at the University of Iowa or any other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an International Organization for Standardization-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol. For the purposes of these rules, an independent laboratory is a laboratory operated by an entity that has no equity ownership in a medical cannabidiol manufacturer.

"*Limit of detection*" or "*LOD*" means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

"*Limit of quantitation*" or "*LOQ*" means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

"*Lot*" means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"*Lot number*" means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

"*Manufacture*" or "*manufacturing*" means the process of converting harvested cannabis plant

material into medical cannabidiol.

"*Manufacturer*" means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. "Manufacturer" includes the employees and agents of the manufacturer.

"*Manufacturing facility*" means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

"*Market withdrawal*" means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

"*Mass spectrometry*" means an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio.

"*Matrix*" means the component or substrate that contains the analyte of interest.

"*Matrix spike duplicate*" means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

"*Matrix spike sample*" means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

"*Medical assistance program*" means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

"*Medical cannabidiol*" means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter. This definition shall not apply to any cannabis-derived investigational product or cannabis-derived product approved as a prescription drug medication by the United States food and drug administration.

"*Medical cannabidiol tracking number*" means the sales identification number assigned by a dispensary to a transaction at the time of the sale of a medical cannabidiol product.

"*Medical cannabidiol waste*" means medical cannabidiol that is unused, unwanted, damaged, defective, expired, or contaminated and that is returned to a dispensary or manufacturer for disposal.

"*Medical cannabis goods*" means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

"*Method blank*" means an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

"*Moisture content*" means the percentage of water in a dry sample by weight.

"*National criminal history background check*" means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

"*Non-target organism*" means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

"*Owner*" means a person with a 5 percent or greater ownership interest in an applicant or licensed manufacturer or dispensary.

"*Patient*" means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

"*Patient registration number*" means the unique identification number issued to a patient by the department of transportation upon approval of a patient's application by the department as described in these rules.

"*Percent recovery*" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

"*Permanent resident*" means a natural person who physically resides in Iowa as the person's

principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,
7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

"*Pharmaceutical grade*" means medical cannabidiol that meets standards for content, contamination, and consistency set by the department as determined by testing conducted at a laboratory pursuant to Iowa Code chapter 124E and these rules.

"*Plant material*" means any plant of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

"*Plant material waste*" means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

"*Primary caregiver*" means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 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 cannabidiol pursuant to the provisions of Iowa Code chapter 124E and these rules.

"*Primary care provider*" means any health care practitioner involved in the diagnosis and treatment of a patient's debilitating medical condition.

"*Primary sample*" means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

"*Process lot*" means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

"*Product expiration date*" means the date after which a medical cannabidiol product may not be sold by a manufacturer or a dispensary.

"*Production*" or "*produce*" means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

"*Proficiency test*" means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

"*Proficiency test sample*" means a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

"*Public or private school*" means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

"*Qualitative analysis*" means identification of an analyte in a substance or mixture.

"*Quality assurance*" means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

"*Quality control*" means a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

"*Quality control samples*" means samples produced and used for the purpose of assuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

"*Quantitative analysis*" means measurement of the quantities of chemical components present in a substance or mixture. Quantitative analysis typically uses a certified reference material, if available, to create a calibration curve.

"*Reagent*" means a compound or mixture added to a system to cause a chemical reaction or to test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

"*Recall*" means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

"*Reference material*" means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

"*Reference method*" means a method by which the performance of an alternate method is measured or evaluated.

"*Relative percent difference*" or "*RPD*" means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value (primary sample measurement - duplicate sample measurement) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

"*Relative standard deviation*" or "*RSD*" means the standard deviation expressed as a percentage of the mean recovery. "RSD" is the coefficient of variation multiplied by 100. If any results are less than the limit of quantitation, then the absolute value of the limit of quantitation is used in the following equation: RSD = (s / x) × 100, where s = standard deviation and x = mean recovery.

"*Requester*" means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

"*Residual solvents and processing chemicals*" means volatile organic chemicals that are used or produced in the manufacture or production of medical cannabidiol.

"*Restricted access area*" means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

"*Sample*" means a representative part of or a single item from a larger whole or group.

"*Sanitize*" means to sterilize, disinfect, or make hygienic.

"*Semiquantitative analysis*" means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

"*Significant figures*" means the number of digits used to express a measurement.

"*Stability*" or "*stable*" means that after storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

"*Standard operating procedure*" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

"*State*" means a state of the United States, the District of Columbia, Puerto Rico, the Virgin

Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

"*Synthetic cannabinoid*" means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce biological effects similar to those of natural cannabinoids.

"*Tamper-evident*" means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

"*Target organism*" means an organism that is being tested for in an analytical procedure or test method.

"*Testing laboratory record*" means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

"*THC*" or "*delta-9 THC*" means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

"*THCA*" means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

"*Total tetrahydrocannabinol*" means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of tetrahydrocannabinol.

"*Validation*" means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

"*Written certification*" means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

REGISTRATION CARDS

641—154.2(124E) Health care practitioner certification—duties and prohibitions.

154.2(1) 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:

a. 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 (www.idph.iowa.gov).

(1) If the health care practitioner provides written certification that a patient's qualifying debilitating medical condition is a terminal illness with a life expectancy of less than one year, the health care practitioner shall determine an appropriate total tetrahydrocannabinol cap. The health care practitioner shall indicate the total tetrahydrocannabinol cap on the written certification.

(2) If the health care practitioner determines that 4.5 grams of total tetrahydrocannabinol in a 90-day period is insufficient to treat a patient's qualifying debilitating medical condition and the patient has participated in the medical cannabidiol program, the health care practitioner may recommend a higher total tetrahydrocannabinol cap. The health care practitioner shall indicate the higher total tetrahydrocannabinol cap on the written certification.

b. Provide explanatory information to the patient as provided on the department's website (www.idph.iowa.gov) about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

154.2(2) Subsequently, the health care practitioner shall do the following:

a. 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.

b. Otherwise comply with all requirements in this chapter and requests from the department for

more information.

154.2(3) A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this rule.

154.2(4) Health care practitioner prohibitions.

a. A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify a patient's condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification of a qualifying debilitating medical condition.

b. A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify an individual as a primary caregiver for a patient with respect to the use of medical cannabidiol, other than accepting a fee for a consultation to determine if the individual is a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol.

c. A health care practitioner shall not advertise certifying a qualifying debilitating medical condition as one of the health care practitioner's services.

d. A health care practitioner shall not certify a qualifying debilitating medical condition for a patient who is the health care practitioner or a family or household member of the health care practitioner.

e. A health care practitioner shall not be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

f. A health care practitioner shall not receive or provide medical cannabidiol product samples.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.

154.3(1) Subject to subrule 154.3(7), the department may issue a medical cannabidiol registration card to a patient who:

a. Is at least 18 years of age.

b. Is a permanent resident of Iowa.

c. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

d. Submits an application to the department, on a form created by the department and available at the department's website (www.idph.iowa.gov), that contains all of the following:

(1) The patient's full legal name, Iowa residence address, mailing address (if different from the patient's residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card, or
3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver's license or an Iowa nonoperator's identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver's license or an Iowa nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient's identity through a process established by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient's health care practitioner.

(4) Full legal name, residence address, date of birth, and telephone number of each primary

caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

e. Submits the required fee, as described in subrule 154.12(1).

154.3(2) Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall issue a medical cannabidiol registration card to the patient.

154.3(3) A medical cannabidiol registration card issued to a patient by the department shall contain all of the following:

a. The patient's full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)"*d*"(2)"3." If the patient's name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification, the patient shall first update the patient's Iowa driver's license or nonoperator's identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the patient's social security number.

d. A statement that the medical cannabidiol registration card is not valid for identification purposes.

154.3(4) Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa.

154.3(5) An authorization to use medical cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

154.3(6) A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allow an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E, except that an out-of-state patient in Iowa shall not obtain medical cannabidiol from a medical cannabidiol dispensary in Iowa.

154.3(7) The department shall not issue a medical cannabidiol registration card for a patient who is enrolled in a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.

154.4(1) For a patient in a primary caregiver's care, the department may issue a medical cannabidiol registration to a primary caregiver who:

a. Is at least 18 years of age.

b. Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

c. Submits an application as a primary caregiver for each patient for whom the person is the primary caregiver. The primary caregiver application must be on a form created by the department and available at the department's website (www.idph.iowa.gov) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from

the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name, date of birth, and parent or legal guardian's name if the patient is under the age of 18.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or
4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

d. Submits the required fee, as described in subrule 154.12(2).

154.4(2) Upon the completion, verification, and approval of the primary caregiver's application, the department shall issue a medical cannabidiol registration card to the primary caregiver.

154.4(3) A medical cannabidiol registration card issued to a primary caregiver shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1)"*c*"(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The medical cannabidiol registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the patient in the primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's medical cannabidiol registration number.

e. A statement that the medical cannabidiol registration card is not valid for identification purposes.

f. A statement distinguishing the medical cannabidiol registration cardholder as a primary caregiver.

154.4(4) A patient who is 18 years of age or older must have an approved application and a distinguishing medical cannabidiol registration number that is not the patient's social security number

prior to the issuance of a medical cannabidiol registration card to the patient's primary caregiver.

154.4(5) An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.5(124E) Tamperproofing. Rescinded **ARC 5200C**, IAB 10/7/20, effective 11/11/20.

641—154.6(124E) Denial and cancellation. The department may deny an application for a medical cannabidiol registration card, or may cancel a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.
2. The department is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)"*d*"(2)"3" or 154.4(1)"*c*"(3)"4."
3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.
4. A patient, the patient's legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient's medical cannabidiol registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver's patient has been canceled.
5. A primary caregiver requests in writing that the department cancel the primary caregiver's medical cannabidiol registration card. The department shall notify a patient in writing when the registration card of the patient's primary caregiver has been canceled.
6. The department becomes aware of the death of a patient or primary caregiver.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.7(124E) Appeal. If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.8(124E) Duplicate card.

154.8(1) *Lost, stolen, or destroyed card.* To replace a medical cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)"*d*"(2)"3" or 154.4(1)"*c*"(3)"4."

154.8(2) *Change in card information and voluntary replacement.*

a. To replace a medical cannabidiol registration card that is damaged, the cardholder shall surrender to the department the card to be replaced and present the cardholder's valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)"*d*"(2)"3" or 154.4(1)"*c*"(3)"4."

b. A patient or primary caregiver to whom a medical cannabidiol registration card is issued shall

notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a medical cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department the card to be replaced and present a valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4" that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

c. To replace a medical cannabidiol registration card held by a primary caregiver to change, add, or remove a patient's medical cannabidiol registration number or the name of a patient's parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(124E). A medical cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

154.8(3) *Expiration date.* A duplicate medical cannabidiol registration card shall have the same expiration date as the medical cannabidiol registration card being replaced, changed, or amended.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.9(124E) Renewal. A medical cannabidiol registration card shall be valid for one year from the date of issuance unless canceled pursuant to rule 641—154.6(124E).

154.9(1) A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department at least 60 days prior to the date of expiration.

a. A patient applying for renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

154.9(2) A cardholder who fails to renew the medical cannabidiol registration card may not lawfully possess medical cannabidiol pursuant to this chapter.

[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.10(124E) Confidentiality. The department shall maintain a confidential file of the names of each patient to or for whom the department issues a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under Iowa Code section 124E.4.

154.10(1) Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

154.10(2) Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department as necessary to perform the duties of the department pursuant to Iowa Code chapter 124E and these rules.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E and these rules.

c. To a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

d. To a health care practitioner for the purpose of determining whether a patient seeking a written certification pursuant to Iowa Code section 124E.3 and these rules has already received a written certification from another health care practitioner.

e. To authorized employees of a medical cannabidiol dispensary, but only for the purposes of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued

pursuant to Iowa Code chapter 124E and these rules and that a person has not purchased total tetrahydrocannabinol in excess of the amount authorized by Iowa Code chapter 124E and these rules.
[**ARC 1640C**, IAB 10/1/14, effective 1/30/15; **ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.11(124E) Agreement with department of transportation. Rescinded **ARC 5200C**, IAB 10/7/20, effective 11/11/20.

641—154.12(124E) Fees. All fees are nonrefundable.

154.12(1) *Patient medical cannabidiol registration card fee.*

a. Each application fee is $100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1)*"b."*

b. Each reduced application fee is $25 if the patient attests to receiving social security disability benefits, supplemental security income payments, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

c. Each renewal fee is the same as the initial card application fee.

154.12(2) *Primary caregiver medical cannabidiol registration card fee.*

a. Each application fee is $25.

b. Each renewal fee is $25.

[**ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.13(124E) Use of medical cannabidiol—smoking prohibited. A patient shall not consume medical cannabidiol possessed or used pursuant to Iowa Code chapter 124E by smoking medical cannabidiol.
[**ARC 3150C**, IAB 7/5/17, effective 6/13/17]

641—154.14(124E) Allowable forms of medical cannabidiol.

154.14(1) *Modification of allowable forms.* The allowable forms of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

154.14(2) *Allowable forms.*

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.
2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule 641—154.1(124E).

[**ARC 3150C**, IAB 7/5/17, effective 6/13/17; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4399C**, IAB 4/10/19, effective 5/15/19; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.15 Reserved.

MANUFACTURING

641—154.16(124E) Duties of the department.

154.16(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of manufacturers.

154.16(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of manufacturers. If the department determines there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety, including but not limited to:

a. Loss or theft of medical cannabidiol or plant material;

b. Diversion or potential diversion of medical cannabidiol or plant material;

c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or

d. Other violations of law.

154.16(3) *Inspection of manufacturers.* The department or its agents shall conduct regular inspections of manufacturers and manufacturing facilities as described in rule 641—154.28(124E).

154.16(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

a. Inventory of plant material, medical cannabidiol, and waste material;

b. Transport of plant material, waste material, and laboratory samples;

c. Application and use of crop inputs and other solvents and chemicals;

d. Sales of medical cannabidiol to dispensaries;

e. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

154.16(5) *Licensure and licensure renewal of manufacturers.* The department shall issue a request for proposals to select and license by December 1, 2017, up to two manufacturers to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant manufacturer shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant manufacturer shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If an applicant manufacturer is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant manufacturer shall agree to begin supplying medical cannabidiol to licensed medical cannabidiol dispensaries in Iowa no later than December 1, 2018.

c. The initial license to manufacture medical cannabidiol shall be valid from December 1, 2017, through November 30, 2018. The license shall be renewed annually unless a manufacturer relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to manufacture issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol manufacturer:

(1) The technical expertise of an applicant manufacturer regarding medical cannabidiol;

(2) The qualifications of an applicant manufacturer's employees;

(3) The long-term financial stability of an applicant manufacturer;

(4) The ability to provide appropriate security measures on the premises of an applicant manufacturer;

(5) Whether an applicant manufacturer has demonstrated an ability to meet certain medical cannabidiol production needs for medical use regarding the range of recommended dosages for each debilitating medical condition, the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the debilitating medical conditions, and the form or forms of medical cannabidiol that may be appropriate for the approved debilitating medical conditions;

(6) An applicant manufacturer's projection of and ongoing assessment of wholesale product costs.

f. Pursuant to Iowa Code section 124E.6(1)*"b,"* information submitted during the application process shall be confidential until the licensure process is completed unless otherwise protected from disclosure under state or federal law.

g. A licensed manufacturer shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

h. The department shall notify a manufacturer of the decision to approve or deny the manufacturer's license by August 1 of the year in which the renewal application is submitted.

154.16(6) *Collection of fees from manufacturers.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. Fees to the department.

(1) Each application for licensure as a manufacturer shall include a nonrefundable application fee of $7,500.

(2) Licensed manufacturers shall pay an annual fee to the department to cover costs associated with regulating and inspecting manufacturers and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year by August 1, payable by the manufacturer to the department no later than December 1.

b. Fees to the department of public safety.

(1) An applicant manufacturer shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed manufacturer. The department of public safety shall retain the right to bill a manufacturer for additional background investigations, as needed.

(2) Each manufacturer submitting an application for licensure shall, at the time of application, submit to the department of public safety a deposit of $10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer.

(3) A licensed manufacturer shall pay a deposit of $200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the manufacturer. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

154.16(7) *Recall of medical cannabidiol products.* Medical cannabidiol products may be recalled in the following ways:

a. By manufacturer. Recalls may be undertaken voluntarily and at any time by a licensed manufacturer.

b. By department. If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a manufacturer to recall such violative medical cannabidiol products from dispensaries. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall take into account, but need not be limited to, each of the following factors:

(1) Whether any disease or injuries have already occurred from the use of the medical cannabidiol.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(7) The findings of the department during a directed inspection of the licensed manufacturing facility.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter]

641—154.17(124E) Manufacturer operations.

154.17(1) *Operating documents.*

a. A manufacturer shall maintain operating documents that accurately reflect the manufacturer's standard operating procedures. Unless otherwise noted, a manufacturer shall make the operating documents available to the department upon request through secure electronic mail, an electronic file-sharing service, or other secure means.

b. The operating documents of a manufacturer shall include all of the following:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

1. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

2. The methods of planting, harvesting, drying, and storing cannabis. A manufacturer may make operating documents for these procedures available on site only;

3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

4. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;

5. The disposal methods for all waste materials;

6. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;

7. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;

8. Strategies for identifying and reconciling discrepancies in inventory of plant material or

medical cannabidiol;

9. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;

10. Medical cannabidiol packaging and labeling procedures;

11. Procedures for recall and market withdrawal of medical cannabidiol;

12. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary. A manufacturer may make operating documents for these procedures available on site only;

13. A business continuity plan. A manufacturer may make this operating document available on site only;

14. Records relating to all transport activities; and

15. Other information requested by the department.

(2) Procedures to ensure accurate record keeping.

(3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only.

c. Operating documents may be trade secrets if designated as such by a manufacturer and shall be considered confidential records pursuant to Iowa Code section 22.7(3).

154.17(2) *Prohibited activities.* A manufacturer shall not:

a. Own or operate a medical cannabidiol manufacturing facility unless the manufacturer is licensed by the department pursuant to Iowa Code chapter 124E and these rules;

b. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

c. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;

d. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;

e. Sell or distribute medical cannabidiol to any person or business other than a dispensary;

f. Refuse to sell, deliver, transport, or distribute medical cannabidiol in any form or quantity produced by the manufacturer to a dispensary, unless deemed appropriate in the manufacturer's reasonable business judgment and approved by the department in writing;

g. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);

h. Sell medical cannabidiol that is not packaged and labeled in accordance with rule 641—154.21(124E);

i. Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department, subject to recommendation by the medical cannabidiol board and approval by the board of medicine;

j. Permit any person to consume medical cannabidiol on the property of the manufacturer;

k. Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense;

l. Manufacture edible medical cannabidiol products.

154.17(3) *Criminal background investigations.*

a. A manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

b. An employee of a manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

c. An applicant or licensed manufacturer shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

154.17(4) *Relationship to health care practitioners.* A manufacturer shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19]

641—154.18(124E) Security requirements. The department may request assistance from the department of public safety in ensuring manufacturers meet the security requirements in this rule.

154.18(1) *Visitor logs.* Visitors to the manufacturing facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

154.18(2) *Restricted access.* A manufacturer shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its manufacturing facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry to and exit from the facility;

(4) Store data for retrieval for a minimum of one year; and

(5) Limit access to authorized individuals in the event of a power failure.

b. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.

c. A manufacturer shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

d. Restricted access areas shall be identified with signs that state: "Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only."

154.18(3) *Perimeter intrusion detection system.*

a. Computer-controlled video surveillance system. A manufacturer shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

(1) All phases of medical cannabidiol production;

(2) All areas that might contain plant material and medical cannabidiol, including all safes and vaults;

(3) All points of entry and exit;

(4) The entrance to the video surveillance control room; and

(5) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a manufacturing facility or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. Video recording specifications.

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A manufacturer shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A manufacturer shall ensure that recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. Required signage. A manufacturer shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.18(4) *Security alarm system requirements.*

a. A manufacturer shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

(1) Facility entrances and exits;

(2) Rooms with exterior windows;

(3) Rooms with exterior walls;

(4) Roof hatches;

(5) Skylights; and

(6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

(1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;

(2) Motion detectors;

(3) Pressure switches;

(4) A duress alarm;

(5) A panic alarm;

(6) A holdup alarm;

(7) An automatic voice dialer; and

(8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A manufacturer's security alarm system and all devices shall continue to operate during a power outage.

d. A manufacturer's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A manufacturer shall provide documentation of the annual inspection and device testing to the department upon request.

154.18(5) *Personnel identification system.* A manufacturer shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and that meets the requirements of this subrule and subrule 154.18(1).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A manufacturer's employee shall keep the identification card visible at all times when the employee is in a manufacturing facility, a dispensary, or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a manufacturer shall immediately:

(1) Revoke the employee's access to the manufacturing facility; and

(2) Obtain and destroy the employee's identification card, if possible.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.19(124E) Location. All of a manufacturer's manufacturing, cultivating, harvesting, packaging, processing, and storage of medical cannabidiol shall take place in one secured manufacturing facility location at a physical address provided to the department during the licensure and application processes.

154.19(1) *Proximity to dispensary.* A manufacturer shall not operate a manufacturing facility at the same physical location as a medical cannabidiol dispensary.

154.19(2) *Proximity to school.* A manufacturer shall not operate a manufacturing facility in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, storing, or supplying, within 1,000 feet of a public or private school existing before the date of the manufacturer's licensure by the department.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.20(124E) Advertising and marketing.

154.20(1) *Permitted marketing and advertising activities.*

a. A manufacturer may:

(1) Display the manufacturer's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;
2. Colloquial references to cannabis;
3. Names of cannabis plant strains or varieties;
4. Unsubstantiated medical claims; or
5. Medical symbols that bear a reasonable resemblance to established medical associations. Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department;

(2) Display signs on the manufacturing facility; and

(3) Maintain a business website that contains the following information:

1. The manufacturer's name and contact information;
2. The medical cannabidiol forms and quantities manufactured in Iowa; and
3. Other information as approved by the department.

b. The business website shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

c. The department reserves the right to review a manufacturer's marketing and advertising materials and to require a manufacturer to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a manufacturer.

154.20(2) *Other marketing and advertising activities.* A manufacturer shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.20(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a manufacturer. In the event the department fails to respond to a manufacturer within 30 days with an approval, denial, or request for additional information, the manufacturer's marketing and advertising activity requests shall be deemed approved.

154.20(3) *Inconspicuous display.* A manufacturer shall arrange displays of medical cannabidiol,

interior signs, and other exhibits to reasonably prevent public viewing from outside the manufacturing facility.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.21(124E) Packaging and labeling.

154.21(1) *Medical cannabidiol packaging.* A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:

a. The manufacturer shall properly package medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients.

b. The manufacturer shall label packaged medical cannabidiol as described in subrule 154.21(3).

c. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 641—154.46(124E);

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available nonmedical commercial products.

e. The manufacturer shall package medical cannabidiol in a manner that minimizes the package's appeal to children.

f. The manufacturer shall not depict images other than the manufacturer's business name or logo on the packaging.

154.21(2) *Trade names.* A manufacturer's medical cannabidiol trade names shall comply with the following:

a. Names shall be limited to those that clearly reflect the form's medical cannabidiol nature;

b. Any name that is identical to, or similar to, the name of an existing nonmedical cannabidiol product is prohibited;

c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and

d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

154.21(3) *Package labeling.*

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name of the manufacturer;

(2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

(4) Instructions for storage, including light and temperature requirements, if any;

(5) Product expiration date;

(6) The date of manufacture and lot number;

(7) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

(8) The universal warning symbol provided by the department; and

(9) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

b. Labeling text shall not include any false or misleading statements.

c. A package may contain multiple labels if the information required by this rule is not obstructed.

d. A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19]

641—154.22(124E) Transportation of medical cannabidiol and plant material.

154.22(1) *Transport of medical cannabidiol.* A manufacturer is authorized to transport medical cannabidiol to and from:

a. Dispensaries;

b. A laboratory for testing;

c. A waste facility for disposal;

d. Other sites only with departmental approval.

154.22(2) *Transport of plant material.* A manufacturer is authorized to transport cannabis plant material from its manufacturing facility to:

a. A waste disposal site;

b. Other sites only with departmental approval.

154.22(3) *Chain-of-custody tracking system.*

a. A manufacturer shall use the secure sales and inventory tracking system, if available, or a department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

(1) The name and address of the destination;

(2) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;

(3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;

(4) The date and time the shipment is accepted at the delivery destination;

(5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment; and

(6) Any handling or storage instructions.

b. Before transporting medical cannabidiol, a manufacturer shall:

(1) Record in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and

(2) Notify the dispensary, laboratory, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, or waste facility, if applicable.

c. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when the transport vehicle is departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, or waste facility.

d. An authorized employee at the dispensary, laboratory, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, or waste facility shall also maintain a signed copy of manifest, and shall maintain records of the inventory received consistent with these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

154.22(4) *Vehicle requirements for transport.*

a. A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:

(1) Packaged in tamper-evident, bulk containers;

(2) Transported so it is not visible or recognizable from outside the vehicle; and

(3) Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer.

b. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

(1) Travel directly to a dispensary or other department-approved locations; and

(2) Document refueling and all other stops in transit, including:

1. The reason for the stop;
2. The duration of the stop; and
3. The location of the stop.

c. If the vehicle must be stopped due to an emergency situation, the employee shall notify 911 and complete an incident report on a form approved by the department.

d. Under no circumstance shall any person other than a designated manufacturer employee have actual physical control of the motor vehicle that is transporting the medical cannabidiol.

e. A single employee may transport medical cannabidiol to the laboratory.

f. An employee in a transport motor vehicle shall have telephone or other communication access with the manufacturer's personnel and have the ability to contact law enforcement via telephone or other method at all times that the motor vehicle contains medical cannabidiol.

g. An employee shall carry the employee's identification card at all times when transporting or delivering medical cannabidiol and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.

h. A manufacturer shall not leave a vehicle that is transporting medical cannabidiol unattended overnight.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter]

641—154.23(124E) Disposal of medical cannabidiol and plant material.

154.23(1) *Return of medical cannabidiol from dispensaries and laboratory.*

a. A manufacturer shall collect at no charge medical cannabidiol waste from dispensaries. A manufacturer shall:

(1) Collect medical cannabidiol waste from each dispensary on a schedule mutually agreed upon by the manufacturer and dispensary;

(2) Dispose of medical cannabidiol waste as provided in subrule 154.23(2); and

(3) Maintain a written record of disposal that includes:

1. The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;
2. The date the medical cannabidiol waste was collected;
3. The quantity of medical cannabidiol waste collected; and
4. The type and lot number of medical cannabidiol waste collected.

b. A manufacturer shall collect at no charge medical cannabidiol and medical cannabidiol waste from a laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

(1) Collect medical cannabidiol and medical cannabidiol waste from a laboratory on a schedule

mutually agreed upon by the manufacturer and laboratory.

(2) Maintain a written record of return that includes:

1. The date the medical cannabidiol and medical cannabidiol waste were collected;
2. The quantity of medical cannabidiol and medical cannabidiol waste collected; and
3. The type and lot number of medical cannabidiol collected.

(3) A manufacturer may use medical cannabidiol returned from a laboratory for research and development or retained samples, but a manufacturer shall not introduce medical cannabidiol returned from a laboratory into lots or products intended for sale.

(4) A manufacturer shall dispose of medical cannabidiol waste returned from a laboratory as provided in subrule 154.23(2).

154.23(2) *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, and manage medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

a. The manufacturer shall dispose of medical cannabidiol waste at a waste facility according to federal and state law and in a manner which renders it unusable.

b. The manufacturer shall dispose of plant material waste at an approved solid waste disposal facility, according to federal and state law.

c. Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of nonconsumable, solid wastes including:

(1) Paper waste;

(2) Cardboard waste;

(3) Food waste;

(4) Yard waste;

(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;

(6) Soil; or

(7) Other waste approved by the department.

154.23(3) *Liquid and chemical waste disposal.* A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with all applicable federal, state, and local regulations.

154.23(4) *Waste-tracking requirements.* A manufacturer shall use forms approved by the department to maintain accurate and comprehensive records regarding waste material. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter]

641—154.24(124E) Record-keeping requirements.

154.24(1) *Sales and distribution.* A manufacturer shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

a. The date of each sale or distribution;

b. The item number, product name and description, and quantity of medical cannabidiol sold or otherwise distributed; and

c. The sale price.

154.24(2) *Financial transactions.* A manufacturer shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records;

d. Records of all financial transactions, including contracts and agreements for services performed or services received;

154.24(3) *Other records.*

a. A manufacturer shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records;

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol or plant material;

(3) Transport manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A manufacturer shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Crop input records;

(2) Production records;

(3) Transportation records; and

(4) Inventory records, including disposal of waste.

154.24(4) *Entry into the department's secure sales and inventory tracking system.* Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department's secure sales and inventory tracking system.

a. A manufacturer shall enter data in real time for data related to:

(1) Transport of plant material, waste material, and laboratory samples; and

(2) Sales of medical cannabidiol to dispensaries.

b. A manufacturer shall enter data on changes to inventory of plant material, medical cannabidiol, and waste material by the end of the business day in which the changes occurred.

c. A manufacturer shall enter data within five business days for data related to:

(1) Application and use of crop inputs and other solvents and chemicals; and

(2) Other manufacturing and production records not related to inventory of plant material, medical cannabidiol, and waste material.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter]

641—154.25(124E) Production requirements.

154.25(1) *Cultivation and processing.*

a. Only a licensed manufacturer is authorized to produce and manufacture medical cannabidiol.

b. All phases of production shall take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with rule 641—154.18(124E).

c. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

d. Each production area shall allow for access, observation, and inventory of each plant group.

e. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

154.25(2) *Crop inputs and plant batches.*

a. The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application; and

(5) A copy of or electronic link to the safety data sheet for the crop input applied.

b. At the time of harvesting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

c. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the department's secure sales and inventory tracking system or other manifest system.

154.25(3) *Production of medical cannabidiol.*

a. A manufacturer shall comply with all state and local building and fire code requirements.

b. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

c. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

d. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

e. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

f. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the department's secure sales and inventory tracking system or other manifest system.

154.25(4) *General sanitation requirements.* A manufacturer shall take all reasonable measures and precautions to ensure that:

a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;

b. Hand-washing facilities are:

(1) Convenient and furnished with running water at a suitable temperature;

(2) Located in all production areas; and

(3) Equipped with effective hand-cleaning and -sanitizing preparations and sanitary towel service or electronic drying devices;

c. All employees working in direct contact with plant material and medical cannabidiol use hygienic practices while on duty, including:

(1) Maintaining personal cleanliness; and

(2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

d. Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

e. Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

f. Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;

g. Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;

h. Any buildings, fixtures, and other facilities are maintained in a sanitary condition;

i. Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;

j. All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;

k. The manufacturing facility water supply is sufficient for necessary operations;

l. Plumbing size and design meets operational needs and all applicable state and local laws;

m. Employees have accessible toilet facilities that are sanitary and in good repair; and

n. Plant material and medical cannabidiol that could support the rapid growth of undesirable

microorganisms are isolated to prevent the growth of those microorganisms.

154.25(5) *Storage.*

a. A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring that:

(1) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and

(2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area if a process is not completed at the end of a business day.

b. A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and

(2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.

c. To prevent degradation, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable medical cannabidiol under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

d. A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter]

641—154.26(124E) Quality assurance and control.

154.26(1) *Quality control program.* A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

154.26(2) *Sampling protocols.* A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

a. Conduct sample collection in a manner that provides analytically sound and representative samples;

b. Document every sampling event and provide this documentation to the department upon request;

c. Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;

d. Ensure that random samples from each lot are:

(1) Taken in an amount necessary to conduct the applicable test;

(2) Labeled with the lot number; and

(3) Submitted for testing;

e. Retain the results from the random samples for at least five years; and

f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

154.26(3) *Sampling and testing.* A manufacturer shall:

a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;

b. Conduct sampling and testing of plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of plant material and lots shall occur as described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

c. Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;

d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria when remixing and retesting are not warranted;

e. Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:

(1) Criteria for when remixing and retesting are warranted;

(2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and

(3) Instructions for determining the source of contamination;

f. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

154.26(4) *Stability testing.*

a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:

(1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;

(2) Storage conditions for samples retained for testing; and

(3) Reliable and specific test methods.

b. Stability studies shall include:

(1) Medical cannabidiol testing at appropriate intervals; and

(2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.

c. If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.

d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.

e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

154.26(5) *Reserve samples.*

a. A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.

b. A manufacturer shall retain the reserve for at least two years from the date of manufacture.

c. After two years from the date of manufacture, reserve samples shall be destroyed as provided in subrule 154.23(2).

154.26(6) *Retesting.* If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of plant material or medical cannabidiol.

154.26(7) *Disposal of substandard product.* A manufacturer shall dispose of all medical

cannabidiol as provided in subrule 154.23(2) when samples fail to meet established standards, specifications, and other relevant quality control criteria and when an adequate remedy for remixing and retesting as provided in paragraph 154.26(3)*"c"* is unavailable.

154.26(8) *Recall and market withdrawal procedures.* Each manufacturer shall establish a procedure for recalling or withdrawing from the market, as applicable, medical cannabidiol that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

a. Factors that make a recall or market withdrawal necessary;

b. Manufacturer's personnel who are responsible for overseeing the recall or market withdrawal; and

c. How to notify affected parties of a recall or market withdrawal.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter]

641—154.27(124E) Supply and inventory.

154.27(1) *Reliable and ongoing supply.* A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

154.27(2) *Inventory controls and procedures.* A manufacturer shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.27(3) *Real-time inventory required.* A manufacturer shall use the department-approved secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary. The manufacturer shall use the system to maintain a real-time record of the manufacturer's inventory of plant material and medical cannabidiol to include:

a. The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

b. The amount of plants being grown at the manufacturing facility on a daily basis;

c. The names of the employees or employee conducting the inventory; and

d. Other information deemed necessary and requested by the department.

154.27(4) *Waste inventory.* A manufacturer shall maintain a record of its inventory of all medical cannabidiol waste and plant material waste for disposal.

154.27(5) *Reconciliation.* No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the department's secure sales and inventory tracking system.

a. Reconciliation shall include:

(1) Plant material at the manufacturing facility and in transit; and

(2) Medical cannabidiol at the manufacturing facility, at distribution and storage facilities, and in transit.

b. Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the department's secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of plant material or medical cannabidiol to the department and law enforcement within 72 hours of discovery.

(2) A manufacturer shall have up to 72 hours to reconcile discrepancies in the manufacturer's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the manufacturer cannot reconcile the manufacturer's physical inventory with the secure sales and inventory tracking system's inventory within 72 hours but diversion of plant material or medical cannabidiol is not suspected, the manufacturer shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.28(4)*"b."*

154.27(6) *Scales.* All scales used to weigh usable plant material for purposes of these rules shall

be certified in accordance with ISO/IEC Standard 17025, which is incorporated herein by reference.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.28(124E) Inspection by department or independent consultant. A manufacturer is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

154.28(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The manufacturing facility;

c. Vehicles used for transport or delivery of medical cannabidiol or plant material;

d. Financial information and inventory documentation;

e. Physical and electronic security alarm systems; and

f. Other inspections as determined by the department.

154.28(2) *Local safety inspections.* A manufacturer may be subject to inspection of its manufacturing facility and grounds by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol manufacturing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.28(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

a. The department has reasonable grounds to believe that the manufacturer is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations; or

b. The department has reasonable grounds to believe that the manufacturer was the cause or source of contamination of medical cannabidiol.

154.28(4) *Compliance required.* A manufacturer shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer license as authorized by these rules.

d. At the department's request and in a timely manner, a manufacturer shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.29(124E) Assessment of penalties. The department shall assess to a manufacturer a civil penalty of up to $1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.30(124E) Suspension or revocation of a manufacturer license.

154.30(1) The department may suspend or revoke a manufacturer license upon any of the following grounds:

a. Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

b. Failure to submit required reports and documents.

c. Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

d. Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

e. Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

f. False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

g. Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

h. Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

i. Failure to correct a deficiency within the time frame required by the department.

j. Failure of a manufacturer's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

154.30(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.30(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.30(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

154.30(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.30(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.30(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.30(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

154.30(9) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

154.30(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.30(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.30(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.30(13) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.
2. Certified mail, return receipt requested, to the last address on file with the department.
3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number

for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19]

641—154.31(124E) Closure of operations.

154.31(1) *Notice.* A manufacturer shall notify the department at least six months before the closure of the manufacturing facility.

154.31(2) *Procedures.* If a manufacturer ceases operation, the manufacturer shall work with the department to verify the remaining inventory of the manufacturer and ensure that any plant material, plant material waste, and medical cannabidiol are destroyed at a waste facility as provided in subrule 154.23(2).

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.32 to **154.39** Reserved.

DISPENSING

641—154.40(124E) Duties of the department.

154.40(1) *Interagency agreements.* The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of dispensaries.

154.40(2) *Notice to law enforcement.* The department shall notify local law enforcement agencies and the department of public safety of the locations of dispensaries. If the department has sufficient cause to believe that there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety including but not limited to:

a. Loss or theft of medical cannabidiol;

b. Diversion or potential diversion of medical cannabidiol;

c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or

d. Other violations of law.

154.40(3) *Inspection of dispensaries.* The department or its agents shall conduct regular inspections of dispensaries and their facilities as described in rule 641—154.52(124E).

154.40(4) *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

a. Inventory of medical cannabidiol and waste material;

b. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

c. Total tetrahydrocannabinol purchased in the last 90 days by a patient and the patient’s primary caregiver.

154.40(5) *Licensure and licensure renewal of dispensaries.* The department shall issue a request for proposals to select and license by April 1, 2018, up to five dispensaries to dispense medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant dispensary shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant dispensary shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If the applicant dispensary is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant dispensary shall agree to begin dispensing medical cannabidiol to patients and primary caregivers in Iowa no later than December 1, 2018.

c. The initial license to dispense medical cannabidiol shall be valid from April 1, 2018, through November 30, 2018. The license shall be renewed annually unless a dispensary relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to dispense medical cannabidiol issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol dispensary:

(1) Geographical location of the proposed dispensary facility;

(2) The technical expertise of an applicant dispensary's staff regarding medical cannabidiol;

(3) The qualifications of an applicant dispensary's employees;

(4) The long-term financial stability of an applicant dispensary;

(5) The ability of an applicant dispensary to provide appropriate security measures on the premises of the dispensary;

(6) An applicant dispensary's projection of and ongoing assessment of retail product costs, including any dispensing fees.

f. Pursuant to Iowa Code section 124E.8(1)*"b,"* information submitted during the application process shall be confidential until an applicant dispensary is licensed by the department unless otherwise protected from disclosure under state or federal law.

g. A licensed dispensary shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

h. The department shall notify a dispensary of the decision to approve or deny the dispensary's license by August 1 of the year in which the renewal application is submitted.

154.40(6) *Collection of fees from dispensaries.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. Fees to the department.

(1) One application is required for each dispensary location.

(2) Each application for licensure as a dispensary shall include a nonrefundable application fee of $5,000.

(3) Licensed dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting dispensaries and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year on August 1, payable by the dispensary to the department no later than December 1.

b. Fees to the department of public safety.

(1) An applicant dispensary shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed dispensary. The department of public safety shall retain the right to bill a dispensary for

additional background investigations, as needed.

(2) Each dispensary submitting an application for licensure shall, at time of application, submit to the department of public safety a deposit of $10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary.

(3) A licensed dispensary shall pay a deposit of $200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the dispensary. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the dispensary shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

154.40(7) *Recall of medical cannabidiol products.* If the department determines, based on an evaluation of the health hazard presented, that there is a reasonable probability that use of, or exposure to, a violative medical cannabidiol product will cause a serious adverse health consequence or death, the department may require a dispensary to recall such violative medical cannabidiol products from the dispensary facility and from patients. An evaluation of the health hazard presented by medical cannabidiol being considered for recall shall be conducted by an ad hoc committee of scientists appointed by the director of the department and shall take into account, but need not be limited to, each of the following factors:

a. Whether any disease or injuries have already occurred from the use of the medical cannabidiol.

b. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

c. Assessment of hazard to various segments of the population, e.g., children, who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

d. Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

e. Assessment of the likelihood of occurrence of the hazard.

f. Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

g. The findings of the department during a directed inspection of the licensed manufacturing facility.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 4928C**, IAB 2/12/20, effective 6/1/20; see correction note at end of chapter; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.41(124E) Dispensary operations.

154.41(1) *Operating documents.* The operating documents of a dispensary shall include all of the following:

a. Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:

(1) The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;

(2) The estimated forms and quantities of medical cannabidiol waste to be generated or collected;

(3) The disposal methods for all waste materials;

(4) Employee training methods for the dispensary employees;

(5) Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;

(6) Procedures to ensure the dispensary does not dispense more than a patient's certified cap of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a 90-day period;

(7) Medical cannabidiol labeling procedures;

(8) Procedures for recall or market withdrawal of medical cannabidiol;

(9) Plans for responding to a security breach at the dispensary facility;

(10) A business continuity plan; and

(11) Other information requested by the department.

b. Procedures to ensure accurate record keeping.

c. Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

154.41(2) *Prohibited activities.*

a. A person or entity shall not own or operate a dispensary unless the person or entity is licensed by the department pursuant to Iowa Code chapter 124E and these rules.

b. A dispensary shall not:

(1) Dispense medical cannabidiol in any location except in those areas approved by the department;

(2) Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;

(3) Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;

(4) Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;

(5) Sell or distribute more than 4.5 grams of total tetrahydrocannabinol to a patient and the patient's primary caregiver(s) in a 90-day period, unless the patient's health care practitioner has certified a higher total tetrahydrocannabinol cap;

(6) Transport or deliver medical cannabidiol to any location, unless approved by the department;

(7) Sell medical cannabidiol that is not packaged and labeled in accordance with rules 641—154.21(124E) and 641—154.46(124E);

(8) Repackage medical cannabidiol or remove the manufacturer's label;

(9) Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department and adopted by rule;

(10) Permit any person to consume medical cannabidiol on the property of the dispensary;

(11) Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense.

154.41(3) *Criminal background checks.*

a. An owner of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

b. An employee of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

c. An applicant or licensed dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

154.41(4) *Relationship to health care practitioners.* A dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

154.41(5) *Employment of a pharmacist or pharmacy technician.* A medical cannabidiol

dispensary shall employ a pharmacist or pharmacy technician licensed or registered pursuant to Iowa Code chapter 155A for the purpose of making dosing recommendations.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.42(124E) Security requirements. The department may request assistance from the department of public safety in ensuring dispensaries meet the security requirements in this rule.

154.42(1) *Restricted access.* A dispensary shall have a controlled access system to limit entrance to all restricted access areas of the dispensary facility. Visitors to restricted access areas shall sign manifests with name, date, and times of entry and exit, if the controlled access system cannot electronically record visitors. Visitors shall wear badges that are visible at all times and identify them as visitors.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry to and exit from restricted access areas;

(4) Store data for retrieval for a minimum of one year; and

(5) Limit access to authorized individuals in the event of a power failure.

b. A dispensary shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

c. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.

d. Restricted access areas shall be identified with signs that state: "Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only."

154.42(2) *Perimeter intrusion detection system.*

a. Computer-controlled video surveillance system. A dispensary shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

(1) All areas that might contain medical cannabidiol, including all safes, vaults, and storage areas;

(2) All points of entry and exit;

(3) The entrance to the video surveillance control room; and

(4) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a dispensary or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. Video recording specifications.

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to

disposal of any storage medium.

d. Additional requirements. A dispensary shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A dispensary shall ensure that recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for at least 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a dispensary is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. Required signage. A dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the dispensary that reads, "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE."

154.42(3) *Security alarm system requirements.*

a. A dispensary shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

(1) Dispensary entrances and exits;

(2) Rooms with exterior windows;

(3) Rooms with exterior walls;

(4) Roof hatches;

(5) Skylights; and

(6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

(1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;

(2) Motion detectors;

(3) Pressure switches;

(4) A duress alarm;

(5) A panic alarm;

(6) A holdup alarm;

(7) An automatic voice dialer; and

(8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A dispensary's security alarm system and all devices shall continue to operate during a power outage.

d. A dispensary's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A dispensary shall provide documentation of the annual inspection and device testing to the department upon request.

154.42(4) *Personnel identification system.* A dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the dispensary and that meets the requirements of this subrule and subrule 154.42(1).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A dispensary's employees shall keep the identification card visible at all times when the employee is in a dispensary or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a dispensary shall immediately:

(1) Revoke the employee's access to restricted access areas of the dispensary; and

(2) Obtain and destroy the employee's identification card, if possible.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.43(124E) Location. All dispensing of medical cannabidiol shall take place in an enclosed facility at one physical address provided to the department during the licensure process.

154.43(1) *Proximity to manufacturers.* A dispensary shall not operate at the same physical location as a manufacturer.

154.43(2) *Proximity to schools.* A dispensary shall not operate in any location within 1,000 feet of a public or private school existing before the date of the dispensary's licensure by the department.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.44(124E) Advertising and marketing.

154.44(1) *Permitted marketing and advertising activities.*

a. A dispensary may:

(1) Display the dispensary's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;
2. Colloquial references to cannabis;
3. Names of cannabis plant strains or varieties;
4. Unsubstantiated medical claims; or
5. Medical symbols that bear a reasonable resemblance to established medical associations. Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department.

(2) Display signs on the dispensary; and

(3) Maintain a business website that contains the following information:

1. The dispensary's name and contact information;
2. The medical cannabidiol forms and quantities provided;
3. Medical cannabidiol pricing;
4. Hours of operation; and
5. Other information as approved by the department.

b. The business website shall not include any false, misleading, or unsubstantiated statements.

c. The department reserves the right to review a dispensary's marketing and advertising materials and to require a dispensary to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a dispensary.

154.44(2) *Other marketing and advertising activities.* A dispensary shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.44(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a dispensary. In the event the department fails to respond to a dispensary within 30 days with an approval, denial, or request for additional information, the dispensary's marketing and advertising activity requests shall be deemed approved.

154.44(3) *Inconspicuous display.* A dispensary shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the dispensary.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.45(124E) Storage.

154.45(1) *Storage of saleable medical cannabidiol.*

a. A dispensary shall store medical cannabidiol to prevent diversion, theft, or loss, including ensuring that:

(1) Medical cannabidiol is kept in a secure and monitored location within the dispensary; and

(2) Cabinets or storage containers inside the secure and monitored area are locked at the end of a business day.

b. A dispensary shall store all medical cannabidiol:

(1) In areas that are maintained in a clean, orderly, and well-ventilated condition;

(2) In areas that are free from infestation by insects, rodents, birds, and other pests of any kind;

(3) According to the manufacturer's requirements regarding temperature, light exposure, or other environmental conditions;

(4) Under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

154.45(2) *Storage of returned medical cannabidiol.* A dispensary shall maintain a separate secure storage area for medical cannabidiol that is to be returned to a manufacturer for disposal, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the medical cannabidiol is collected by a manufacturer. For purposes of this subrule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.46(124E) Dispensing.

154.46(1) *Access to all forms of product.* A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

154.46(2) *Dispensing to a patient.*

a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

(1) Verify the patient's identity using a valid photo ID. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A U.S. passport,
4. A U.S. military ID or veteran ID,
5. A tribal ID card/document;

(2) Verify that the patient is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;

(3) Check the secure sales and inventory tracking system for the patient's total tetrahydrocannabinol 90-day purchase cap and the amount of total tetrahydrocannabinol that the patient and the patient's primary caregiver(s) have purchased on behalf of the patient in the past 90 days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the patient does not exceed the patient's cap;

(4) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient;

(5) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The patient registration number;

(6) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules. Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the patient name, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

154.46(3) *Dispensing to a primary caregiver.*

a. Prior to dispensing any medical cannabidiol to a primary caregiver, a dispensary shall do all of the following:

(1) Verify the primary caregiver's identity using a valid photo ID. Acceptable photo identification includes:

1. A valid Iowa driver's license,
2. A valid Iowa nonoperator's identification card,
3. A U.S. passport,
4. A U.S. military ID or veteran ID,
5. A tribal ID card/document;

(2) Verify that the patient and the primary caregiver are registered and listed in the secure sales and inventory tracking system and have valid medical registration cards;

(3) Check the secure sales and inventory tracking system for the associated patient's total tetrahydrocannabinol 90-day purchase cap and the amount of total tetrahydrocannabinol that the patient and patient's primary caregiver(s) have purchased on behalf of the patient in the past 90 days to ensure that the amount of total tetrahydrocannabinol sold by the dispensary to the primary caregiver does not exceed the patient's cap;

(4) Assign a medical cannabidiol tracking number to any medical cannabidiol that is to be dispensed to the primary caregiver;

(5) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The patient registration number;

(6) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules. Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the names of the patient and primary caregiver, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.47(124E) Transportation of medical cannabidiol. A dispensary is not authorized to transport medical cannabidiol, unless approved by the department. Any approved transport shall be logged in the secure sales and inventory tracking system.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.48(124E) Disposal of medical cannabidiol.

154.48(1) *Identification of excess, expired, or damaged medical cannabidiol.*

a. Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol for return to manufacturers.

b. Unused, excess, expired, or damaged medical cannabidiol shall be stored as described in subrule 154.45(2).

154.48(2) *Return of medical cannabidiol from a patient or primary caregiver to a dispensary.*

a. A dispensary shall accept at no charge medical cannabidiol waste from any patient or primary caregiver. A dispensary shall provide all medical cannabidiol waste to the manufacturer for disposal.

b. The dispensary shall enter the following information into the secure sales and inventory tracking system for all medical cannabidiol returned from a patient or primary caregiver:

(1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

(2) The date the medical cannabidiol was returned;

(3) The quantity of medical cannabidiol returned; and

(4) The type and lot number of medical cannabidiol returned.

c. A dispensary shall store medical cannabidiol returned from patients and primary caregivers as described in subrule 154.45(2).

154.48(3) *Return of medical cannabidiol to a manufacturer.*

a. A manufacturer shall collect and dispose of medical cannabidiol from dispensaries as provided in rule 641—154.23(124E).

b. A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:

(1) The date the medical cannabidiol was collected by the manufacturer;

(2) The quantity of medical cannabidiol collected; and

(3) The type and lot number of medical cannabidiol collected.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter]

641—154.49(124E) Record-keeping requirements.

154.49(1) *Sales.* A dispensary shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

a. The name of the patient and, if purchase is made by the primary caregiver, the name of the primary caregiver;

b. The date of each sale;

c. The item number, product name and description, and quantity of medical cannabidiol sold;

d. The sale price;

e. Other information required by the department.

154.49(2) *Financial transactions.* A dispensary shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records;

d. Records of all financial transactions, including contracts and agreements for services performed or services received.

154.49(3) *Other records.*

a. A dispensary shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records; and

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol.

b. A dispensary shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A dispensary shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Inventory records;

(2) Return of medical cannabidiol from a patient or primary caregiver; and

(3) Return of unused, excess, expired, or damaged medical cannabidiol to a manufacturer.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.50(124E) Quality assurance and control. A dispensary shall cooperate with manufacturers and the department on quality assurance and control procedures, including participating in stability-testing studies, developing sampling strategies, and returning medical cannabidiol that has been recalled or withdrawn from the market.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.51(124E) Inventory.

154.51(1) *Inventory controls and procedures.* A dispensary shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

154.51(2) *Real-time inventory required.* A dispensary shall use the department-approved secure sales and inventory tracking system to maintain a real-time record of the dispensary's inventory of medical cannabidiol to include:

a. The quantity and form of saleable medical cannabidiol maintained at the dispensary on a daily basis;

b. The amount of damaged, expired, or returned medical cannabidiol being held at the dispensary for return to a manufacturer; and

c. Other information deemed necessary and requested by the department.

154.51(3) *Reconciliation.* At least once a calendar week, a dispensary shall reconcile all medical cannabidiol at the dispensary with the inventory recorded in the department's secure sales and inventory tracking system. Discrepancies shall be handled as follows:

a. A dispensary shall report suspected diversion of medical cannabidiol to the department and law enforcement within 24 hours of discovery.

b. A dispensary shall have up to 24 hours to reconcile the dispensary's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the dispensary cannot reconcile the dispensary's physical inventory with the secure sales and inventory tracking system's inventory within 24 hours but diversion of product is not suspected, the dispensary shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.52(4)*"b."*

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.52(124E) Inspection by department or independent consultant. A dispensary is subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and these rules or state or local laws and regulations.

154.52(1) *Types of inspections.* Inspections may include:

a. Aspects of the business operations;

b. The physical location of a dispensary, including any storage facilities;

c. Financial information and inventory documentation;

d. Physical and electronic security alarm systems; and

e. Other aspects or areas as determined by the department.

154.52(2) *Local safety inspections.* A dispensary may be subject to inspection of its dispensary by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol dispensing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

154.52(3) *Health and sanitary inspection.* The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

a. The department has reasonable grounds to believe that the dispensary is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws,

rules or regulations;

b. The department has reasonable grounds to believe that the dispensary was the cause or source of contamination of medical cannabidiol; or

c. The department has reasonable grounds to believe that the dispensary was the cause of loss of product quality or change in chemical composition due to improper storage and handling of medical cannabidiol.

154.52(4) *Compliance required.* A dispensary shall respond to deficiencies found during inspections or inventory reconciliation as follows:

a. Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a dispensary shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

b. Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the dispensary cannot reconcile the dispensary's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the dispensary shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

c. Failure to complete actions in the action plan within the timelines mutually agreed upon by the dispensary and the department shall result in assessment of penalties or in suspension or revocation of a dispensary license as authorized by these rules.

d. At the department's request and in a timely manner, a dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.53(124E) Assessment of penalties. The department shall assess to a dispensary a civil penalty of up to $1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.54(124E) Suspension or revocation of a dispensary license.

154.54(1) The department may suspend or revoke a dispensary license upon any of the following grounds:

a. Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

b. Failure to submit required reports and documents.

c. Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

d. Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

e. Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

f. False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

g. Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

h. Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

i. Failure to correct a deficiency within the time frame required by the department.

j. Failure of a dispensary's business owner to have a satisfactory result in a background

investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

154.54(2) The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

154.54(3) A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

154.54(4) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

154.54(5) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

154.54(6) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

154.54(7) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

154.54(8) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.
b. All evidence received or considered and all other submissions by recording or transcript.
c. A statement of all matters officially noticed.
d. All questions and offers of proof, objections, and rulings thereon.
e. All proposed findings and exceptions.
f. The proposed decision and order of the administrative law judge.

154.54(9) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

154.54(10) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

154.54(11) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa

50319-0075.

154.54(12) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

154.54(13) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.
2. Certified mail, return receipt requested, to the last address on file with the department.
3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.55(124E) Closure of operations.

154.55(1) *Notice.* A dispensary shall notify the department at least six months before the closure of the dispensary.

154.55(2) *Procedures.* If a dispensary ceases operation, the dispensary shall work with the department to verify the remaining inventory of the dispensary and ensure that any medical cannabidiol is returned to a manufacturer.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.56 to **154.59** Reserved.

MEDICAL CANNABIDIOL BOARD

641—154.60(124E) Purpose and duties of board.

154.60(1) The purpose of the board is to administer the provisions of Iowa Code section 124E.5.

154.60(2) Responsibilities of the board include but are not limited to:

a. Accepting and reviewing petitions to add medical conditions, medical treatments, or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E.

b. Making recommendations to the board of medicine relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under Iowa Code chapter 124E would be medically beneficial.

c. Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

d. Advising the department regarding the location of manufacturers and dispensaries throughout the state.

e. Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

f. Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.61(124E) Organization of board and proceedings.

154.61(1) *Membership.* The board shall be composed of nine members appointed by the governor pursuant to Iowa Code section 124E.5. The appointments, unless provided otherwise by law, shall be for three-year staggered terms which shall expire on June 30. Board members shall be knowledgeable about the use of medical cannabidiol. The medical practitioners appointed to the board shall be licensed in Iowa and be nationally board-certified in their area of specialty.

154.61(2) *Vacancies.* Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

154.61(3) *Absences.* Three consecutive unexcused absences shall be grounds for the governor to consider dismissal of a board member and to appoint another. Department staff is charged with providing notification of absences to the governor's office.

154.61(4) *Board meetings.*

a. The board shall convene at least twice per year.

b. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

c. The department's office of medical cannabidiol shall schedule the time, date and location of meetings.

d. A majority of the members shall constitute a quorum for conducting business of the board.

e. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

154.61(5) *Facilities and staffing.* The department shall furnish the board with the necessary facilities and employees to perform the duties required by this chapter but shall be reimbursed for all costs incurred by fee revenue generated from licensing activities and registration card applications.

154.61(6) *Subcommittees.* The board may designate one or more subcommittees to perform such

duties as may be deemed necessary.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.62(124E) Official communications. All official communications, including submissions, petitions and requests, may be addressed to the Medical Cannabidiol Board, Office of Medical Cannabidiol, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.63(124E) Office hours. The board office is open for public business from 8 a.m. to 4:30 p.m., Monday to Friday of each week, except holidays.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.64(124E) Public meetings. Members of the public may be present during board meetings unless the board votes to hold a closed session. Dates and location of board meetings may be obtained through the Iowa department of public health's website (idph.iowa.gov/mcarcp) or directly from the board office.

154.64(1) *Exclusion of participants.* The person presiding at a meeting of the board may exclude a person from an open meeting for behavior that obstructs the meeting.

154.64(2) *Recording of meetings.* Cameras and recording devices may be used at open meetings, provided the cameras or recording devices do not obstruct the meeting. If the user of a camera or recording device obstructs the meeting by the use of such device, the presiding department staff member at the meeting may request the user to discontinue use of the camera or device.
[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.65(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases. Petitions for the addition or removal of medical conditions, medical treatments, or debilitating conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E may be submitted to the board pursuant to this rule.

154.65(1) *Petition form.* Any person or entity may file a petition to add or remove medical conditions, medical treatments or debilitating diseases with the board. A petition is deemed filed when it is received by the medical cannabidiol office. The board must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE MEDICAL CANNABIDIOL BOARD

Petition by (Name of Petitioner) for the (addition or removal) of (medical conditions, medical treatments or debilitating diseases) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.	}	PETITION FOR (ADDITION or REMOVAL)

The petition must provide the following information:

a. A statement of the specific medical condition, medical treatment or debilitating disease the petitioner is seeking to add to or remove from the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.

b. A brief summary of the petitioner's arguments in support of the action urged in the petition.

c. A brief summary of any data or scientific evidence supporting the action urged in the petition.

d. A list of reference material supporting the petition.

e. A list of subject matter experts who are willing to testify in support of the petition. The list of

subject matter experts must contain names, credentials (if applicable), email addresses, telephone numbers, and mailing addresses.

f. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.

154.65(2) *Signature and address.* The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, telephone number and email address of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

154.65(3) *Denial for format.* The board may deny a petition because it does not substantially conform to the required form.

154.65(4) *Briefs.* The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person or entity concerning the substance of the petition.

154.65(5) *Inquiries.* Inquiries concerning the status of a petition may be made to the Office of Medical Cannabidiol, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

154.65(6) *Additional information.* The board may request the petitioner to submit additional information concerning the petition. The board may also solicit comments from any person on the substance of the petition. Comments on the substance of the petition may be submitted to the board by any person.

154.65(7) *Presentation to the board.* The board may request or allow the petitioner to make an oral presentation of the contents of a petition at a board meeting following submission of the petition.

154.65(8) *Board response.* Within six months after the filing of the petition, or within any longer period agreed to by the petitioner, the board must, in writing, either deny the petition and notify the petitioner of the board's action and the reasons therefore, or grant the petition and notify the petitioner that the board has recommended addition or removal of the medical condition, medical treatment, or debilitating disease to the board of medicine. A petitioner shall be deemed notified of the denial or recommendation on the date when the board mails the required notification to the petitioner.

154.65(9) *Denials.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

[**ARC 3606C**, IAB 1/31/18, effective 3/7/18]

641—154.66 to **154.68** Reserved.

LABORATORY TESTING

641—154.69(124E) Requirements of the department.

154.69(1) *Laboratory testing requirements and acceptance criteria.* The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall:

a. Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

b. Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

c. Describe the minimum requirements for sample size and testing intervals for stability testing;

d. Be available on the department's website (www.idph.iowa.gov).

154.69(2) *Review and approval of manufacturer sampling protocols.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's sampling protocols required pursuant to subrules 154.26(2) and 154.26(3).

154.69(3) *Review and approval of manufacturer stability-testing procedures.* The department shall have up to two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures required pursuant to subrule 154.26(4).

154.69(4) *Establish a laboratory review committee.* The department shall establish a laboratory review committee to assist with the review of applications by laboratories and the establishment of accepted laboratory testing standards and practices.

154.69(5) *Review of laboratory applications.* The department shall establish a process to review applications from prospective medical cannabidiol testing laboratories. Prospective laboratories shall submit an application to the department on a form created by the department. The department shall determine whether the laboratory meets the criteria for an independent medical cannabidiol testing facility as set forth in the definition of "laboratory" in Iowa Code section 124E.2 in addition to determining whether the laboratory meets laboratory requirements pursuant to rules 641—154.70(124E) to 641—154.76(124E).

154.69(6) *Regulation of independent laboratories.* The department shall determine on an annual basis whether any approved independent laboratory continues to meet criteria as set forth in the definition of "laboratory" in Iowa Code section 124E.2 and laboratory requirements pursuant to rules 641—154.70(124E) to 641—154.76(124E). The department shall establish a process for the annual review of approved independent laboratories. An independent laboratory is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

[**ARC 4078C**, IAB 10/10/18, effective 11/14/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter; **ARC 5200C**, IAB 10/7/20, effective 11/11/20]

641—154.70(124E) Requirements of a laboratory.

154.70(1) *Minimum testing requirements.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals.

154.70(2) *Additional tests upon request.* A laboratory shall establish and implement test methods and corresponding standard operating procedures for other analyses as requested by the department.

154.70(3) *Level of quantitation.* A laboratory shall be able to demonstrate that its LOQ is below any action level established by the department.

154.70(4) *Inventory tracking.*

a. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the receipt of medical cannabis goods from a manufacturer for testing.

b. A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the return of medical cannabis goods or waste to a manufacturer.

154.70(5) *Hazardous waste disposal.*

a. A laboratory shall discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

b. A laboratory shall document the waste disposal procedures followed for each sample.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.71(124E) Requirements of a manufacturer.

154.71(1) *Assuming costs.* A manufacturer shall assume the costs for all laboratory testing requested by the department or laboratory for medical cannabis goods produced by the manufacturer.

154.71(2) *Sample waste retrieval.* A manufacturer shall retrieve analyzed samples and waste

containing medical cannabis goods from the laboratory at a duration and frequency approved by the department.

154.71(3) *Obtaining approval for sampling protocols.* A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols pursuant to subrule 154.26(2) prior to submitting samples for laboratory testing related to content and contamination.

154.71(4) *Obtaining approval for stability-testing procedures.* A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures pursuant to subrule 154.26(4) prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18]

641—154.72(124E) Content testing.

154.72(1) *Cannabinoids.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;

(2) THCA;

(3) CBD; and

(4) CBDA.

b. A laboratory shall report that the primary sample passed or failed THC potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

c. A laboratory shall report that the primary sample passed or failed CBD potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

d. For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraph 154.72(1)"*b.*"

e. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

154.72(2) *Contaminants—residual solvents and processing chemicals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall analyze primary samples for residual solvents and processing chemicals.

b. The department shall provide a list of residual solvents and processing chemicals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each residual solvent or processing chemical for which a primary sample is tested, a laboratory shall report that the primary sample passed the testing if the concentration of residual solvent or processing chemical is at or below the action level approved by the department.

d. For each residual solvent or processing chemical for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of residual solvent or processing chemical is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for residual solvents and processing chemicals and the laboratory determines that a primary sample contains residual solvent or processing chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative

identification and semiquantitative results of the residual solvent or processing chemical analytes.

f. The laboratory may test for and provide test results for additional residual solvents or processing chemicals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each residual solvent or processing chemical for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any target residual solvent or processing chemical that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(2)"*c*" and 154.72(2)"*d.*"

(3) The names and amounts of any additional residual solvents and processing chemicals identified by the laboratory.

h. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

i. When a laboratory identifies additional residual solvents and processing chemicals in a primary sample, the laboratory shall:

(1) Notify the department of the additional residual solvents and processing chemicals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(3) *Contaminants—pesticides.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for pesticides.

b. The department shall provide a list of pesticides for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of pesticide is at or below the action level approved by the department.

d. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of pesticide is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for pesticides and the laboratory determines that a primary sample contains pesticide analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the pesticide analytes.

f. The laboratory may test for and provide test results for additional pesticides if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each pesticide for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any pesticide that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(3)"*c*" and 154.72(3)"*d.*"

(3) The names and amounts of any additional pesticides identified by the laboratory.

h. If the primary sample fails testing for pesticides, the lot fails laboratory testing.

i. When a laboratory identifies additional pesticides in a primary sample, the laboratory shall:

(1) Notify the department of the additional pesticides and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(4) *Contaminants—metals.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for metals.

b. The department shall provide a list of metals for which primary samples are to be tested with corresponding action levels on the department's website (www.idph.iowa.gov).

c. For each metal for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of metal is at or below the action level approved by the department.

d. For each metal for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of metal is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for metals and the laboratory determines that a primary sample contains metal analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the metal analytes.

f. The laboratory may test for and provide test results for additional metals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each metal for which the primary sample was tested.

1. The concentrations shall be listed in micrograms per gram or other units as determined by the department.

2. The laboratory shall report a result of "detected but not quantified" for any metal that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(4)"*c*" and 154.72(4)"*d.*"

(3) The names and amounts of any additional metals identified by the laboratory.

h. If the primary sample fails testing for metals, the lot fails laboratory testing.

i. When a laboratory identifies additional metals in a primary sample, the laboratory shall:

(1) Notify the department of the additional metals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(5) *Contaminants—microbiological impurities.*

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for microbiological impurities.

b. The department shall provide a list of microbiological impurities for which primary samples are to be tested on the department's website (www.idph.iowa.gov).

c. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the microbiological impurity is not detected in 1 gram of matrix or as approved by the department. A primary sample may be reported as passed if a screening procedure yields a negative result or if a presumptively positive result is not found to be positive on the confirmatory procedure.

d. For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the microbiological impurity is detected in 1 gram of matrix or as approved by the department. Confirmatory procedures shall be conducted on all presumptively positive results.

e. If a laboratory is using methods to test primary samples for microbiological impurities and the

laboratory determines that a primary sample contains microbiological impurities that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification of the biological impurity.

f. The laboratory may test for and provide test results for additional microbiological impurities if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name of each microbiological impurity for which the primary sample was tested.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(5)*"c"* and 154.72(5)*"d."*

(3) The names of any additional microbiological impurities identified by the laboratory.

h. If the primary sample fails testing for microbiological impurities, the lot fails laboratory testing.

i. When a laboratory identifies additional microbiological impurities in a primary sample, the laboratory shall:

(1) Notify the department of the additional microbiological impurities detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.72(6) *Additional tests.* The laboratory may perform additional tests if asked to do so by a requester.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4078C**, IAB 10/10/18, effective 11/14/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19; see Delay note at end of chapter]

641—154.73(124E) Reporting requirements.

154.73(1) *Reporting test results.* The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

154.73(2) *Tentatively identified analytes.* A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

a. Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.73(3) *Additional reporting requirements.*

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

(1) All requirements of Standard ISO/IEC 17025;

(2) Date of primary sample collection;

(3) Date the primary sample was received by the laboratory;

(4) Date of each analysis;

(5) The LOQ and action level for each analyte, as applicable;

(6) Whether the primary sample and lot passed or failed laboratory testing; and

(7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements ≥ LOD but < LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.74(124E) Record-keeping requirements.

154.74(1) *Data package.* A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

a. The name and address of the laboratory that performed the analytical procedures;

b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel that performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;

c. All primary sample and analytical batch quality control sample results;

d. Raw data for each primary sample analyzed;

e. Instrument raw data, if any was produced;

f. Instrument test method with parameters;

g. Instrument tune report, if one was created;

h. All instrument standard calibration data;

i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

k. The analytical batch sample sequence;

l. The field sample log; and

m. The chain-of-custody form.

154.74(2) *Review of data package.* After the laboratory has compiled a data package, another individual at the laboratory shall independently review the data package. The reviewer shall:

a. Assess the analytical results for technical correctness and completeness;

b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;

c. Verify that the measurements can be traced back; and

d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.74(3) *Data package record retention.* The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.74(4) *Other records.* A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabis goods.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabis goods:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method

detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

641—154.75(124E) Quality control. The laboratory shall have quality control protocols that include the following elements:

154.75(1) *Quality control samples required.*

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

154.75(2) *Types of quality control samples.* At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website (www.idph.iowa.gov).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample as described in the laboratory testing requirements and acceptance criteria document in subrule 154.69(1). The acceptance criterion between the primary sample and the duplicate sample is less than or equal to 20 percent relative percent difference.

154.75(3) *Certified reference material for chemical analysis.* The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

154.75(4) *Calibration standards.* The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

154.75(5) *Quality control-sample report.* A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

154.75(6) *Limit-of-detection and limit-of-quantitation calculations.* For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18; **ARC 4489C**, IAB 6/5/19, effective 7/10/19]

641—154.76(124E) Security requirements. The department may request assistance from the department of public safety in ensuring a laboratory meets the security requirements in this rule.

154.76(1) *Security policy requirement.* A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabis goods and samples. The security policy shall apply to all

staff and visitors at a laboratory facility.

154.76(2) *Visitor logs.* Visitors to a laboratory facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

154.76(3) *Restricted access.* A laboratory shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its laboratory facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

(1) Limit access to authorized individuals;

(2) Maintain a log of individuals with approved access, including dates of approvals and revocations;

(3) Track times of personnel entry;

(4) Track times of personnel movement between restricted access areas;

(5) Store data for retrieval for a minimum of one year; and

(6) Remain operable in the event of a power failure.

b. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted areas.

c. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

154.76(4) *Personnel identification system.* A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility and that meets the requirements of this subrule and subrule 154.76(2).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

(1) Revoke the employee’s access to the laboratory; and

(2) Obtain and destroy the employee’s identification card, if possible.

154.76(5) *Video monitoring and surveillance.*

a. Video surveillance system. A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

b. Camera specifications. Cameras shall:

(1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;

(2) Have the ability to produce a clear, color still photograph live or from a recording;

(3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and

(4) Continue to operate during a power outage.

c. Video recording specifications.

(1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.

(2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.

(3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.

(4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. Additional requirements. A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. Retention. A laboratory shall ensure that 24-hour recordings from all video cameras are:

(1) Available for viewing by the department upon request;

(2) Retained for a minimum of 60 days;

(3) Maintained free of alteration or corruption; and

(4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

154.76(6) *Chain-of-custody policy and procedures.* A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

a. Chain of custody is maintained for samples which may have probable forensic evidentiary value; and

b. Annual training is available for individuals who will be involved with testing medical cannabis goods.

154.76(7) *Information technology systems security.* A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.

[**ARC 3836C**, IAB 6/6/18, effective 7/11/18]

These rules are intended to implement Iowa Code chapter 124E as amended by 2020 Iowa Acts, House File 2589.

[Filed ARC 1640C (Notice ARC 1571C, IAB 8/6/14), IAB 10/1/14, effective 1/30/15]
[Filed Emergency ARC 3150C, IAB 7/5/17, effective 6/13/17]
[Filed ARC 3606C (Notice ARC 3420C, IAB 10/25/17), IAB 1/31/18, effective 3/7/18]
[Filed ARC 3836C (Notice ARC 3707C, IAB 3/28/18), IAB 6/6/18, effective 7/11/18]
[Filed ARC 4078C (Notice ARC 3899C, IAB 7/18/18), IAB 10/10/18, effective 11/14/18]
[Filed ARC 4399C (Notice ARC 4240C, IAB 1/16/19), IAB 4/10/19, effective 5/15/19]
[Filed ARC 4489C (Notice ARC 4363C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19][1]
[Filed ARC 4928C (Notice ARC 4772C, IAB 11/20/19), IAB 2/12/20, effective 6/1/20][2]
[Filed ARC 5200C (Notice ARC 5082C, IAB 7/15/20), IAB 10/7/20, effective 11/11/20]

[1] July 10, 2019, effective date of Items 1, 4, 7, 10, 11, 12, 13, 15, 21, 22, and 24 of **ARC 4489C** delayed until the adjournment of the 2020 session of the General Assembly by the Administrative Rules Review Committee at its meeting held July 9, 2019.

[2] The effective date of **ARC 4928C** was corrected to June 1, 2020, in the March 11, 2020, Iowa Administrative Bulletin.

IOWA DEPARTMENT OF PUBLIC HEALTH
Office of Medical Cannabidiol
(Phone) 515-725-2076
(Fax) 515-725-0615
(E-mail) medical.cannabidiol@idph.iowa.gov
(Website) https://idph.iowa.gov/omc

MEDICAL CANNABIDIOL REGISTRATION CARD – ADULT PATIENT APPLICATION

For adult patients with a designated primary caregiver, the caregiver must also complete the Primary Caregiver Application. For patients under 18 years old (minors), use the Primary Caregiver Application, and do not complete this Adult Patient Application.

We now accept electronic applications! For online submission of registration applications, go to https://idph.iowa.gov/omc. Online submission is preferred and may result in quicker review and approval.

Print clearly. Incomplete applications may be denied. Application fees are non-returnable.

PATIENT INFORMATION

1. Full Name:_____ _____ _____
First Middle Last

2. Gender ☐ Male ☐ Female ☐ Other

3. Date of Birth (must be 18 or older) _____/_____/_____

4. Driver's License Number or Iowa Nonoperator's Identification Card Number:_____

5. Phone:_____ ☐ Check this box if a confidential message may be left at this number.

6. E-mail Address (our preferred contact method, please print legibly):_____

7. Address Where You Live: _____
house number, street, unit # (if any)

_____
City State Zip

8. Mailing Address #(if different):_____
P.O. Box, apt. #

_____
City State Zip

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 the patient's qualifying debilitating medical condition, and the dispensing of medical 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 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 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, §124E and the associated administrative rules, Iowa administrative code 641—154.

I certify under penalty of perjury that all of the information provided by me on this application is true and correct. I understand that providing false or misleading information may result in the denial or cancellation of my Medical Cannabidiol Registration Card and that the law provides severe penalties (fine and/or imprisonment) for the willful submission of known false information. I understand that I am required to know and comply with the provisions of the Medical Cannabidiol Act and the administrative rules which implement this Act. I agree to notify the Office of Medical Cannabidiol, in writing, within 10 days of any change to the information provided.

Once applications are processed, communication will be sent to your residence or email address (if provided) with further instructions. **Please provide an email address for communication and program updates.**

Any Registration Card that is lost or stolen must be reported to the Office of Medical Cannabidiol immediately.
Applicant information changes that are printed on the Registration Card (such as name or address) will require a new card to be issued.

Patient Signature(required):_____ _____/_____/_____
Date of Signature

Legal Guardian/Power of Attorney Signature(if any):_____ _____/_____/_____
Date of Signature

Legal Guardian/Power of Attorney Name(if any):_____ _____/_____/_____
Date of Signature

Legal Guardian/Power of Attorney Phone(if any):_____

Adult Patient Application Checklist (for reference only)

1. Patient Information and Attestation Section

- Patient must sign and date all areas of this application in the Patient Attestation Section.

2. Health Care Practitioner Certification Included

- Patient's health care practitioner has completed the Health Care Practitioner form and certified that the patient has one or more of the qualifying debilitating medical conditions.

3. Applicant - Patient - Documentation

- A clear copy of the patient's valid photo identification card must be attached.
    - This must be: a valid Iowa Driver's License or a valid Iowa Nonoperator's Identification Card
    - If the Iowa resident patient does not have an Iowa issued ID, contact the office for further instructions

4. APPLICATION FEE

- Fee (A check or money order should be made out to "Iowa Department of Public Health." Cash will also be accepted.)
    - Regular Application Fee - $100
    - Reduced Application Fee - $25 The patient must provide ONE of the following items listed below as proof for reduced fee. (documentation must be current within the past 12 months)
    - Social Security Disability Benefit Recipient (provide copy of current benefit notice)
    - Supplemental Security Income Payment Recipient (provide a copy of current receipt)
    - Iowa Medicaid (provide a copy of the member card)

To submit a paper application, mail the completed application and required materials to:

Iowa Department of Public Health

ATTN: OMC

321 E. 12th Street

Des Moines, IA 50319-0075

If the adult patient needs to have a caregiver with responsibility for managing his or her well-being in relation to the use of medical cannabidiol, or to assist with the transportation and handling of the medical cannabidiol, a separate Primary Caregiver application must be completed.

Person Account
Carl Olsen

+ Follow | Edit | New Contact | New Lead

Phone	Email	Registration Number	NewestAppID
	carl@carl-olsen.co...		a188y00000017dF

Details Related Chatter Activity

Application Type

Home Phone
515-343-9933 (tel:515-343-9933)

Account Name
Carl Olsen

Confidential message at home OK

Gender
Male

Mobile

Birthdate
12/26/1951

Confidential message on mobile OK

Age
70

Email
carl@carl-olsen.com (mailto:carl@carl-olsen.com)

mCBD card issuance date

Preferred Contact Method
E-mail

mCBD card expiration date

Driver's License/State ID number
[redacted]

Registration Number

Paper application

Application Count
1

NewestAppID
a188y00000017dF

Name Conversion
CARL OLSEN

Notifications - Status

Current App Status
Denied

Expiration Issue Resolved

Application Status
Denied

Information Needed

THC Data

Dispensary Sales
0

THC Account Total
0.000

90 Day THC Sum
0.000

Max 90 day THC purchased

THC sold in the last 90 days
0.000

Person Account
Carl Olsen

Follow | Edit | New Contact | New Lead

THC Limit
4.50

THC Limit Remaining
4.500

THC Waiver Granted

Phone

Email
carl@carl-olsen.co...

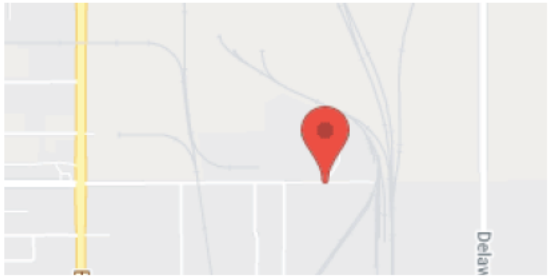
Registration Number

NewestAppID
a188y00000017dF

Over 4.5g in 90 days

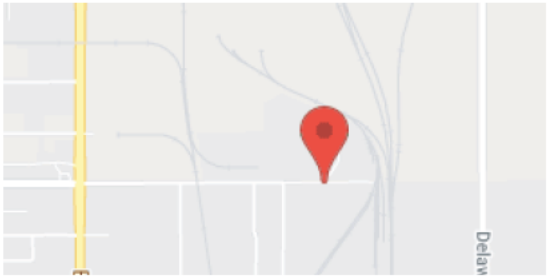
Address Information

Billing Address
130 E Aurora Ave
Des Moines, Iowa 50313



(https://www.google.com/maps?q=130%20E%20Aurora%20Ave%0ADes%20Moines,%20Iowa%2050313)

Shipping Address
130 E Aurora Ave
Des Moines, Iowa 50313



(https://www.google.com/maps?q=130%20E%20Aurora%20Ave%0ADes%20Moines,%20Iowa%2050313)

County
Polk

Billing As Shipping

Information Update Complete

Mailing Address

HCP Information

Medical Condition 1

Physician

Medical Condition Group

HCP signed date

Age Group
61 - 70

HCP Certification Complete

Deceased

System Information

Created By

Last Modified By

IowaReg Site Guest User (/lightning/r/0056A000002h5WHQAY/view)
, 11/24/2021 9:32 AM

Joe Husak (/lightning/r/0056A000002no8CQAQ/view)
, 11/29/2021 1:10 PM

Date Created
11/24/2021

Business Unit
Iowa

Person Account
Carl Olsen
State Patient Record

Follow | Edit | New Contact | New Lead

Account Owner
Iowa Department Of Public Health (/lightning/r/005t0000002bbh7AAA/view)

Phone | Email | Registration Number | NewestAppID

Account Type
Patient

Email
carl@carl-olsen.co...

Email Opt Out
a188y00000017dF

Geocode Billing Address
☑

Email Bounced
☐

Set County
☐

DataLoad
☐

formAck
☐

Send 60 Day to Expire
☐

Days to Expire is 60
☐

Oldest Sale within 90 days

Formerly Minor Patient
☐

Duplicate
☐

Custom Links

Google Search (/servlet/servlet.Integration?lid=00b6A0000010gaD&eid=0018y000004QL93AAG&ic=1)

Google Maps (/servlet/servlet.Integration?lid=00b6A0000010gaB&eid=0018y000004QL93AAG&ic=1)

Google News (/servlet/servlet.Integration?lid=00b6A0000010gaC&eid=0018y000004QL93AAG&ic=1)

Hoovers Profile (/servlet/servlet.Integration?lid=00b6A000001GaGf&eid=0018y000004QL93AAG&ic=1)

Applications (1) (/lightning/r/0018y000004QL93AAG/related/Applications__r/view)

a188y00000017dF (/lightning/r/a188y00000017dFAAQ/view)
Application Date: 11/24/2021
Approval Date:
Application Status: Denied

View All
(/lightning/r/Account/0018y000004QL93AAG/related/Applications__r/view)

Sales (Patient) (0) (/lightning/r/0018y000004QL93AAG/related/Sales1__r/view)

Declaration of Carl Olsen - November 24, 2021

In the Beginning

I began using psychedelic substances in the late 1960s. Because these substances were prohibited, it was difficult to know whether they were cut with depressants or stimulants (also prohibited for anything other than pharmaceutical use). Everything was for sale on the illicit market. I ended up addicted to methamphetamine and barbiturates.

I lost weight. I could not string a sentence together. Some of my more health conscious friends were shifting toward cannabis. When I got desperate, with help from these friends, I tried replacing methamphatamine and barbiturates with cannabis. Cannabis gave me a high and helped me sleep. I can't prove cannabis saved my life, but it certainly helped.

These friends went to Jamaica in the late 1960s and used cannabis with the Rastafarians. They came back saying Christ had resurrected as a black man by the name of George Baker Ivy.

Christ resurrecting as a person was difficult to follow, but sacramental use of cannabis made sense. Something else made sense, the comparison of blacks in Jamaica (the result of the slave trade) to Israelites in the Bible.

'Black Moses' Lives On: How Marcus Garvey's Vision Still Resonates

Desmond Dekker & The Aces – "Israelites"

In 1970, Brother Ivy died mysteriously.

Walter Wells wrote, "It was Brother Ivy who fully opened the doors of Salvation to the white inhabitants of the world within this dispensation; and taught black and white to unite together for one common cause ..."

John 10:11 ("I am the good shepherd: the good shepherd giveth his life for the sheep"); Matthew 26:31 ("I will smite the shepherd, and the sheep of the flock shall be scattered abroad"); Mark 14:27 ("I will smite the shepherd, and the sheep shall be scattered").

Christ in the Bible

The Bible describes Christ as a collective body, not just a single individual. *See* I Corinthians 12:27 ("Now ye are the body of Christ, and members in particular."). A single individual would have physical blood circulating through their body. So the blood of Christ (as a collective body of individuals) must be something constantly flowing through the members of that body. *See* I Corinthians 11:25 ("After the same manner also *he took* the cup, when he had supped, saying, This cup is the new testament in my blood: this do ye, as oft as ye drink *it*, in remembrance of me"). Cannabis is exactly that to me.

Many Jamaicans believe the Emperor of Ethiopia (Ras Tafari) is the resurrected Christ. Again, the Bible describes God as more than one person. Genesis 1:26 ("And God said, Let us make man in our image, after our likeness: ..."), again describing a collective body, people, not a person.

https://en.wikipedia.org/wiki/Rastafari
https://en.wikipedia.org/wiki/Haile_Selassie

Stevie Wonder – "Superstitious"

Niah Keith

After Brother Ivy died, leadership passed to Keith Gordon. Gordon and others incorporated the Ethiopian Zion Coptic Church in 1976.

https://www.ethiopianzioncopticchurch.org/pdfs/jamaica_1976.pdf

Responding to media reports comparing the church to a mass suicide cult in Jonestown, Guyana, Walter Wells wrote about the history of the Ethiopian Zion Coptic Church in the church's publication, The Coptic Time.

https://www.ethiopianzioncopticchurch.org/history/

October 28, 1979, CBS Sixty Minutes reported, "Law enforcement agencies say that with his new-found American friends, Keith Gordon's marijuana business took off like a turpentined cat."

https://www.ethiopianzioncopticchurch.org/pdfs/Sixty_Minutes_1979_10_28.pdf

November 1, 1979, The Florida Supreme Court wrote, "the Ethiopian Zion Coptic Church is not a new church or religion but the record reflects it is centuries old and has regularly used cannabis as its sacrament." *Town v. State ex rel. Reno*, 377 So.2d 648, 649 (Fla. 1979).

https://www.ethiopianzioncopticchurch.org/cases/town/

July 18, 1984, The Iowa Supreme Court wrote, "Testimony at his trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it." *State v. Olsen*, No. 171-69079.

https://www.ethiopianzioncopticchurch.org/cases/olsen1986/

In 1984, Gordon and Wells authorized me as the registered agent in Florida for the Ethiopian Zion Coptic Church in Jamaica. I witnessed for the church in federal tax and civil court cases.

https://www.ethiopianzioncopticchurch.org/pdfs/1986_Florida_Secretary_of_State.pdf
https://www.ethiopianzioncopticchurch.org/cases/king/
https://www.ethiopianzioncopticchurch.org/pdfs/1984_Pre_Trial_Conference.pdf
https://www.ethiopianzioncopticchurch.org/cases/olsen1989/

Before going to prison, I incorporated the church in Iowa.

https://www.ethiopianzioncopticchurch.org/pdfs/1984_Iowa_Secretary_of_State.pdf

Prison

I went to prison in 1985, passing through several state and federal institutions: (1) Classification Center in Oakdale, IA; (2) Correctional Facility in Mt. Pleasant, IA; (3) State Penitentiary in Ft. Madison, IA; (4); Federal Penitentiary in Ft. Leavnworth, KS; (5) Federal Penitentiary in Terra Haute, IN; (6) Federal Correctional Institution in Talladega, AL; and (7) Federal Correctional Institution in Tallahasse, FL.

Soon after being released in 1987, I enrolled in a two year Legal Assistant Associate Degree program (sometimes referred to as a paralegal) at the Des Moines Area Community College

and began working as a clerical for the Iowa Department of Transportation.

Appeals

The U.S. Court of Appeals rejected my petition for religious exemption in 1989. By that time, several state and federal courts had rejected similar claims, "each has rejected the argument that accommodation to sacramental use of the drug is feasible and therefore required." *Olsen v. DEA*, 878 F.2d 1458, 1462 (D.C. Cir. 1989).

I based my argument on state and federal religious exemptions for another church, the Native American Church, and another Schedule I controlled substance, peyote. 21 C.F.R. § 1307.31 Native American Church; Iowa Code § 124.204(8) Native American Church.

The dissenting opinion in *Employment Division v. Smith*, 494 U.S. 872, 918 (1990) (Blackmun, J., with whom Brennan, J., and Marshall, J., joined, dissenting), summed it up [Some religions, for example, might not restrict drug use to a limited ceremonial context, as does the Native American Church. See, e.g., *Olsen*, 878 F.2d, at 1464 ("[T]he Ethiopian Zion Coptic Church . . . teaches that marijuana is properly smoked 'continually all day'").]

Smith

Many people, including myself, were not expecting the Supreme Court to find religious use of peyote unprotected by the First Amendment. In 1973, a new federal law was enacted to overturn *Smith*, the Religious Freedom Restoration Act (RFRA), Pub. L. No. 103-141, 107 Stat. 1488 (November 16, 1993).

Only a few years later, the Supreme Court found Congress violated separation of powers by trying to legislate how the court should interpret the Constitution. See *City of Boerne v. Archbishop Flores*, 521 U.S. 507 (1997). The judicial and legislative branches are co-equal. While Congress has the sole authority to make laws, the Supreme Court has the sole authority to interpret the Constitution. So, the *Smith* decision still stands.

Peyote

The federal peyote exemption was created in 1966. Congressional Record - House, July 8, 1965, Vol. 111, pp. 15977-15978; Federal Register, March 19, 1966, Vol. 31, pp. 4679-4680; Code of Federal Regulations, 21 C.F.R. § 166.3(c)(3) (1968); U.S. House Hearings, February 3, 1970, 1970 Serial No. 91-45, pp. 117-118.

The federal peyote exemption was originally going to be included in a statute, because many people assumed it was constitutionally required by the First Amendment. However, it was decided to create it by regulation. Congress removed it from proposed legislation because Congress wanted a federal administrative agency to have complete authority over the sustances being placed under the agency's control. The difference here is key. If the peyote exemption had been included in a federal statute, the federal administrative agency would have no control over it. By including it in a regulation, it became a privilege rather than a right.

The *Smith* decision makes sense if you look at it from this historical perspective. No federal right to use peyote had ever been created.

In 1988, the Supreme Court of Oregon found religious use of peyote was protected by the First Amendment. The U.S. Supreme Court overturned the Oregon Supreme Court's opinion in *Smith*.

Oregon did not have any religious exemptions for controlled substance. Oregon's law was

"neutral toward religion" and "generally applicable". As long as these two requirements were met, the Supreme Court ruled, a religious act prohibited by state law is not protected by the First Amendment.

The *Smith* decision upheld states' rights, as long as state law is both neutral toward religion and generally applicable to everyone.

Further federal legislation was enacted in 1994 to make sacramental use of peyote a federally protected right, the American Indian Religious Freedom Act Amendments (AIRFAA), Pub. L. No. 103-344, 108 Stat. 3125 (October 6, 1994). See 42 U.S.C. § 1996a.

Unlike Oregon, Iowa enacted a statutory exemption for the religious use of peyote in 1967, immediately following the creation of the federal exemption in 1966. House File 285, Chapter 189 (July 5, 1967) (creating a statutory exemption for the religious use of peyote). House File 69, Chapter 52 (March 27, 1925) (prohibiting the use of peyote).

My Response

I stopped using cannabis in 1990. I could see it was no longer possible to argue the religious use of cannabis was protected by the First Amendment, at least not under those conditions. The federal government was supplying cannabis to patients under FDA Compassionate Use protocol, but that was considered research not accepted medical use. Patients participating in the Compassionate Use protocol received 300 cigarettes per month with a prescription to smoke 10 per day. That seemed unusual for something classified as dangerous as heroin.

I waited for cannabis to gain greater acceptance. Eventually, the law prohibiting cannabis would no longer be generally applicable.

Iowans for Medical Marijuana

In 1990, I joined with two Iowa patients in the Compassionate Use protocol who were receiving medical cannabis from the federal government (George McMahon and Barbara Douglass). The three of us formed an organization by the name of Iowans for Medical Marijuana.

Cannabis did gain greater acceptance. The federal government stopped accepting new applications for the Compassionate Use program in 1992, but California voters legalized personal cultivation of cannabis for medical use in 1996. The Clinton Administration tried to stop California from implementing the new law, but failed. See *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002), and see the personal statements from George McMahon and Barbara Douglass attached.

U.S. Supreme Court (2006)

In 2006, the U.S. Supreme Court affirmed that the exemption for the religious use of peyote is not based on race or religion. *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 434 (2006) ("Nothing about the unique political status of the Tribes makes their members immune from the health risks the Government asserts accompany any use of a Schedule I substance, nor insulates the Schedule I substance the Tribes use in religious exercise from the alleged risk of diversion").

Iowa Board of Pharmacy

In 2006, the three of us incorporated Iowans for Medical Marijuana to petition the Iowa Board of Pharmacy to reclassify cannabis as medicine in Iowa. We were successful. In 2010, the

Iowa Board of Pharmacy recommended the legislature reclassify marijuana as medicine in Iowa.

Iowa Board of Pharmacy, February 17, 2010

Iowa Supreme Court, May 14, 2010

Iowa Code Chapter 124D (2014)

The law prohibiting cannabis was generally applicable in Iowa until 2014. In 2014, the legislature enacted Senate File 2360, Chapter 1125 (May 30, 2014), the Medical Cannabidiol Act. The act allowed certified individuals to bring "a nonpsychoactive cannabinoid found in the plant" with "a tetrahydrocannabinol level of no more than three percent" from out of state into the state of Iowa. *Id.*, § 124D.2(1).

Jamaica (2015)

In 2015, Jamaica recognized religious use of cannabis. The Dangerous Drugs Act as Amended by 2015 Act No. 5. This aligns with the findings in *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, *O Centro Espirita Beneficiente Uniao do Vegetal v. Ashcroft*, 342 F.3d 1170, 1174 (2003) ("Brazil, in which there are about 8,000 Uniao do Vegetal members, recognizes Uniao do Vegetal as a religion and exempts sacramental use of hoasca from its prohibited controlled substances.").

Iowa Code Chapter 124E (2017)

In 2017, the legislature enacted House File 524, Chapter 162 (May 12, 2017), the Medical Cannabidiol Act. The act allowed certified businesses to set up large scale cultivation operations and distribution centers, and continued to allow certified individual to bring "any pharmaceutical grade cannabinoid found in the plant" with "a tetrahydrocannabinol level of no more than three percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule" from out of state into the state of Iowa. *Id*, § 124E.2(6).

Iowa Medical Cannabidiol Board

In 2019, I petitioned the Iowa Medical Cannabidiol Board to recommend petitioning the DEA for a federal exemption, like the one for peyote, for the state medical cannabidiol program. The board agreed and voted unanimously to make the recommendation on August 2, 2019.

Amendments to Chapter 124E (2020)

In 2020, the legislature enacted House File 2589, Chapter 1116, removing the three percent cap on tetrahydrocannabinol in product formulations and replaceing it with a limit of "a combined total of four and one-half grams of total tetrahydrocannabinol to a patient and the patient's primary caregiver in a ninety-day period" (which can be waived by the patient's healthcare provider). *Id.*, §§ 124E.2(6), 124E.9(14), 124E.9(15).

HF 2589 also required the department to seek federal funding guarantees for facilities openly facilitating violation of federal drug law. Chapter 1116, § 31.

Iowa Department of Public Health

On September 4, 2020, the Iowa Department of Public Health determined that the only way

to guarantee federal funding for facilities that facilitate violation of federal drug is to obtain a federal exemption like the one for peyote. Medical Cannabidiol Program Update.

Religious Exemption

Iowa has authorized cultivation, distribution, and use of cannabis, but I haven't been able to use my sacrament since 1990. Iowa law is not neutral toward religion because Iowa has recognized a statutory right to use a Schedule I controlled substance, peyote, for religious use since 1967. Iowa law is not generally applicable because Iowa allows 2 licenses to grow cannabis, 5 licenses to distribute cannabis extracts, and unlimited licenses to use cannabis extracts, while denying me that same right for long established religious use.

Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313
515-343-9933
carl@carl-olsen.com
https://carl-olsen.com

Iowa Government Online

Electronic Payment Solutions

Exit

Confirmation

Please keep a record of your Confirmation Number, or print this page for your records.

Confirmation Number **IOWMCR010740454**

Payment Details

Description	Iowa Medical Cannabidiol Registration Annual Cannabidiol Reg. Fee https://idph.iowa.gov/omc
Payment Amount	$100.00
Payment Date	11/24/2021
Status	PROCESSED

Payment Method

Payer Name	Carl Olsen
Card Number	[redacted]
Card Type	Visa
Approval Code	02127D
Confirmation Email	carl-olsen@mchsi.com

Billing Address

Address 1	130 E Aurora Ave
City/Town	Des Moines
State/Province/Region	Iowa
Zip/Postal Code	50313
Country	United States

January 7, 2022

Mr. Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313

Dear Mr. Olsen,

Your application for an Iowa medical cannabidiol registration card was received by the Department on November 24, 2021. A complete patient application requires the submission of a healthcare practitioner certification form, pursuant to Iowa Code Chapter 124E.4.1.*c*, below:

1. Issuance to a patient. Subject to subsection 6, the department may issue a medical cannabidiol registration card to a patient who:
   c. *Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.*

Because you did not submit a written certification from your health care practitioner, the Department is unable to approve your application, and it has been denied. Your credit card was automatically processed for the application fee when you submitted your application. Your payment is in the process of being refunded to you.

You maintain the right to appeal this decision. The process for appeal of this denial is outlined in 641 IAC 154.7, below:

- *If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.*

Sincerely,

Owen Parker, MPH
Chief, Bureau of Medical Cannabidiol
Iowa Department of Public Health

Cc: Joseph Husak

EXHIBIT 3

January 20, 2022

Iowa Department of Public Health
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319-0075
Certified Mail Return Receipt: 7015 0920 0002 1767 5776

Department of Public Health:

On November 7,2020, the department denied my application for a medical cannabidiol registration card. The letter denying the application is attached to this letter.

Carl Olsen hereby appeals the denial a medical cannabidiol registration in accordance with 641 Iowa Administrative Code – Chapter 154, Section 7.

Please forward this request within five working days to the department of inspections and appeals.

Thank you!

Carl Olsen
130 E Aurora Ave
Des Moines, Iowa 50313-3654
515-343-9933
carl@carl-olsen.com

EXHIBIT 4

January 7, 2022

Mr. Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313

Dear Mr. Olsen,

Your application for an Iowa medical cannabidiol registration card was received by the Department on November 24, 2021. A complete patient application requires the submission of a healthcare practitioner certification form, pursuant to Iowa Code Chapter 124E.4.1.c, below:

1. Issuance to a patient. Subject to subsection 6, the department may issue a medical cannabidiol registration card to a patient who:
   c. *Submits a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition.*

Because you did not submit a written certification from your health care practitioner, the Department is unable to approve your application, and it has been denied. Your credit card was automatically processed for the application fee when you submitted your application. Your payment is in the process of being refunded to you.

You maintain the right to appeal this decision. The process for appeal of this denial is outlined in 641 IAC 154.7, below:

- *If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department's address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.*

Sincerely,

Owen Parker, MPH
Chief, Bureau of Medical Cannabidiol
Iowa Department of Public Health

Cc: Joseph Husak

Medical Cannabidiol, IDPH <medical.cannabidiol@idph.iowa.gov>

Re: Enrollment for Medical Cannabidiol Program Received

Carl Olsen <carl@carl-olsen.com> Mon, Dec 27, 2021 at 7:08 AM
To: "medical.cannabidiol@idph.iowa.gov" <medical.cannabidiol@idph.iowa.gov>
Cc: Colin Murphy <ccmurphy@grllaw.com>

Hello,

I submitted an application on November 24, 2021.

application number is **IACBD0024953**

Can you give me an update on the status of my application?

Thank you!

--

Carl Olsen

130 NE Aurora Ave

Des Moines, Iowa 50313-3654

515-343-9933

carl@carl-olsen.com

https://carl-olsen.com

From: "carl@carl-olsen.com" <carl@carl-olsen.com>
Date: Sunday, December 5, 2021 at 9:34 AM
To: "medical.cannabidiol@idph.iowa.gov" <medical.cannabidiol@idph.iowa.gov>
Cc: Colin Murphy <ccmurphy@grllaw.com>, "carl@carl-olsen.com" <carl@carl-olsen.com>
Subject: Re: Enrollment for Medical Cannabidiol Program Received

Dear Department:

There were a couple of typographical errors in the declaration of religious use I filed with my application, so I'm attaching a corrected declaration.

I believe 7 business days would be approximately tomorrow, Monday, December 6, 2021.

Can you give me an update on the status of my application?

Thank you!

--

Carl Olsen

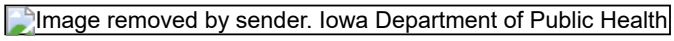
130 NE Aurora Ave

Des Moines, Iowa 50313-3654

515-343-9933

carl@carl-olsen.com

https://carl-olsen.com



Dear Carl Olsen:

The Iowa Department of Public Health has received your application for a Medical Cannabidiol Registration Card. Our staff **will review your application** within the next 7 business days. You may receive occasional updates at this email address throughout the review process. Your application has not been approved yet.

Your application number is **IACBD0024953**. This is for your reference until this application process is complete. Please do not reply to this email but send inquiries to:

Medical.Cannabidiol@idph.iowa.gov

Thank you,

Office of Medical Cannabidiol
Iowa Department of Public Health
Website: https://idph.iowa.gov/omc

From: <noreply@salesforce.com> on behalf of "medical.cannabidiol@idph.iowa.gov" <medical.cannabidiol@idph.iowa.gov>
Date: Wednesday, November 24, 2021 at 9:32 AM
To: "carl@carl-olsen.com" <carl@carl-olsen.com>
Cc: "medical.cannabidiol@idph.iowa.gov" <medical.cannabidiol@idph.iowa.gov>
Subject: Enrollment for Medical Cannabidiol Program Received

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building, Third Floor
Des Moines, IA 50319

CARL OLSEN, Appellant, v. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	CASE NO. 22IDPH0002 **RESPONSE TO REQUESTS FOR ADMISSION**

COMES NOW Appellant, by and through the undersigned, and, pursuant to Iowa Code section 17A.13, 641 Iowa Administrative Code (IAC) 173.13, and Iowa Rule of Civil Procedure 1.510, and submits the following Responses to the Requests for Admission:

RESPONSE TO REQUEST FOR ADMISSIONS

1. Do you admit that you do not have a "debilitating medical condition" (as defined in Iowa Code section 124E.2(2), 641 IAC 154.1, and 653 IAC 13.15(1))?

Admit ___X___ Deny _____

2. Do you admit that you did not submit a "written certification" (as defined in Iowa Code section 124E.2(14) and 641 IAC 154.1) to the Respondent in conjunction with your medical cannabidiol registration card application?

Admit ___X___ Deny _____

3. Do you admit that you have never used "medical cannabidiol" (as defined in Iowa Code section 124E.2(10) and 641 IAC 154.1) that was sold by a "dispensary" (as defined in 641 IAC 154.1)?

Admit ___X___ Deny _____

EXHIBIT 5

Respectfully submitted,

/s/ Colin Murphy AT0005567
By: Colin Murphy
440 Fairway, Suite 210
West Des Moines, IA 50266
Phone: (515) 226-0500
Fax: (515) 244-2914
ccmurphy@grllaw.com

ATTORNEYS FOR APPELLANT

Sent via email only to:

Heather Adams
Laura Steffensmeier

Proof of Service

The undersigned certifies that the foregoing instrument was served upon Attorney for Appellant by delivery in the following manner on the 18th day of March, 2022.

___ U.S. Mail	___FAX
___ Hand Delivery	___Overnight Courier
___ Federal Express	___Other
_X_ Electronically	

Signature: /s/ Colin Murphy

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building – Third Floor
Des Moines, Iowa 50319

Carl Olsen,	)	
	)	Docket No. 22IDPH0002
Appellant	)	
	)	
v.	)	**Order Rescheduling**
	)	**Telephone Hearing**
Iowa Department of Public Health,	)	
	)	
Respondent	)	

This is an appeal from a decision of the Iowa Department of Public Health to deny the Appellant's application for an Iowa medical cannabidiol registration card. A telephone hearing is scheduled for April 19, 2022. Prior to the hearing, the Appellant moved to continue the matter pending a decision in a related district court action. The Respondent does not resist the motion. Accordingly, the motion is granted. The hearing is re-scheduled for **9:00 a.m. on Wednesday, June 15, 2022.**

At the date and time of the hearing, all parties must call the toll-free number **1-866-770-6601. The system will ask if you are the organizer. You are not the organizer – Do not press 2.** You will be placed on hold until the judge enters the conference call.

Dated this 15th day of April, 2022.

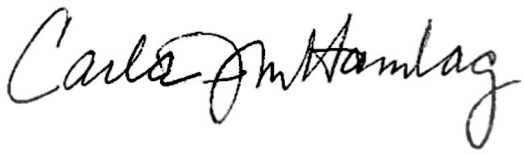
Carla J. Hamborg
Administrative Law Judge
cc: Carl Olsen (by Mail and Email)
Colin Murphy, Attorney for Appellant (by Mail and Email)
Laura Steffensmeier, AAG (By AEDMS)
Heather Adams, AAG (By Email)
Sarah Reisetter, IDPH (By Email)
Owen Parker, IDPH (By Email)

Case Title: CARL OLSEN V. IOWA DEPARTMENT OF PUBLIC HEALTH

Case Number: 22IDPH0002

Type: Order

IT IS SO ORDERED.



Carla Hamborg, Administrative Law Judge

ELECTRONICALLY FILED 2022 JUL 08 1:12 PM ADMIN HEARING E-FILING SYSTEM
E-FILED 2023 MAR 20 10:52 AM POLK - CLERK OF DISTRICT COURT

Iowa Department of Inspections and Appeals
Division of Administrative Hearings

CARL OLSEN, Appellant, v. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	)))))))))	DIA Docket No. 22IDPH002 **RESPONDENT'S POST-HEARING BRIEF**

I. SUMMARY OF THE CASE

The Iowa Department of Public Health ("Department") administers the Medical Cannabidiol Act ("Act) contained at Iowa Code chapter 124E, which authorizes patients who suffer from debilitating medical conditions to possess and use medical cannabidiol upon receipt of a medical cannabidiol registration card ("registration card"). The Act requires – as a condition of obtaining a registration card – that an applicant obtain a written certification from a health care practitioner that the applicant suffers from a debilitating medical condition which qualifies for the use of medical cannabidiol. Iowa Code §§ 124E.3, 124E.4.

On November 24, 2021, Appellant Carl Olsen submitted an online application for a registration card to the Department. Department's Exhibit 2. Appellant's application did not contain the required health care practitioner certification form. Department's Exhibits 2 and 5, Testimony of Owen Parker. Appellant admits he does not have a debilitating medical condition as defined by the Act, and that he does not meet the requisite statutory qualifications to use medical cannabidiol for the legally authorized purposes. Department's

Exhibit 5.

In lieu of submitting the health care practitioner certification form, Appellant submitted a personal "Declaration" describing his religious use of cannabis as a member of the Ethiopian Zion Coptic Church. Department's Exhibit 2, Testimony of Owen Parker. Owen Parker, Chief of the Bureau of Medical Cannabidiol within the Department, reviewed Appellant's application. Testimony of Owen Parker. Mr. Parker could not approve the application because it lacked the required health care practitioner certification form. Testimony of Owen Parker. Mr. Parker consulted with his supervisor, Sarah Reisetter, Deputy Director of the Department, who confirmed that he did not have any authority to approve the application. Testimony of Owen Parker. Mr. Parker denied Appellant's application and sent written notification regarding the denial to Appellant on January 7, 2022. Department's Exhibit 3, Testimony of Owen Parker. The denial letter provided information regarding Appellant's right to appeal the denial. Department's Exhibit 3. On January 20, 2022, Mr. Olsen filed a timely appeal. Department's Exhibit 4.

II. APPLICABLE LAW

The Medical Cannabidiol Act, Iowa Code chapter 124E, provides the authority for the Department to issue registration cards to eligible patients and primary caregivers. The Act provides a list of the requirements that must be satisfied before the Department may issue a registration card to a patient, which includes that the applicant must 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. Iowa Code §§ 124E.4(1)(*c*), 124E.3; 641 IAC 154.3(1)"c". The Medical Cannabidiol Act solely authorizes the possession and use of medical cannabidiol for medical purposes: the Act does not

reference any religion or religious use of medical cannabidiol and does not provide a mechanism for individuals to apply for a registration card for religious use.

III. ARGUMENT

A. The Department was required to deny Appellant's application for a registration card based on the undisputed facts and clear statutory requirements.

Based on the undisputed facts, Appellant's application for a registration card was properly denied because he (admittedly) failed to submit a written health care practitioner certification form. Appellant further admits that he does not have a "debilitating medical condition" as defined in Iowa Code section 124E.2(2) and 641 IAC 154.1. Under Iowa law, access to medical cannabidiol is restricted to individuals that have debilitating medical conditions. Based on the clear language of chapter 124E, and accompanying administrative rules, the Department was required to deny Appellant's application for a registration card because Appellant failed to meet the minimum requirements for issuance.

Appellant's brief cites to other contexts in which the Department provides for religious exemptions or waivers as support for his argument that the Department should recognize a religious exemption in this matter. This argument fails for three reasons. First, the examples cited by Appellant involve circumstances in which the Department recognizes a religious exemption to a generally applicable state requirement. In certain circumstances in which the legislature has imposed a mandated activity to protect public health – such as childhood screenings or immunizations – it has chosen to provide exemptions to the required activity if it conflicts with an individual's sincere religious beliefs. In contrast to the other examples provided by Appellant, Iowa's Medical Cannabidiol Act does not impose a requirement or obligation on all Iowans that would potentially educe a similar exemption

process.[1]

Second, in each of the examples cited by Appellant – including dental and vision screening of children, blood lead testing of children, immunization of children, the placement of prophylactic solutions in the eyes of newborns, and specific courses of medical treatment – the ability for the Department to authorize a religious exemption or waiver was expressly established by the legislature. In enacting the Medical Cannabidiol Act, the legislature did not include any provision that would authorize the Department to waive or exempt any of the statutory requirements to allow for the religious use of medical cannabidiol.

Finally, while the Department does have a general process for requesting waivers, the Department cannot waive a provision of law that is specifically mandated by statute. Iowa Code § 17A.9A(2)(*c*); 641 IAC 178. Because the requirement for a written health care practitioner certification form is mandated by the Act, the Department would lack

[1] It is important to note that while the Iowa legislature has chosen to provide for religious exemptions to certain required screenings and immunizations, it is not constitutionally obligated to do so. For example, the states of California, Connecticut, Maine, Mississippi, New York, and West Virginia do not allow religious exemptions to childhood vaccinations and authorize exemptions only on medical grounds. Courts have consistently held that states are not required to include religious exemptions to generally applicable state requirements. *See, e.g., Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015) (holding state "could constitutionally require that all children be vaccinated in order to attend public school."); *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App'x 348, 353–54 (4th Cir. 2011) (finding state statute requiring school vaccinations does not unconstitutionally infringe the right to free exercise and that "this conclusion is buttressed by the opinions of numerous federal and state courts that have reached similar conclusions in comparable cases."); *Whitlow v. California*, 203 F. Supp. 3d 1079, 1084 (S.D. Cal. 2016) (holding "the Constitution does not require the provision of a religious exemption to vaccination requirements."); *McCarthy v. Boozman*, 212 F.Supp.2d 945, 948 (W.D. Ark. 2002) (finding it is "well settled that a state is not required to provide a religious exemption from its immunization program. The constitutional right to freely practice one's religion does not provide an exemption for parents seeking to avoid compulsory immunization for their school-aged children.")

authority to approve a request for waiver if Appellant submitted such a request.

B. The agency cannot decide Appellant's constitutional challenges to the Medical Cannabidiol Act.

Appellant argues the presiding officer should rule on his constitutional challenge to Iowa Code chapter 124E. The Department disagrees. While it is necessary for Appellant to raise his constitutional challenge at the agency level in order to preserve it for judicial review, the agency lacks authority to rule on Appellant's constitutional challenge to the statute. *Endress v. Iowa Dep't of Human Servs.*, 944 N.W.2d 71, 83 (Iowa 2020) (stating "It is true DHS's final decision preserved Endress's constitutional arguments for judicial review. This is because DHS lacked authority to decide her constitutional issues. Moreover, Endress is required to raise constitutional issues at the agency level, even though the agency lacks the authority to decide the issues, in order to preserve the constitutional issues for judicial review."). Under the separation of powers doctrine, the judiciary is the branch of government responsible for determining the constitutionality of legislation. *ABC Disposal Sys., Inc. v. Dep't of Natural Res.*, 681 N.W.2d 596, 605 (Iowa 2004) (stating "We will not give any deference to the view of the agency with respect to the constitutionality of a statute or administrative rule, because it is exclusively up to the judiciary to determine the constitutionality of legislation and rules enacted by the other branches of the government."). Therefore, a decision in this appeal need only note Appellant's constitutional argument, but need not rule on the constitutionality of Iowa's Medical Cannabidiol Act.

Appellant's brief references the recent district court ruling in *Olsen v. Iowa Department of Public Health*, which dismissed the case due to Appellant's failure to exhaust administrative remedies. CVCV062566 (Polk Co. District Court, May 3, 2022).

The ruling does not state that the agency can or should rule on his constitutional challenge. Rather, it states "Mr. Olsen's constitution claims could be fully adjudicated and the declaratory relief he seeks obtained through a judicial review proceeding under chapter 17A." *Id.* at 6–7. It then directs him to "seek relief through Chapter 17A proceedings, after his administrative remedies have been exhausted." *Id.* at 7. The requirement for Appellant to complete the administrative process prior to seeking judicial review does not equate to a requirement for the agency to rule on his constitutional challenge.

C. Even if the agency were to rule on Appellant's constitutional challenge, the Act is constitutional.

The Free Exercise Clause of the First Amendment, applicable to the States under the Fourteenth Amendment, provides that "Congress shall make no law . . . prohibiting the free exercise" of religion. *Fulton v. City of Philadelphia, Pennsylvania*, 141 S. Ct. 1868, 1876 (2021). The Free Exercise Clause, however, "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes).'" *Employment Div. v. Smith*, 494 U.S. 872, 879 (1990) (quoting *United States v. Lee*, 455 U.S.252, 263 (1982) (Stevens, J., concurring)). The analysis of a free exercise claim begins with a determination of whether or not the challenged law is a neutral law of general applicability governed by *Smith*.

The Iowa Supreme Court has followed a three-step framework for analyzing whether a law is a neutral law of general applicability. *See Mitchell Cnty. v. Zimmerman*, 810 N.W.2d 1, 9–11 (Iowa 2012). First, a court considers whether the law is facially neutral. *Id.* at 9. If a law is facially neutral, a court next considers whether the law is operationally neutral. *Id.* at 10. If a law is operationally neutral, a court finally considers whether the law

is generally applicable. *Id.* at 11.

If a court finds the challenged law satisfies all three of these tests, then *Smith* governs and the free exercise claim must fail. *Id.* at 8–9. If a court finds the challenged law fails any of these three tests, then the court must analyze whether the challenged law can pass constitutional muster under a strict scrutiny analysis. *Id.* A law can survive strict scrutiny if it advances interests of the highest order and is narrowly tailored to achieve those interests. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993). The Free Exercise Clause does not prohibit a state from enforcing a regulatory law that is both neutral and generally applicable. *Mitchell Cnty.*, 810 N.W.2d at 8.

The specific laws that prohibit Appellant from engaging in the sacramental use of marijuana are Iowa Code section 124.204(4)(*m*), which places marijuana in Schedule I of the Iowa Controlled Substances Act, and Iowa Code section 124.401, which establishes criminal penalties for the unlawful possession of marijuana. Pursuant to Iowa Code chapter 124E, the legislature has authorized Iowans with specific debilitating medical conditions to legally access medical cannabidiol. Medical cannabidiol falls under the definition of marijuana in Iowa Code section 124.101(20), and is therefore a Schedule I controlled substance; however, Iowa Code section 124E.12 provides an affirmative defense to criminal prosecution for the charge of unlawful possession of marijuana to a patient in possession of medical cannabidiol with a valid registration card. In addition, Iowa Code section 124.401(5) 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 chapter 124E." The laws cited herein are the pertinent laws to analyze in evaluating neutrality and general applicability.

"The most basic requirement of neutrality is 'that a law not discriminate on its face.'" *Mitchell Cnty.*, 810 N.W.2d at 9 (quoting *Lukumi*, 508 U.S. at 533). "'A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." *Id.* The laws governing marijuana in Iowa are indisputably facially neutral – they do not reference religion in any way.

Appellant argues that Iowa Code chapter 124 is not neutral towards religion because of the statutory exemption for the religious use of peyote. However, this specific argument is barred by the doctrine of *res judicata*. The doctrine of *res judicata* includes both the doctrines of claim preclusion and issue preclusion. *Winnebago Indus., Inc. v. Haverly*, 727 N.W.2d 567, 571–72 (Iowa 2007). Under the doctrine of issue preclusion (also known as collateral estoppel), once a court has decided an issue of law or fact necessary to its judgment, the same issue cannot be re-litigated in a subsequent proceeding. *Id.* at 571. Issue preclusion serves the important dual purposes of protecting parties from "the vexation of relitigating identical issues with identical parties…and to further the interest of judicial economy and efficiency by preventing unnecessary litigation." *Id.* at 572.

Our Supreme Court follows a four-factor test to determine if the issue preclusion doctrine applies to bar re-litigation of an issue – namely, the court will review whether:

1) the issue determined in the prior action is identical to the present issue;
2) the issue was raised and litigated in the prior action;
3) the issue was material and relevant to the disposition in the prior action; and

4) the determination made of the issue in the prior action was necessary and essential to that resulting judgment.

Id.

Appellant's argument that Iowa Code chapter 124 is not neutral due to the peyote exemption has been rejected several times, including by the Eighth Circuit in a prior case initiated by Appellant. *Olsen v. Mukasey*, 541 F.3d 827 (8th Cir. 2008). In *Olsen v. Mukasey*, Appellant argued "the [Controlled Substances Acts] are not generally applicable because they exempt the use of alcohol and tobacco, certain research and medical uses of marijuana, and the sacramental use of peyote." *Id.* at 832. In response to this argument, the Eighth Circuit held "[g]eneral applicability does not mean absolute universality . . . [e]xceptions do not negate that the CSAs are generally applicable." *Id.* Ultimately, the Eighth Circuit held that Olsen's "free exercise claim—alone or hybrid—is barred by collateral estoppel." *Id.* (Based on the fact that his free exercise claim had been previously denied by courts in *State v. Olsen*, 315 N.W.2d 1 (Iowa 1982); *U.S. v. Rush*, 738 F.2d 497 (1st Cir. 1984); and *Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458 (D.C. Cir. 1989)). The decision in *Olsen v. Mukasey* clearly satisfies each of the four elements necessary to invoke issue preclusion. Consequently, in light of the above case law and the doctrine of res judicata, Appellant's arguments on this issue are barred and any reviewing body should find that Iowa's Controlled Substances Act is facially neutral towards religion and is constitutional despite the exemption for peyote. *See also McBride v. Shawnee County*, 71 F.Supp.2d 1098 (D. Kansas 1999).

Appellant has not asserted, and would have no basis to assert, that Iowa's Medical Cannabidiol Act is not facially neutral. There are no references to religion or any specific religious practices in Iowa Code chapter 124E. Clearly, Iowa Code chapter 124E is facially

neutral. Based on issue preclusion and a plain reading of chapter 124E, the pertinent laws are all facially neutral.

To determine operational neutrality, a court must "look beyond the language" to determine whether there is a religious practice being targeted for discriminatory treatment. *Mitchell Cnty.*, 810 N.W.2d at 10. Appellant does not allege, and has never alleged in prior cases, that laws placing marijuana in Schedule I were passed to target the religious practices of the members of the Ethiopian Zion Coptic Church. This stands in sharp contrast to the ordinances at issue in *Lukumi*, wherein the City of Hialeah passed ordinances to prohibit religious animal sacrifice by members of the Santeria church. 508 U.S. at 527–28. Although the ordinances themselves did not explicitly reference religion or the Santeria church, the record overwhelming established that the city council members passed the ordinances specifically to prevent religious animal sacrifice by church members. The Supreme Court held that a facially neutral law is not neutral if the objective of the law is to infringe on certain practices due to religious motivation. *Id.* at 533.

Given that Iowa, along with the federal government and the remaining 49 states, enacted laws classifying marijuana as a Schedule I controlled substance to prevent drug abuse and promote the public health – and not to hinder the religious practices of the Ethiopian Zion Coptic Church – there can be no dispute that the laws are operationally neutral.

> A law fails the general applicability requirement if it burdens a category of religiously motivated conduct but exempts or does not reach a substantial category of conduct that is not religiously motivated and that undermines the purposes of the law to at least the same degree as the covered conduct that is religiously motivated.

Mitchell Cnty., 810 N.W.2d at 13 (quoting *Blackhawk v. Pennsylvania*, 381 F.3d 202,

209 (3rd Cir. 2004)). "[F]ederal courts have generally found laws to be neutral and generally applicable when the exceptions, even if multiple, are consistent with the law's asserted general purpose." *Id*. The purpose of classifying marijuana as a Schedule I controlled substance was to prevent drug abuse and protect the public health. *See* Iowa Code § 124.201 (setting forth the factors to consider in making scheduling recommendations); *State v. Olsen*, 315 N.W.2d 1, 8–9 (Iowa 1982). This purpose applies universally to the numerous controlled substances listed in the five schedules set forth in chapter 124.

Appellant is specifically requesting a lawful right to purchase, possess, and use medical cannabidiol for religious purposes in accordance with Iowa Code chapter 124E. Admittedly, Iowa Code chapter 124E does provide an exception to the general law that marijuana is illegal. But it does not follow that the laws making marijuana illegal are not generally applicable. Iowa's Medical Cannabidiol Act provides for controlled access to a controlled substance for medical use. This highly regulated access to medical cannabidiol is similar to the familiar concept of patient access to controlled substances through a prescription authorized by a health care practitioner.

As previously stated, Iowa's Controlled Substances Act establishes criminal penalties for the possession of a controlled substance. Iowa Code § 124.401. But chapter 124 also makes it lawful for an individual to possess a controlled substance if prescribed or furnished by a licensed health care professional for a legitimate medical purpose. Iowa Code § 124.401(5). For example, the possession of hydrocodone, a controlled substance, is illegal for someone who does not have a prescription for it, while the possession of hydrocodone is legal for someone who has a valid prescription. This disparity exists

because a licensed health care professional has determined that a patient under their care has a medical need for hydrocodone. The prescribing of controlled substances occurs in a highly regulated environment, with regulation by the federal Drug Enforcement Administration, the Iowa Board of Pharmacy, and the various licensing boards established under Iowa Code chapter 147 that license health care practitioners with prescriptive authority.

Iowa's Medical Cannabidiol Act – the "exception" cited by Appellant – is analogous to the allowance in chapter 124 for access to controlled substances via prescription for a medical reason. Neither chapter 124 nor chapter 124E establish a system of government assessment of individual exemptions. Rather, they establish the allowance for medical use of controlled substances as authorized (either through a prescription in chapter 124 or a written certification of a debilitating medical condition in chapter 124E) by a patient's health care provider. This medical allowance is categorically unique. It allows health care providers to authorize treatment of medical conditions using controlled substances. Chapter 124E does not authorize use of medical cannabidiol outside of a medical context in which a health care practitioner diagnoses, or affirms a diagnosis for, a patient with a debilitating medical condition and provides the patient with explanatory information about the "therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment." Iowa Code § 124E.3. Use of a controlled substance for medical treatment does not undermine the goals of the Controlled Substances Act to prevent drug abuse and protect the public health. Society has recognized that tightly controlled access to controlled substances is a cornerstone of medical care. Because of the nature of this excepted category of use, the laws prohibiting the use of marijuana

outside of the medical context remain generally applicable and the State can refuse to extend access to medical cannabidiol to individuals with a religious hardship. A contrary finding would allow a person to seek access to any controlled substance of their choosing, including opioids that have led to the ongoing opioid epidemic, for religious use.

Because the laws making controlled substances, including marijuana, illegal except for medical purposes are neutral and generally applicable, they "need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." *Lukumi*, 508 U.S. at 531. The Free Exercise Clause does not relieve someone of obligation to comply with a valid and neutral law of general applicability. *Smith*, 494 U.S. at 879–80. Therefore, there is no basis to declare Iowa Code chapter 124 or 124E unconstitutional as Appellant urges.

Even a contrary finding would not necessarily result in a mandate for the Department to issue Appellant a registration card. Based on the record established at the contested case hearing, Appellant has not demonstrated how access to medical cannabidiol – as that term is defined in Iowa Code section 124E.2(10) and 641 IAC 154.1 – would allow him to practice his religion consistent with the beliefs of the Ethiopian Zion Coptic Church. Specifically, Appellant has indicated through testimony at hearing and in prior litigation that his religious use primarily entails smoking marijuana – a practice expressly prohibited by the Act. Iowa Code § 124E.17.

IV. CONCLUSION

The Department's denial of Appellant's application for a registration card should be AFFIRMED.

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

/s/ Heather Adams
HEATHER ADAMS
Assistant Attorney General
1305 East Walnut Street, 2nd Fl.
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/s/ Laura Steffensmeier
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Assistant Attorney General
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Email: Laura.Steffensmeier@ag.iowa.gov

ATTORNEYS FOR IOWA
DEPARTMENT OF PUBLIC HEALTH

Filed electronically via AEDMS.

Copy to:

Colin Murphy
ATTORNEY FOR APPELLANT
ccmurphy@grllaw.com

Proof of Service

The undersigned certifies that the foregoing instrument was served upon Attorney for Appellant by delivery in the following manner on the 8th day of July, 2022.

___ U.S. Mail	___FAX
___ Hand Delivery	___Overnight
___ Federal Express	___Other
_X_ Electronically	

Signature: */s/ Laura Steffensmeier*

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building
Des Moines, Iowa 50319

CARL OLSEN, Appellant, vs. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	Docket No. ***22IDPH0002*** ***BRIEF IN SUPPORT OF APPEAL OF DENIAL OF MEDICAL CANNABIDIOL REGISTRATION CARD***

COMES NOW Appellant Carl Olsen, through counsel, Colin Murphy, and submits the following Brief in Support of Appeal of Denial of Medical Cannabidiol Registration Card.

BRIEF

FINDINGS OF FACT

Appellant established through his declaration and testimony at hearing that he is a member of the Ethiopian Zion Coptic Church, and his sacrament is marijuana.

This is consistent with prior findings and stipulations in both state and federal courts over the last 43 years that address Appellant's religious beliefs and practices. *See Town v. State ex rel. Reno*, 377 So. 2d 648, 650-52 (Fla. 1979)("[t]he record substantiated the trial court's findings that the [Ethiopian Zion Coptic Church] was a religion within the first amendment, that petitioner sincerely subscribed to the beliefs of the church, and that the use of cannabis was an integral part of the religion") ((noting also this worship has been conducted for centuries before the discovery of America and the adoption of the United States Constitution); *State v. Olsen*, 315 N.W.2d 1, 7-9 (Iowa 1982) ("[w]e assume . . . that the religion practices by Olsen is one which is protected by the free exercise clause and that Olsen's belief in the marijuana sacrament is 'sincere and central' to the religion");

U.S. v. Rush, 738 F.2f 497, 512 (1st Cir. 1984) ("[t]here is no question that marijuana use is an integral part of the religious doctrine and practice of the Ethiopian Zion Coptic Church, and that appellants [including Carl Olsen] are sincere practicing members of that Church"); *Olsen v. State of Iowa*, 1986 WL 4045 *1, 3 (S.D. Iowa Mar. 19, 1986)('[p]laintiff is a priest of the Ethiopian Zion Coptic Church. This religion uses marijuana as an integral part of its religious doctrine") ("Olsen is a member and priest of the Ethiopian Zion Coptic Church. Testimony at this trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it")(quoting *State v. Olsen*, No. 171-69079 (Iowa Jul. 18, 1984) attached to the ruling as Exhibit A); *Olsen v. Drug Enforcement Admin.* 878 F.2d 1458, 1462 (D.C. Cir. 1989) ("[t]he [Drug Enforcement Administration], for purposes of this decision . . . accepts that the Ethiopian Zion Coptic Church is a bona fide religion whose sacrament is marijuana"); *U.S. v. Lepp*, 2008 WL 3843282 *11 (N.D. Cal. Aug. 14, 2008)("[p]etitioner Olsen [was] a member and priest of the Ethiopian Zion Coptic Church . . . . Olsen asserts, and the government concedes for purposes of this case, that the church's sacrament is marijuana . . . ."'); *Olsen v. Holder*, 610 F. Supp. 2d 985 (S.D. Iowa 2009)("[p]laintiff is a member and priest of the Ethiopian Zion Coptic Church, a recognized religion that employs marijuana as 'an essential portion of [its] religious practice'").

Appellant applied for an Iowa Medical Cannabidiol Registration Card on November 24, 2021 and uploaded a declaration detailing his religious beliefs and request for a religious exemption for the use of marijuana extracts. The declaration was meant to serve as the functional equivalent of the certification by a health care practitioner.

ARGUMENT

THE DEPARTMENT OF INSPECTIONS AND APPEALS HAS JURISDICTION OVER THE ISSUE OF A PERSONAL RELIGIOUS EXEMPTION FOR THE POSSESSION AND USE OF MEDICAL CANNABIDIOL.

Appellant contends the Department of Inspections and Appeals has jurisdiction over the issue he is raising in support of the appeal of the denial of his medical cannabidiol registration card application: whether the denial violates Appellant's constitutional right to the free exercise of his religion as a member of the Ethiopian Zion Coptic Church.

Iowa law requires Appellant to raise constitutional issues before state agencies in order to preserve them for judicial review. *See Garwick v. Iowa Dep't of Transp.*, 611 N.W.2d 286, 288-89 (Iowa 2000); *Soo Line R Co. v. Iowa Dep't of Transp.*, 521 N.W.2d 685, 691 (Iowa 1994); *Fisher v. Iowa Bd. of Optometry Examiners*, 478 N.W.2d 609, 612 (Iowa 1991). This is true even though the agency may lack the authority to decide the issue. *Endress v. Iowa Dept. of Human Servs.*, 944 N.W.2d 71, 83 (Iowa 2020).

One of the grounds upon which the district court may grant judicial review is whether an agency action is "unconstitutional on its face or as applied or is based on a provision of law that is unconstitutional on its face or as applied." See Iowa Code § 17A.19(10)(a) (2022). Appellant believes this statute provides the Department of Inspections and Appeals with jurisdiction to consider constitutional issues surrounding the application of a "provision of law" like Iowa Code Chapter 124E.

Also, Appellant and the Iowa Department of Public Health (the "**Department**") were previously parties to a matter before the Iowa District Court in Polk County where Appellant sought a declaratory judgment regarding whether the sacramental use of cannabis should be considered a qualifying condition for purposes of the medical

cannabidiol registration card. That case was dismissed on procedural grounds, but the takeaway is that Appellant needed to first fully adjudicate his constitutional claims before the agency because that is his exclusive remedy. *See* Ex. 1 May 3, 2022 Ruling on Motions to Dismiss, Polk County No. CVCV062566. The conclusions of law provide additional justification in support of the jurisdiction to raise and litigate the constitutional issues here.

It is important to also note that Appellant is unable to petition for a waiver from the rule requiring "a written certification to the department signed by the patient's health care practitioner that the patient is suffering from a debilitating medical condition" because the Department has not "established by rule an application, evaluation and issuance procedure permitting waivers" of the application requirements of a registration card. *See* Iowa Code § 17A.9A(1) (2022); *see also* Iowa Admin. Code r. 641 – 154 (no mention of procedure permitting waivers). However, the Department has long maintained processes to review and ostensibly approve similar religious exemptions or waivers in a variety of different contexts, including: (1) specific embalming and disposition of corpses; (2) dental screening of children[1]; (3) vision screening of children; (4) blood lead testing of children[2]; (5) immunization of children[3]; (6) the placement of prophylactic solutions in the eyes of newborns; and (7) specific courses of medical

1. The religious exemption certificate can be found at: https://idph.iowa.gov/Portals/1/Files/OralHealthCenter/Certificate%20of%20Dental%20Screening%20Exemption.rev.9.13.12.pdf
2. The religious exemption certificate can be found at: https://idph.iowa.gov/Portals/1/userfiles/106/ReligiousExemptionCertificate.pdf
3. The religious exemption certificate can be found at: https://iris.iowa.gov/docs/Certificate_of_Immunization_Exemption_Religious.pdf

treatment for any person. *See* Iowa Code §§ 135.11(7), .17(1)(d), .35D(10), .105D(4), .146; *see also* Iowa Code §§ 139A.8(4)(a)(2), .38, .39 (2022).

The Department, as an agency of the State of Iowa, may also be subject to the new Iowa law on waiving COVID-19 vaccination requirements in cases where the jab conflicts with religious tenets and practices. *See* Iowa Code § 94.2(2) (2022) (noting "employer" means "a person, as defined in chapter 4, who employs an individual in this state for wages") ("person" under section 4.1(20) includes "government or governmental subdivision or agency"). This provision took effect on October 28, 2021 and predates Appellant's application of an Iowa medical cannabidiol registration card on November 24, 2021.

CHAPTERS 124 AND 124E ARE NEITHER NEUTRAL NOR GENERALLY APPLICABLE.

The government may burden religious exercise only through neutral regulations of general applicability. *See Employment Div., Dept. of Human Resources of Or. v. Smith*, 494 U.S. 872, 879 (1990). A regulation that is not neutral or generally applicable violates the Free Exercise Clause unless the government can prove that it is narrowly tailored to advance a compelling interest of the highest order. *Church of the Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 533 (1993); *Mitchell County v. Zimmerman*, 810 N.W.2d 1 (Iowa 2012).

A. Chapter 124 is not Neutral Toward Religion.

Iowa has maintained a statutory exception for the religious use of peyote by the Native American Church since 1967. *See* Iowa Code § 124.204(8) (2021) (noting "[n]othing in this chapter shall apply to peyote when used in bona fide religious

ceremonies of the Native American Church; however, persons supplying the product to the church shall register, maintain appropriate records of receipts and disbursements of peyote, and otherwise comply with all applicable requirements of this chapter and rules adopted pursuant thereto.")

Writing for the majority of a three-judge panel of the Court of Appeals for the District of Columbia Circuit, then Judge Ruth Bader Ginsburg noted that statutory exemption for peyote - authorized for the Native American Church only and for which no other church may qualify - amounts to a "denominational preference" that is not easily reconcilable with the establishment clause. *See Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458, 1461 (D.C. Cir. 1989) (*citing Larson v. Valente*, 456 U.S. 228, 245, 102 S. Ct. 1673, 1683-84, 72 L.Ed.2d 33 (1982)). She called the contention that the Drug Enforcement Administration could turn away all churches save one a "grave constitutional question." *Id.* To be sure, the DEA now accepts applications for the religious use of controlled substances following the decision in *Gonzales v. O Centra Espirita Beneficente Unaio do Vegetal*, 546 U.S. 418, 126 S. Ct. 1211, 163 L.Ed.2d 1017 (2006).[4] Indeed, Appellant applied for a religious exemption with the DEA. *See* Ex. 2.

The denominational preference for peyote in Chapter 124 demonstrates a lack of neutrality toward religion. The law need not target a specific religious practice to violate neutrality.

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[4] The application for the federal religious exemption for any controlled substance, including cannabis, can be found at:
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-5)%20Guidance%20Regarding%20Petitions%20for%20Religious%20Exemptions.pdf

B. Chapter 124 is No Longer Generally Applicable as a Result of the Enactment of Chapter 124E.

A law is generally applicable if it equally burdens religious and non-religious conduct without making exceptions that undermine its purpose. *Lukumi*, 508 U.S. at 533-540, 543-546. Here, the prohibition in Iowa law in Chapter 124 against the possession and use of marijuana extracts is not generally applicable because Chapter 124E contains exceptions that undermine its purpose.

In *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, the Supreme Court struck down a series of city ordinances that prohibited the practice of religious animal sacrifice while allowing other animal killings, including those associated with hunting, fishing, meat production, and pest control. *Lukumi,* 508 U.S. at 536-537. The Court examined the city's interests allegedly supporting the ordinances—preventing cruelty to animals and protecting public health. It found that the ordinances were "underinclusive for these ends" because they "fail to prohibit nonreligious conduct that endangers these interests in a similar or greater degree than [religious animal sacrifice]." *Id.* at 543. The law was underinclusive not only because it allowed secular conduct similar to the religious conduct that was forbidden, but also because it allowed dissimilar conduct that caused the same harms or undermined the same governmental interests as the religious conduct that was forbidden. Because the garbage bins of restaurants posed the same health risks as were allegedly caused by sacrifice of animals, but the restaurants were not as tightly regulated as sacrifice, the ban on sacrifice required strict scrutiny. *Id.* at 544-45.

In *Employment Division v. Smith*, the Court distinguished *Sherbert v. Verner*, 374 U.S. 398 (1963), and similar cases involving persons who lost their jobs because of their

religious practice and then applied for unemployment compensation. Those unemployment compensation laws had "individualized exemptions" that allowed some people to collect unemployment benefits even when their inability to find work was caused by their own personal choices. There could not be many acceptable reasons for refusing work but still collecting unemployment compensation, but the law allowed "at least some 'personal reasons.'" *Smith*, 494 U.S. at 884 (quoting *Sherbert*). The reason why the Court did not apply strict scrutiny in *Smith* is because there was no compelling reason to extend the *Sherbert* test to a state criminal law (Oregon's controlled substances act) involving across-the-board prohibitions, *i.e.*, no individual exemptions.

In *Lukumi*, the Court repeated *Smith*'s statement about the importance of "individual exemptions" in triggering strict scrutiny. But in *Lukumi*, the Court also relied on categorical exceptions, such as the exceptions for hunting, fishing, and pest control. "[C]ategories of selection are of paramount concern when a law has the incidental effect of burdening religious practice." *Lukumi*, 508 U.S. at 542. In *Lukumi*, few killings of animals were prohibited except for religious sacrifices, but the Court stated explicitly that the rule was not limited to that situation. The Court said that "these ordinances fall well below the minimum standard necessary to protect First Amendment rights." *Id.* at 543.

Because the law was underinclusive and burdened Free Exercise, the Court applied strict scrutiny to the ordinances. It found that the city's interests "could be achieved by narrower ordinances that burdened religion to a far lesser degree" and found that, under its strict scrutiny analysis, "[t]he absence of narrow tailoring suffices to establish the invalidity of the ordinances." *Id.* at 546. "It is established in our strict scrutiny jurisprudence that a law cannot be regarded as protecting an interest of the highest order

. . . when it leaves appreciable damage to that supposedly vital interest unprohibited." *Id.* at 547 (internal quotations omitted).

Two Third Circuit cases, authored by then-Judge Samuel Alito, further illustrate the *Smith/Lukumi* general-applicability analysis. In *Fraternal Order of Police Newark Lodge v. City of Newark*, 170 F.3d 359 (3rd Cir. 1999), the court considered a police policy that prohibited officers from wearing beards but offered exemptions to two categories: (1) officers who had medical reasons for wearing a beard; and (2) officers who were undercover. *Id.* at 360. Two Muslim officers requested an exemption from the policy for religious reasons but were denied. The City's reason for the policy was to promote uniform appearance among its officers. *Id.* at 366. The exception for undercover officers did not harm the purpose of the policy—as undercover officers are, by nature, out of uniform—and accordingly would not have resulted in imposition of heightened scrutiny. However, the exemption for medical reasons did undermine that policy—it applied to uniformed officers who would be recognized as officers and rendered their appearance non-uniform to the extent of their beards. *Id.* The court in *Newark* emphasized that the rule and its exception implied a value judgment that medical needs were less important than religious needs, and that it was this implicit value judgment that the Free Exercise Clause prohibits. *Id.* at 364-65, quoting *Lukumi*, 508 U.S. at 537-38. Thus, the policy as it was applied to the Muslim officers was subject to heightened scrutiny under the Free Exercise Clause and found to be unconstitutional. *Id.*

In *Blackhawk v. Pennsylvania*, 381 F.3d 202 (3d Cir. 2004), a Lakota Indian kept two bears on his property to conduct religious ceremonies in keeping with his tribe's traditions. *Id.* at 204. A state law prohibited privately keeping wildlife without paying a

fee for a permit. The purported state interest in the law was to discourage "the keeping of wild animals in captivity" and to generate revenue. *Id.* at 211. Nonetheless, zoos and nationally recognized circuses were exempt from the fee requirement. *Id.* As a result, the court found the law not generally applicable under *Smith* and *Lukumi*, because the zoo and circus exemptions "work against the Commonwealth's asserted goal of discouraging the keeping of wild animals in captivity" and its interest in generating revenue. *Id.* Thus, Pennsylvania's decision not to grant an exemption for religious reasons was subject to strict scrutiny and declared to be unconstitutional as a violation of the Free Exercise Clause.

Here, Chapter 124E contains exemptions that undermine the purpose of Chapter 124, the state's Uniform Controlled Substance Act. The exemptions permit the possession and use of marijuana extracts. They provide affirmative defenses to the prosecution for possession of marijuana in the form of medical cannabidiol, both misdemeanors and felonies, as well as felony drug tax stamp violations. *See* Iowa Code § 124E.12(4)(a) (2022).

These exemptions undermine the Department's purpose of preventing drug abuse through diversion and promoting the public health. Why does the state maintain that marijuana has "no accepted medical use for treatment in the United States; or lacks accepted safety for use in treatment under medical supervision" (one of the criteria for classifying marijuana as a schedule I controlled substance in Iowa Code § 124.203) but authorize the Department to establish a medical cannabidiol program that dispenses marijuana extracts to alleviate symptoms associated with certain qualifying conditions based on a health care provider's certification?

The bottom line is that that Iowa's medical cannabidiol law, Chapter 124E, provides a secular exception for the possession and use of marijuana but makes no allowance for religious use. This makes the law underinclusive and not generally applicable. As a result, it must pass strict scrutiny before it can be applied in a manner to burden Appellant's religious beliefs and practices.

The Department may not understand or fully appreciate the essential sacramental role that cannabis plays in the Ethiopian Zion Coptic Church, but it must treat the resulting religious practice as favorably as it treats the secular reasons for allowing the possession and use of marijuana extracts by Iowa patients. That is the lesson of *Smith*, *Lukumi*, and *Newark*. For these reasons, the law is not generally applicable and can be upheld only if it is narrowly tailored to further a compelling interest. *See Smith*, 494 U.S. at 879.

C. There is no Narrowly Tailored Compelling Government Interest Sufficient to Justify a Prohibition Against Religious Use of Marijuana Extracts.

The Department does not have a compelling interest here, and even if it did, denying Appellant the same legal protections to possess and use marijuana extracts is not narrowly tailored to achieve that interest. "A law burdening religious practice that is not neutral or not of general application must undergo the most rigorous of scrutiny." *Lukumi*, 508 U.S. at 46. Such a law "must advance 'interests of the highest order' and must be narrowly tailored in pursuit of those interests." *Id.*, quoting *McDaniel v. Paty*, 435 U.S. 618, 628 (1978), and *Wisconsin v. Yoder*, 406 U.S. 205, 215 (1972).

For several decades, the State has permitted the religious use of another schedule I controlled substance, peyote, by members of the Native American Church. That alone is robust evidence that there is not suddenly a compelling need to restrict one person from similarly using a controlled substance as part of his religious practice.

Even if the Department had a compelling interest, the outright prohibition against religious use is not narrowly tailored to serve that interest. Appellant's access to marijuana extracts would be limited to the same number of grams per month that are available to qualified patients. Nothing more or less. This is why the prior cases in which Appellant was involved are no longer persuasive. His position was hindered by the enormity of the marijuana control problem in the United States existing at the time. However, much has changed. A majority of states now have highly regulated medical cannabis programs that provide legal access to marijuana.

Medical cannabidiol has been available in Iowa since December 1, 2018. There are more than 10,200 patient and caregiver cardholders as of May 2022.[5] The record before the agency demonstrates not one adverse health effect or diversion to date, which means that the program is succeeding in meeting its twin goals of preventing drug abuse and promoting public health. It strains credulity to believe that one additional cardholder, whose possession and use would be circumscribed by regulations, is going to upset that dynamic. The Department can certainly allow Appellant to freely exercise its religious traditions without suffering any harm.

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5. The number of active patient and caregiver registration cards as of May 2022. https://idph.iowa.gov/Portals/1/userfiles/234/Files/2022_05%20Monthly%20Website%20Program%20Update.pdf

CONCLUSION

The compelling interest test does not mean that every religious belief and practice will automatically trump every law that burdens it. What it does mean, however, is that before a law can be enforced in such a manner as to require a person to abandon his sincerely held religious beliefs, the Department should have a compelling reason that cannot be accomplished in some other way.

Appellant is protected by the Free Exercise Clauses of both the State and federal constitutions. His religious beliefs are sincere and the use of marijuana as a sacrament is central to his religious beliefs. Chapters 124 and 124E are neither neutral nor generally applicable. A prohibition against the religious use of marijuana cannot be allowed unless it is narrowly tailored to serve a compelling governmental interest of the highest order. There is no sufficient governmental interest in the record before the court to restrict Appellant from exercising his religious belief while 10,200 other Iowans are permitted to access marijuana extracts for secular purposes.

Appellant respectfully requests the Department of Inspections and Appeals reverse the Department's denial of his application for a medical cannabidiol registration card.

Respectfully submitted,

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IN THE IOWA DISTRICT COURT FOR POLK COUNTY

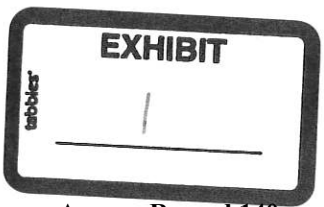
CARL OLSEN, Petitioner, vs. **IOWA DEPARTMENT OF PUBLIC HEALTH,** Respondent.	**Case No. CVCV062566** **RULING ON MOTIONS TO DISMISS**

I. INTRODUCTION

Before the court is a Motion to Dismiss filed by the Iowa Department of Public Health on January 31, 2022. The court held a hearing on the record on March 11, 2022, at which Sam Langholtz represented the Iowa Department of Public Health; and Colin Murphy represented the Petitioner, Carl Olsen. After hearing the arguments of counsel and reviewing the court file, including the Motion and Resistance thereto, and submitted briefs, the court now enters the following ruling on the pending Motion.

II. FACTUAL & PROCEDURAL BACKGROUND

According to his Amended Petition filed January 12, 2022, the Petitioner ("Mr. Olsen") belongs the Ethiopian Zion Coptic Church. Am. Pet. ¶ 9. His sincerely held religious beliefs include "[t]he sacramental, non-drug use of cannabis in bona fide religious worship." *Id.* ¶ 10. He stopped using cannabis as a sacrament a couple decades ago, but now wishes "to resume his religious practice in a manner consistent with the secular use of cannabis extracts" permitted under Iowa's medical cannabidiol laws. *Id.* ¶ 11



Mr. Olsen filed this initial Petition in this matter on September 24, 2021, seeking a declaratory judgment against the State of Iowa that 1) he has a lawful right to purchase, possess and use for bona fide religious purposes medical cannabidiol obtained from a licensed Iowa dispensary and that such rights are coextensive with any future amendments to chapter 124E; 2) he can raise affirmative defenses under chapters 124, 124E and 453B to any prosecution for possession of marijuana or failure to affix a drug tax stamp; and 3) he has a right to exceed the 4.5 gram per 90 day limit by providing the Iowa Department of Public Health with written certification of his religious use and needs. *See* Pet., page 4. On November 23, 2021, the State moved to dismiss the on sovereign immunity grounds. See Motion to Dismiss ¶ 2 (Nov. 23, 2021).

On November 24, 2021, Mr. Olsen applied for a medical cannabidiol registration card from the Iowa Department of Public Health ("IDPH"). Am. Pet. ¶ 12. IDPH denied the application on January 7, 2022. *Id.* ¶ 13, Ex. 2. Mr. Olsen filed a timely request for an appeal on January 20, 2022. Exhibit A (Olsen Appeal Request). The appeal is pending.

On January 12, 2022, Mr. Olsen filed this amended petition substituting IDPH for the State as Respondent. See Am. Pet. ¶ 2. The amended petition modified the declaratory relief requested as well, to that IDPH shall consider Mr. Olsen's religious use of cannabis as a qualifying condition under Iowa Code section 124E.2(2) and, thereafter, respond to his application for a registration card. Am. Pet. at 4.

IDPH filed the pending Motion to Dismiss on January 31, 2022, seeking dismissal of Mr. Olsen's amended petition because chapter 17A is the exclusive means of challenging the Department's denial of a medical cannabidiol registration card and Olsen has failed to exhaust his administrative remedies; and because Mr. Olsen fails to state a claim because Iowa's marijuana

and medical cannabidiol laws are neutral and generally applicable. Mr. Olsen resists dismissal on all grounds.

III. MOTION TO DISMISS

A. LEGAL STANDARD

In deciding a motion to dismiss, "the petition is assessed in the light most favorable to the plaintiffs, and all doubts and ambiguities are resolved in the plaintiffs' favor." *Southard v. Visa U.S.A. Inc.*, 734 N.W.2d 192, 194 (Iowa 2007). *See also Ritz v. Wapello Cty. Bd. of Supervisors*, 595 N.W.2d 786, 789 (Iowa 1999) ("Allegations in the petition are viewed in a light most favorable to the plaintiff and facts not alleged cannot be relied on to aid a motion to dismiss . . . ."); *Haupt v. Miller*, 514 N.W.2d 905, 911 (Iowa 1994) ("The petition should be construed in the light most favorable to the plaintiff with doubts resolved in that party's favor in ruling on the motion."). Furthermore, a "court considers all well-pleaded facts to be true." *U.S. Bank v. Barbour*, 770 N.W.2d 350, 353 (Iowa 2009). *See also Southard*, 734 N.W.2d at 194 ("Well-pled facts in the pleading assailed are deemed admitted."). Affidavits may be considered alongside the pleadings. *Citizens for Responsible Choices v. City of Shenandoah*, 686 N.W.2d 470, 473 (Iowa 2004).

"A motion to dismiss is sustainable only when it appears to a certainty that the plaintiff would not be entitled to relief under any state of facts that could be proved in support of the claims asserted." *Haupt*, 514 N.W.2d at 911. *See also Barbour*, 770 N.W.2d at 353 ("A court should grant a motion to dismiss only if the petition 'on its face shows no right of recovery under any state of facts.'") (quoting *Ritz*, 595 N.W.2d at 789); *Hawkeye Foodservice Distribution, Inc. v. Iowa Educators Corp.*, 812 N.W.2d 600, 609 (2012) (reiterating the standard for granting a motion to dismiss described by the court in *Barbour*). Iowa courts recognize that this is a very high bar, and

therefore traditionally disfavor motions to dismiss. *See Cutler v. Klass, Whicher & Mishne*, 473 N.W.2d 178, 181 (Iowa 1991) (remarking that both the filing and sustaining of motions to dismiss "are poor ideas").

B. ANALYSIS

i. Judicial Review under Iowa Code Chapter 17A is the exclusive remedy.

Mr. Olsen wants this court to tell the IDPH, a State agency, to include his religious use of cannabis as a debilitating medical condition under Iowa Code section 124E.2(2), when considering whether it should issue him a medical cannabidiol registration card under section 124E.4(1). He argues that if IDPH does not do so, it would violate his constitutional rights to free exercise of religion under the 1st and 14th amendments to the U.S. Constitution, and Article 1 section 3 of the Iowa Constitution.

Iowa Code Chapter 124E, known as the "Medical Cannabidiol Act", provides a mechanism for a person to apply for and the IDPH to issue a medical cannabidiol registration card, permitting the applicant to use medical cannabis as it is defined and regulated by the statute. Mr. Olsen invoked that mechanism when he applied for a medical cannabidiol registration card from the IDPH on November 24, 2021.

Judicial review is the exclusive way to challenge agency action unless a statute referencing Iowa Code chapter 17A expressly states otherwise. *See Iowa Code* § 17A.19 ("Except as expressly provided otherwise by another statute referring to this chapter by name, the judicial review provisions of this chapter shall be the exclusive means by which a person or party who is aggrieved or adversely affected by agency action may seek judicial review of such agency action."); *Iowa Farm Bureau Fed'n v. Env't Prot. Comm'n*, 850 N.W.2d 403, 431 (Iowa 2014) ("The IAPA establishes the exclusive means for a person or party adversely affected by

agency action to seek judicial review."). Unless a statute expressly states otherwise, there is no exception to the exclusivity of judicial review for certiorari, declaratory judgment, or injunction. *Salsbury Labs. v. Iowa Dep't of Env't Quality*, 276 N.W.2d 830, 835 (Iowa 1979). Chapter 124E does not provide another method of judicial review aside from the exclusive review under chapter 17A. *See Iowa Code* chapter. 124E. Chapter 17A, therefore, is "the exclusive means by which" Mr. Olsen may seek judicial review of the IDPH's action. *Iowa Code* § 17A.19.

ii. *Exhaustion of Administrative remedies is required.*

Mr. Olsen, in his brief in resistance to IDPH's Motion to Dismiss, argues that he has not "been aggrieved or adversely affected by a final administrative decision so as to trigger judicial review under the Iowa Administrative Procedures Act. Rather, he seeks a declaratory judgment that at the time his application for a medical cannabidiol card is adjudicated, the agency should be required to consider his religious use of marijuana at least on par with qualifying health conditions that entitle patients to use marijuana extracts for secular purposes."

Iowa Code Chapter 124E provides that before one is able to use cannibus in this State, he or she must first apply to the IDPH for a medical cannabidiol registration card, and be issued the same by the IDPH. For the purposes of this suit, anyway, Mr. Olsen is not disputing that he must go through this administrative procedure in order to be able to use cannibus. He simply wants the court, now, to tell the agency to treat his religious use of marijuana the same as a qualifying medical condition when considering his application. It doesn't work that way.

"Exhaustion of adequate administrative remedies is generally required prior to permitting a party to seek relief via judicial review in district court." *IES Utilities Inc. v. Iowa Dep't of Revenue & Fin.*, 545 N.W.2d 536, 539 (Iowa 1996) (*citing Iowa Code* § 17A.19(1); *City of Des Moines v. Des Moines Police Bargaining Unit Ass'n*, 360 N.W.2d 729, 730, 731 (Iowa 1985)).

> The doctrine of exhaustion is not absolute, however. In the following limited situations, we have allowed a litigant to bypass the exhaustion requirement:
>
> (1) plaintiff challenges, by way of *judicial review under Iowa Code section 17A.19*, an agency action as in violation of the rulemaking procedures set forth under the APA, *see Lundy [v. Iowa Department of Human Services, 376 N.W.2d 893, 894 (Iowa 1985)]*;
>
> (2) plaintiff claims an adequate administrative remedy does not exist for the claimed wrong, *see Rowen v. LeMars Mut. Ins. Co.*, 230 N.W.2d 905, 909 (Iowa 1975), or stated otherwise, plaintiff will suffer "irreparable injury of substantial dimension" if not allowed access to district court prior to exhausting all administrative remedies, *see Salsbury Lab.*, 276 N.W.2d at 837; or
>
> (3) plaintiff claims the applicable statute does not expressly or implicitly require that all adequate administrative remedies be exhausted prior to bringing an action in district court, *see Rowen*, 230 N.W.2d at 909.

Id (emphasis in original). None of the limited situations appear here. As to the first exception, Mr. Olsen is not challenging any rulemaking procedure. As to the third exception, Iowa Code chapter 224E does not provide for bringing any action in district court.

As to the second exception, Mr. Olsen does not claim an adequate administrative remedy does not exist for the claimed wrong, or that he will suffer "irreparable injury of substantial dimension" if not allowed access to district court prior to exhausting all administrative remedies. In fact, requiring Mr. Olsen to follow administrative procedures won't prejudice him in any way. In a judicial review proceeding under chapter 17A, a court "shall reverse, modify, or grant other appropriate relief from agency action . . . , if it determines that substantial rights of the person seeking judicial relief have been prejudiced because the agency action is . . . [u]nconstitutional on its face or as applied or is based upon a provision of law that is unconstitutional on its face or as applied." *Iowa Code* § 17A.19(10)(a). Mr. Olsen's constitution claims could be fully adjudicated and the declaratory relief he seeks obtained through a judicial review proceeding

under chapter 17A. Mr. Olsen must seek relief through Chapter 17A proceedings, after his administrative remedies have been exhausted.

ii. Remaining ground for dismissal. The court, having determined above that dismissal is appropriate as set forth above, will nevertheless address the remaining ground raised in the in the Motion to Dismiss.

IDPH asserts that even if the court reaches the merits, Mr. Olsen's suit fails to state a claim because Iowa's marijuana and medical cannabidiol laws are neutral and generally applicable. When the court is asked to get into the merits of a claim, a motion to dismiss should generally not be granted, and "nearly every case will survive a motion to dismiss under notice pleading." *Weizberg v. City of Des Moines*, 923 N.W.2d 200, 217 (Iowa 2018) (*quoting U.S. Bank v. Barbour*, 770 N.W.2d 350, 353 (Iowa 2009)). If a claim is "at all debatable," the filing or sustaining of a motion to dismiss is ill-advised. *Id.* This case is no exception.

In order to sustain IDPH's motion on this ground, the court would have to make a factual determination that all of the laws operating separately or together to prevent Mr. Olsen from legally using marijuana in Iowa are indisputably, not just facially, but operationally neutral. *Mitchell Cty. v. Zimmerman*, 810 N.W.2d 1, 10 (Iowa 2012) (*citing Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 534, 113 S.Ct. 2217, 2227, 124 L.Ed.2d 472, 491 (1993) Lukumi, 508 U.S. at 534, 113 S.Ct. at 2227, 124 L.Ed.2d at 491 (1993)). " 'Facial neutrality is not determinative,' we must examine the ordinance for "governmental hostility which is masked, as well as overt." *Id.* Given the pleadings, Mr. Olsen is entitled to attempt to show government hostility in the operation of these laws. Dismissal on the merits at this stage would not be appropriate.

IV. RULING

For the reasons set forth in sections III(B)(i) and III(B)(ii) above,

IT IS THEREFORE ORDERED that Motion to Dismiss Petitioner's Petition filed by the Iowa Department of Public Health is **GRANTED**. The Petition in the above captioned case is dismissed. Costs are assessed to the Petitioner.

State of Iowa Courts

Case Number	**Case Title**
CVCV062566	CARL OLSEN V STATE OF IOWA
Type:	ORDER REGARDING DISMISSAL

So Ordered

Joseph Seidlin, District Court Judge
Fifth Judicial District of Iowa

Electronically signed on 2022-05-03 14:13:09

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Carl E. Olsen
130 E. Aurora Avenue
Des Moines, Iowa 50313-3654
carl@carl-olsen.com

Dear Mr. Olsen:

With this letter the Drug Enforcement Administration (DEA) hereby acknowledges receipt of your petition, on April 27, 2022, to be exempted from the Controlled Substances Act (CSA) under the Religious Freedom Restoration Act as promulgated under 42 U.S.C. § 2000bb-1(c).

Your petition is currently being reviewed in consideration of the complexity of your petition and DEA's mission to prevent the diversion of controlled substances granted under the authority of the CSA, 21 U.S.C. §§ 801 et. seq.

For information regarding the Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Regulatory Section at (571) 362-8137, or via e-mail at DRG@dea.gov.

Sincerely,

MATTHEW STRAIT

Digitally signed by MATTHEW STRAIT
Date: 2022.06.16 13:47:13 -04'00'

Matthew J. Strait
Deputy Assistant Administrator, Regulatory
Diversion Control Division

EXHIBIT
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Drug Enforcement Administration
United States Department of Justice

Carl Olsen
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Application for Religious Exemption
from the
Controlled Substances Act
pursuant to the
Religious Freedom Restoration Act

April 27, 2022

Assistant Administrator
Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152
ODLP@usdoj.gov

Certified Mail # 7021 2720 0002 2687 0091

Dear Assistant Administrator,

Pursuant to your "Guidance Regarding Petitions for Religious Exemption from the Controlled Substances Act Pursuant to the Religious Freedom Restoration Act (Revised)" EO-DEA007, DEA-DC-5, November 20, 2020, Version 2, attached is my application for a religious exemption.

I would like to receive immediate notification of acceptance or deficiency. I would also be happy to answer any questions you may have and you can reach me at the address, phone number, and email address I have given.

I request a final ruling within 60 days from the date my request is received. I understand the Religious Freedom Restoration Act (RFRA), 42 U.S.C. §§ 2000bb et seq., gives me the right to a judicial proceeding to compel a decision if I don't receive one within the time I have requested.

I agree with your guidance document that an appeal from a final decision is governed by 21 U.S.C. § 877.

Carl Olsen
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Drug Enforcement Administration
United States Department of Justice

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Application for Religious Exemption
from the
Controlled Substances Act
pursuant to the
Religious Freedom Restoration Act
Certified Mail # 7021 2720 0002 2687 0091

To the Assistant Administrator:

Background

I have previously applied to your agency for an exemption like the one for peyote, 21 C.F.R. § 1307.31 (Native American Church), for my church, the Ethiopian Zion Coptic Church. *Olsen v. DEA*, 878 F. 2d 1458 (D.C. Cir., 1989). In 1989 there were a handful of states that had religious exemptions for the use of peyote but there were no states that had any exceptions for the use of marijuana. Nonetheless, I based my request on a memo dated December 22, 1981, from the Office of Legal Counsel, United States Department of Justice, to your agency.

> If such a petition is brought, your agency could: (1) require that the petitioner be a member of a bona fide peyote-using religion in which the actual use of peyote is central to established religious beliefs, practices, dogmas, or rituals; and (2) apply a rebuttable presumption that the exemption is not available, under the foregoing standard, unless the petitioner can allege and establish a significant history of religious use of peyote.

Peyote Exemption for Native American Church, at page 421. My church has a similar history. *Town v. State ex rel. Reno*, 377 So.2d 648, 649 (Fla. 1979) ("the Ethiopian Zion Coptic Church is not a new church or religion but the record reflects it is centuries old and has regularly used cannabis as its sacrament").

Your agency attempted to deny my petition by saying your agency cannot grant religious exemptions.

> The DEA's contention that Congress directed the Administrator automatically to turn away all churches save one opens a grave constitutional question. A statutory exemption authorized for one church alone, and for which no other church may qualify, presents a "denominational preference" not easily reconciled with the establishment clause.

Olsen, at 1461.

After rejecting your claim that your agency cannot grant religious exemptions for marijuana, the court held that my church was not equally situated to the Native American Church because it lacked any limitations to prevent the diversion of the church's sacrament, marijuana.

> Some religions, for example, might not restrict drug use to a limited ceremonial context, as does the Native American Church. *See, e. g.*, *Olsen*, 279 U. S. App. D. C., at 7, 878 F. 2d, at 1464 ("[T]he Ethiopian Zion Coptic Church . . . teaches that marijuana is properly smoked 'continually all day'").

Employment Div., Dept. of Human Resources of Ore. v. Smith, 494 U.S. 872, 918 (1990) (Blackmun, J., dissenting). Again, I point out that in 1989 my church was not authorized to use marijuana by any state, whereas the religious use of peyote was authorized in several states, such as Texas where the peyote comes from.

To exhaust all possibilities, I suggested a narrower personal exemption, self-restricted to a specific time and a specific place, and with marijuana obtained from the only source available at that time, the federal government. *See* Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs, memo dated June 6, 2018, from the Office of Legal Counsel, United States Department of Justice, to your agency, describing the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi.

> Critically, Olsen's proposal would require the government to make supplies of marijuana available to Olsen's church on a regular basis.

Olsen, at 1462.

Establishment Clause

The Office of Legal Counsel told your agency the exemption for religious use of peyote, 21 C.F.R. § 1307.31 (Native American Church), is not required by the First Amendment and must not violate the Establishment Clause. "The Establishment Clause generally prohibits the government from granting certain preferences to religions or religious adherents which are not available to secular organizations or nonreligious individuals." Peyote Exemption for Native American Church, at page 410.

Following the enactment of the Religious Freedom Restoration Act of 1993, the U.S. Supreme Court applied an Establishment Clause / Equal Protection / General Applicability analysis to the peyote exemption.

> Nothing about the unique political status of the Tribes makes their members immune from the health risks the Government asserts accompany any use of a Schedule I substance, nor insulates the Schedule I substance the Tribes use in religious exercise from the alleged risk of diversion.

Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418, 434 (2006).

Substantial Burden

My sincere religious exercise is substantially burdened by the CSA. *Olsen v. DEA*, 878 F.2d 1458, 1459 (D.C. Cir., 1989) ("Petitioner Olsen is a member and priest of the Ethiopian Zion Coptic Church"); *Town v. State ex rel. Reno*, 377 So.2d 648, 649 (Fla. 1979) ("the Ethiopian Zion Coptic Church represents a religion within the first amendment to the Constitution of the United States"); *State v. Olsen*, No. 171-69079 (Iowa, July 18, 1984) ("Testimony at his trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it").

Because my use of marijuana was rejected decisively in *Employment Division v. Smith*, 494 U.S. 872, 889 (1990), citing *Olsen v. Drug Enforcement Administration*, 279 U. S. App. D. C. 1, 878 F. 2d 1458 (1989), I stopped using marijuana in 1990.

Peyote Source

My request for federally supplied marijuana was denied in 1989. At that same time the Native American Church had a state-authorized, private source of peyote (in Texas). The Ethiopian Zion Coptic Church had no state-authorized source of marijuana, private or otherwise at that time.

> Both federal and Texas statutes criminalize the unprescribed distribution and possession of peyote. 21 U.S.C. §§ 812, 841, 844; TEX. HEALTH & SAFETY CODE ANN. §§ 481.101-481.130 (Vernon 1991). But both federal and Texas law exempt bona fide religious use of peyote by NAC members from such criminalization. 21 C.F.R. § 1307.31; TEX. HEALTH & SAFETY CODE ANN. § 481.111 (Vernon 1991).

Peyote Way Church of God, Inc. v. Thornburgh, 922 F.2d 1210, 1212 (5th Cir., 1991).

> There are five licensed peyote dealers in the United States, all of them in South Texas: three in the border town of Rio Grande City; one in Roma, 17 miles to the west; and one in Mirando City, a tiny town 30 miles east of Laredo.

Texas Observer, WITH THE PEYOTEROS, The fruits and thorns of the South Texas cactus trade, by Karen Olsson, March 2, 2001.

When the federal peyote exemption was created in 1966, 21 C.F.R. § 166.3(c)(3), there were several states that had laws protecting the religious use of peyote. *See Peyote Exemption for Native American Church*, Office of Legal Counsel, U.S. Department of Justice, Tuesday, December 22, 1981. In 1967, Iowa enacted a state law identical to 21 C.F.R. § 166.3(c)(3). Iowa Acts 1967 Chapter 189, § 2(12); Iowa Acts 1971 Chapter 148, § 204(5); Iowa Code § 124.204(8) (2022).

Diversion Control

Until 2018, there was no state-authorized source of marijuana in Iowa. In 2017, Iowa authorized two marijuana manufacturers and five marijuana dispensaries. *See* Iowa Code §§ 124E.6-124E.9 (2022). Iowa's medical marijuana program is carefully controlled to prevent both risk to health and risk of diversion.

On January 12, 2021, I filed a Petition for Declaratory Judgement requesting the state add religious use as a qualifying condition for registration in the state medical marijuana program. Since your agency does not recognize state medical use as accepted medical use under the CSA (neither does Iowa, marijuana is still in state Schedule I in Iowa), this would be a secular exemption as far as your agency is concerned. A hearing was held on the state's Motion to Dismiss on March 11, 2022. I'm waiting for a ruling from the Iowa district court.

Shifting Priorities

The governmental interest that existed in 1989 when my last application for a religious exemption was submitted to your agency has greatly diminished over time. This was recently highlighted by Justice Clarence Thomas in *Standing Akimbo v. United States*, 594 U.S. ___ (2021), 141 S.Ct. 2236, No. 20-645 (June 28, 2021).

> Whatever the merits of *Raich* when it was decided, federal policies of the past 16 years have greatly undermined its reasoning. Once comprehensive, the Federal Government's current approach is a half-in, half-out regime that simultaneously tolerates and forbids local use of marijuana. This contradictory and unstable state of affairs strains basic principles of federalism and conceals traps for the unwary.

Id., at 2236-2237.

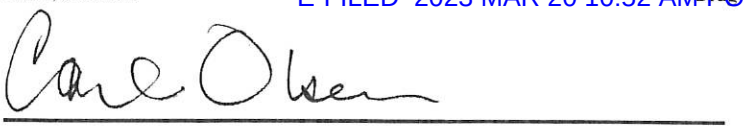
> Whether Congress decides to address the gap with the states or not, federal control of cannabis has evolved from the strict laws and enforcement policies of the 20th century to allowing most states to implement laws authorizing the production and distribution of marijuana.

Congressional Research Service, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap (R44782)*, April 7, 2022.

Conclusion

There is now a state authorized source of marijuana in Iowa. The state program limits the use of that marijuana to specific forms, times, and places, to prevent diversion. Iowa law currently limits amounts that can be purchased and carefully tracks all transactions to ensure full compliance. Failure to comply with these requirements will result in revokation of registration. The requirements are all clearly defined in Iowa Code Chapter 124E, and in 641 Iowa Administrative Code Chapter 154. Your agency will have no difficulty knowing what these requirements are.

Dated this 27th day of April, 2022.



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https://www.texasobserver.org/408-with-the-peyoteros-the-fruits-and-thorns-of-the-south-texas-cactus-trade/
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https://www.legis.iowa.gov/law/iowaCode/sections?codeChapter=124E&year=2022
https://www.legis.iowa.gov/law/administrativeRules/rules?agency=641&chapter=154&pubDate=04-20-2022
https://crsreports.congress.gov/product/details?prodcode=R44782

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building
Des Moines, Iowa 50319

CARL OLSEN, Appellant, vs. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	Docket No. ***22IDPH0002*** ***REPLY BRIEF IN SUPPORT OF APPEAL OF DENIAL OF MEDICAL CANNABIDIOL REGISTRATION CARD***

COMES NOW Appellant Carl Olsen, through counsel, Colin Murphy, and submits the following Reply Brief in Support of Appeal of Denial of Medical Cannabidiol Registration Card.

THE EXISTENCE OF OTHER RELIGIOUS EXEMPTIONS, ESPECIALLY FOR PEYOTE, DEMONSTRATES THE UNDERINCLUSIVENESS OF CHAPTERS 124 AND 124E.

Appellant draws attention to existing religious exemptions only to show that the Department has the ability to evaluate claims for religious exemptions in other health-related contexts.

Chapter 124 is underinclusive because it contains a religious exemption for one substance to the exclusion of other substances and other bona fide religious practices. There is no administrative process available to apply for another exemption, so it lacks due process.

In *Employment Division v. Smith*, 494 U.S. 872 (1990), the United State Supreme Court opined the state could deny a bona fide religious claim if the law, which in that case was a criminal statute regarding the Oregon controlled substances act, was generally applicable. That law was both facially and operational neutral toward religion because there was no religious exemption whatsoever, not even for peyote. It was also generally applicable due to the lack of any exceptions, religious or secular.

In contrast, the Iowa controlled substances act, chapter 124, is neither facially neutral nor operationally neutral toward religion. The state has long recognized a peyote exemption since 1971. And the controlled substances act is not generally applicable because of the secular exemption for marijuana extracts, which are not approved for medical use under chapter 124.

While collateral estoppel may bar Appellant from arguing his use of marijuana is equal to the use of peyote in Iowa, that is not the argument he advances presently. Iowa law contains a quite unique and state-specific exception for the possession and use of marijuana. The right to participate in the program did not exist until 2017 when the General Assembly enacted chapter 124E.

The cases cited by the Department ostensibly hold there is no religious claim for waiving vaccine mandates unless the legislature creates one and further that those laws are otherwise neutral toward religion and generally applicable. However, the legislature has already created religious exemptions in a number of health-related contexts. And, of course, there is a religious exemption for peyote. This is settled law. The fundamental question here is whether a secular exception for medical necessity is underinclusive. In other words, once the legislature creates a religious exemption, then the focus shifts to whether a request for an additional exemption, based on a centuries-old religious practice, is being evaluated fairly.

The examples cited from other states miss the mark for a couple of reasons. The statutes do not have any religious exemptions so the question of whether those exemptions were constitutionally required is irrelevant. The Iowa Controlled Substances Act already has a religious exemption.

Also, Iowa does not limit religious exemptions for vaccine mandates to only members of the Native American Church. It is not a question of whether religious exemptions are required. Rather, the issue is whether the state can limit religious exemptions to specific religions or specific controlled substances to the exclusion of all others. *See Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458, 1461 (D.C. Cir. 1989) ("A statutory exemption authorized for one church alone, and for which no other church may qualify, presents a 'denominational preference' not easily reconciled with the establishment clause")(Ginsburg, J.).

One thing is certain. The aforementioned case and *Olsen v. Mukasey*, 541 F.3d 827 (8th Cir. 2008) both make clear that some religious exemptions are harder to accommodate than others. Peyote and marijuana are not the same. Strict scrutiny was applied by those courts in every instance to deny Appellant's claim based on the differences between the two substances. Also, there was a higher demand for marijuana than peyote. And fewer controls on the religious use of marijuana than peyote. There was source for peyote in Texas that was legal at both the state and federal levels. However, there was no legal state or federal source for marijuana anywhere in the United States at the time.

But that is not the case in Iowa today. Arguably there more demand for marijuana extracts in Iowa with currently 10,000 registered card holders. Iowa has established a legal source for marijuana extracts by licensing two manufacturers and five dispensaries and permitting access to qualified patients and caregivers. There are now regulations and controls to prevent diversion that did not previously exist. Also, federal law provides a process to evaluate exemptions for religious use of controlled substances. Finally, the

religious exemption sought here is *identical* to the secular exemption provided in chapter 124E. Appellant seeks precisely what chapter 124E provides. That distinguishes Appellant's claim from the prior holdings.

Chapter 124E is essentially an amendment to chapter 124. It excepts marijuana and cannabidiol from the context of controlled substances. *See State v. Middlekauff*, 974 N.W.2d 781, 803 (Iowa 2022). It is not possible to evaluate chapter 124E apart from chapter 124.

THERE IS NO CENTURIES-OLD RELIGIOUS PRACTICE THAT EMBRACES THE SACREMENTAL USE OF OPIOIDS, OR ANY OTHER SYNTHETIC, NON-PLANT MATERIAL.

The Department provides a parade of horribles that would result from granting a religious exemption in this case. It goes as far as to say that it would then apply to "any controlled substance of [the person's] choosing" and potentially contribute to the nationwide opioid crisis. *See* Br. at 12.

We should not get too far ahead of ourselves. To be sure, the Native American Church (peyote), Ethiopian Zion Coptic Church (cannabis) and União do Vegetal (UDV) (hoasca) all embrace the bona fide sacramental use of a naturally occurring plant. But there are no known centuries-old religious practices that claim sacramental use of synthetic, non-plant materials of the kind identified in the schedules found in chapter 124. If there were, then the Department would undoubtedly identify them. So, even if there was an administrative process to approve of other religious exemptions, the Department could easily distinguish a religion that believes in the sacramental use of say, hydrocode, a semisynthetic opioid first patented in 1923.

This example raises an especially critical point that the Department has so far ignored. The legislature carved out an exception for marijuana extracts for medical use from chapter 124. Marijuana is a state schedule I controlled substance. It lacks any "accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision." *See* Iowa Code § 124.203 (2022) (listing criteria for schedule I). If the Iowa legislature can establish a non-prescription, federally illegal manufacturing and distribution program for schedule I marijuana extracts, then it can *absolutely* establish a parallel program for substances listed in schedule II, like hydrocodone, which by definition have "currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions." *See* Iowa Code § 124.205 (2022). But the legislature would have to first create that program, which is a hugely speculative outcome at best. And, yes, if such a program existed, then a person with a valid claim for a religious exemption for the sacramental use of hydrocodone could certainly make the same arguments.

We should keep in mind, too, that Appellant is likely the only person in the state of Iowa who can make a valid claim for a religious exemption under chapter 124E. A ruling in his favor is not opening the floodgates to other applicants. It is adding one additional cardholder to the rolls.

THE DEPARTMENT CANNOT USE THE PROHIBITION AGAINST SMOKING MEDICAL CANNABIDIOL TO DEFEAT APPELLANT'S CLAIM FOR A RELIGIOUS EXEMPTION.

While there may be a prohibition against smoking medical cannabidiol in Iowa Code section 124E.17, Appellant is not seeking more than what the program permits. He requests equal access to whatever forms are available to qualifying patients, including

vaporizable and nebulizable medical cannabidiol, in the allowable periodic amounts. *See* Iowa Code 124E.9(14) (4.5 grams of total THC every 90 days); Iowa Admin. Code r. 641-154.2r. 641-154.14(2) (allowable oral and inhaled forms). The record demonstrates that Appellant's past sacramental use of cannabis certainly involved inhalation but extended as well to eating and drinking cannabis preparations. Like any other qualified person, how Appellant chooses to lawfully consume medical cannabidiol under the statute and administrative rules is not the Department's concern.

Respectfully submitted,

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Carl Olsen, Appellant. v. Iowa Department of Public Health, Respondent.	)))))))))	Docket No. 22IDPH0002 **PROPOSED DECISION**

STATEMENT OF THE CASE

The Appellant, Carl Olsen, appealed from a January 7, 2022 decision of the Iowa Department of Public Health (IDPH or the Department) to deny the Appellant's application for an Iowa medical cannabidiol registration card. A telephone hearing was held on June 15, 2022. Attorney Colin Murphy represented Olsen, who appeared for the hearing and testified. Assistant Attorneys General Heather Adams and Laura Steffensmeier represented IDPH. Owen Parker, Chief of the Bureau of Medical Cannabidiol, also appeared and testified for the Department. Department exhibits 1 - 5 were admitted into the record without objection. The Appellant submitted post-hearing briefings on July 1, and July 22, 2022. The Department filed a post-hearing brief on July 8, 2022. The matter is fully submitted.

FINDINGS OF FACT

Olsen is a member of the Ethiopian Zion Coptic Church. His church views cannabis as a sacrament, and considers the non-drug use of cannabis to be an integral part of worship.1 Due to state and federal criminal laws regarding marijuana use, Olsen has not used cannabis as a sacrament during worship for many years. It is his hope, however, to use it legally for religious purposes through Iowa's medical cannabidiol program. (Olsen Testimony).

On November 24, 2021, Olsen applied for a medical cannabidiol registration card from the IDPH, which administers the program. Olsen did not submit a certification from a health care practitioner, which is one of the statutory pre-requisites to receiving a

1 *See, e.g.*, *Olsen v. State of Iowa*, Civ. No. 83-E-301-E, 1986 WL 4045 at *1 (S.D. Iowa Mar. 19, 1986) ("Plaintiff is a priest of the Ethiopian Zion Coptic Church. This religion uses marijuana as an integral part of its religious doctrine.").

registration card.2 Instead, Olsen submitted a "Declaration" outlining his use of cannabis for religious purposes. (Resp. Exhs. 2, 5; Parker Testimony).

On January 7, 2022, the Department notified Olsen by letter that his application for a cannabidiol registration card had been denied. The Department's sole basis for the denial was the lack of a written certification from Olsen's health care practitioner that Olsen suffered from a debilitating medical condition. (Resp. Exh. 3; Parker Testimony).

Olsen filed a timely appeal from the denial as outlined in Iowa Administrative Code rule 641-154.7. Olsen has admitted he has not been diagnosed with a debilitating medical condition as defined in the Medical Cannibidiol Act. (Resp. Exhs. 4, 5).

APPLICABLE LAW AND DISCUSSION

Iowa Code Chapter 124E authorizes certain persons to legally possess and use medical cannabidiol, upon obtaining a registration card issued by the Department. The statute sets out specific requirements to obtain a registration card. One such requirement is a written certification from a health care practitioner that the applicant suffers from a "debilitating medical condition."3

The statute expressly authorizes the IDPH to adopt rules ensuring it administers the program in a manner that serves the medical needs of the patient while addressing public safety issues.4 As per the statute, the rules also limit issuance of a registration card to persons who submit a written certification signed by the applicant's health care practitioner certifying that the person "is suffering from a debilitating medical condition."5

Here, there is no dispute Olsen does not suffer from a debilitating medical condition, and did not submit with his application a written certification from his health care provider. The clear and unambiguous language of both the statute and regulations therefore *required* that the Department deny his application.6

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2 *See* Medical Cannabidiol Act (the Act), Iowa Code §§ 124E.3; 124E.4(1)(c).
3 Iowa Code §§ 124E.2; 124E.3. A list of conditions qualifying as "debilitating medical condition[s]" is provided in § 124E.2; see also Iowa Admin. Code r. 641-154.1.
4 Iowa Code § 124E.11.
5 Iowa Admin. Code r. 641-154.3(1)"c." The remaining requirements are as follows: a) the person is at least 18 years old; b) the person is a permanent resident of Iowa; d) the person submits a completed application on an IDPH form containing the information specified in the subrule; ande) the person submits the required fee. 641-154.3(1).
6 Iowa Code § 124E.2; 641-154.1.; *see also ABC Disposal Sys., Inc. Dep't of Natural Resources*, 681 N.W.2d 596, 603 (Iowa 2004) (plain and rational meaning applied if statute's language is "clear and unambiguous"); *Des Moines Area Regional Transit Authority v. Young*, 867 N.W.2d 839, 842 (Iowa 2015) (substantial deference given to agency's interpretation of its regulations, provided the interpretation does not violate the rule's "plain language and clear meaning").

Olsen contends, however, that the Department's denial of his application for a medical cannabidiol registration card violates his constitutional right to the free exercise of his religion. First, he argues that Chapter 124E (and Chapter 124) are neither religiously-neutral nor generally-applicable. Secondly, Olsen contends there is no narrowly-tailored compelling government interest to justify a prohibition against religious use of marijuana extracts. Olsen believes the Department should allow persons to seek a religious waiver from the requirement of submitting a medical certification from a health care practitioner, much like the religious waivers authorized in other Department-administered programs.7

Notably, the legislature—through the enabling statutes--expressly authorized the waiver processes in the examples cited by the Appellant.8 No such authorization exists in the Medical Cannabidiol Act.

Regardless, it is well-settled that an administrative agency lacks authority to decide constitutional issues.9 And although Olsen was required to raise the issues in this forum to preserve them for judicial review,10 no deference is afforded the agency's opinion regarding the constitutionality of a rule or statute. The Iowa Supreme Court has expressly emphasized: "We will not give any deference to the view of the agency with respect to constitutionality of a statute or administrative rule, because it is exclusively up to the judiciary to determine the constitutionality of legislation and rules enacted by the other branches of the government."11 Accordingly, the merits of Olsen's First Amendment claim are appropriately left for the district court.

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7 *See gen.* App. Brief at 4-5.

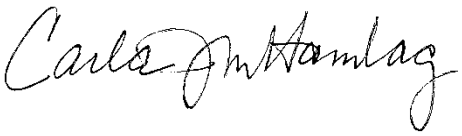
8 *See* Iowa Code §§ 135.11(7) (embalming and disposal of dead bodies); 135.17(1)(d) (children's dental screenings); 135.39D(10) (children's vision screenings); 135.105D(4) (blood lead testing in children); 135.146 (vaccination of first responders); 139A.8(4)(a)(2) (children's immunizations); 139A.38 (prophylactic drops in infant's eyes); 139A.39 (compelling medical treatment to prevent spread of infectious disease).
9 *Endress v. Iowa Dep't of Human Servs.*, 944 N.W.2d 71, 83 (Iowa 2020) (citing *Soo Line R.R. v. Iowa Dep't of Transp.*, 521 N.W. 2d 685, 688 (Iowa 1994)).
10 *See id.*(citing *McCracken v. Iowa Dep't of Human Servs.*, 595 N.W.2d 779, 785 (Iowa 1999)).
11 *ABC Disposal Sys., Inc. v. Department of Natural Resources*, 681 N.W.2d 596, 605 (Iowa 2004) (citing Iowa Code § 17A.19(11)(b)).

DECISION

As set forth above, the Department correctly denied the Appellant's application for a medical cannibidiol registration card under the express language of the statute and applicable regulations. The undersigned lacks authority to consider his constitutional claims.

The Department's January 7, 2022 decision is **AFFIRMED**.

Dated this 11th day of August, 2022.



Carla J. Hamborg
Administrative Law Judge
cc: Carl Olsen (by Mail and Email)
Colin Murphy, Attorney for Appellant (by Mail and Email)
Laura Steffensmeier, AAG (By AEDMS)
Heather Adams, AAG (By Email)
Sarah Reisetter, IDPH (By Email)
Owen Parker, IDPH (By Email)

APPEAL RIGHTS

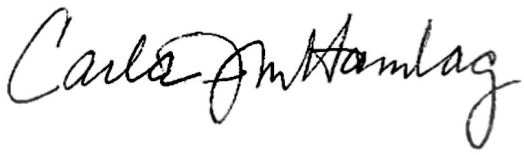
Any adversely affected party may appeal this proposed decision to the director of the Iowa Department of Public Health within 30 days of the date of the decision. The notice of appeal must be signed by the appealing party or a representative and contain a certificate of service. The notice must specify the party(s) initiating the appeal, the proposed decision appealed from, the specific findings or conclusions to which the party(s) takes exception, the relief sought, and the grounds for relief. If there is no appeal within 30 days, the proposed decision shall become the final decision of the department. Iowa Admin. Code r. 641-173.26; 641-173.27.

Case Title: CARL OLSEN V. IOWA DEPARTMENT OF PUBLIC HEALTH

Case Number: 22IDPH0002

Type: Proposed Decision

IT IS SO ORDERED.



Carla Hamborg, Administrative Law Judge

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building
Des Moines, Iowa 50319

CARL OLSEN, Appellant, vs. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	Docket No. ***22IDPH0002*** ***REQUEST FOR REVIEW BY DIRECTOR***

TO: Director, Iowa Department of Public Health

COMES NOW Appellant Carl Olsen, through counsel, Colin Murphy, and in support of the Request for Review by the Director of the August 11, 2022 Proposed Decision by the Administrative Law Judge states:

1. On November 24, 2021, Appellant applied for a medical cannabidiol registration card from the Iowa Department of Public Health (the "**Department**").
2. In lieu of a certification from a health care provider, Appellant submitted a declaration regarding his sacramental use of cannabis as a member of the Ethiopian Zion Coptic Church.
3. On January 7, 2022, the Department denied his application for the card.
4. Appellant timely appealed and raised both Free Exercise and Due Process arguments before the agency.
5. On August 11, 2022, the Administrative Law Judge denied the appeal.
6. The ruling acknowledges Appellant's Due Process claim and partially addresses it, but does not rule on it. *See* Proposed Decision at 3.
7. More importantly, however, the ruling defers Appellant's entire Free Exercise

claim to the district court for judicial review. *See id.*

8. In *Shell Oil v. Bair*, the Iowa Supreme Court opined:

> In *Aircraft & Diesel Equipment Corp.,* the Court's principal reason for taking this position was that permitting the administrative process to first run its course may eliminate the need for reaching potential constitutional claims. We agree with this reasoning and add yet another reason for imposing the exhaustion requirement. Even facial constitutional issues are more effectively presented for adjudication based upon a specific factual record. The place for such record to be developed is, we believe, before the agency entrusted with the determination of the adjudicative facts. *Moreover, it can be expected that facial constitutional challenges will be coupled with claims that the legislation is unconstitutional as applied to the litigant. Efficient and effective judicial administration is therefore better served by having the entire proceeding first determined by the agency.*

Shell Oil v. Bair, 417 N.W.2d 425, 430 (Iowa 1987) (citations omitted) (emphasis added).

9. Appellant's constitutional claims – the *sine qua non* of his appeal - are part of the "entire proceeding" that must be determined by the Department prior to judicial review.

10. "[T]he purpose of these rules [regarding error preservation] is to give both the opposing party and the agency an opportunity to address the issue." *Brewbaker v. State Bd. of Regents*, 843 N.W.2d 466, 471 (Iowa App. 2013) (noting constitutional issues can be raised for first time on petitions for rehearing and intra-agency appeals).

11. The lack of deference given on judicial review to the Department's ruling on constitutional matters, or the fact that the constitutional issues are reviewed *de novo* on appeal, does not mean the Department lacks authority to address these issues in the first place.

12. Appellant is entitled to a ruling by the Director that addresses the issues raised by the parties on appeal, including:

(a) Appellant is not collaterally estopped from asserting a religious use claim to possessing and using medical cannabidiol under Chapter 124E;

(b) Chapter 124E and the administrative rules interpreting it lack due process because they do not provide for a religious exemption or waiver; and

(c) The Department erred in denying Appellant's application for a medical cannabidiol registration card because the statute is underinclusive.

WHEREFORE, Appellant respectfully requests the Director reverse the Department's denial of his application for a medical cannabidiol registration card.

Respectfully submitted,

By: /s/ Colin Murphy AT0005567
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ATTORNEY FOR APPELLANT

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The Hon. Carla Hamborg (carla.hamborg@dia.iowa.gov)
Laura Steffensmeier (laura.steffensmeier@ag.iowa.gov)
Heather Adams (heather.adams@ag.iowa.gov)
Sarah Reisetter (sarah.reisetter@idph.iowa.gov)
Owen Parker (owen.parker@idph.iowa.gov)

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on August 31, 2022

By:
- ☐ U.S. Mail
- ☐ Hand Delivered
- ☐ Certified Mail
- ☐ FAX
- ☐ Overnight Courier
- ☒ Electronic Mail

Signature: Colin Murphy

BEFORE THE IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

CARL OLSEN Appellant v. IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent	DIA NO. 22IDPH0002 **BRIEFING AND ORAL ARGUMENT SCHEDULE**

This matter comes before the Director of the Department of Health and Human Services ("Director") on appeal by Carl Olsen. Administrative Law Judge ("ALJ") Carla J. Hamborg entered a Proposed Decision and Order in this matter on August 11, 2022. The ALJ affirmed the Department's denial of an application for a medical cannabidiol registration card, issued to the appellant on January 7, 2022, pursuant to Iowa Code chapter 124E and Iowa Admin Code r. 641 - 154.3.

Pursuant to Iowa Code section 17A.15 and Iowa Admin. Code r. 641 - 173.27, the appellant has appealed the ALJ's Proposed Decision to the Director. The issue on appeal is whether the ALJ's Proposed Decision and Order is correct as a matter of law.

Pursuant to Iowa Code §17A.15, the appellant and the Department may file with the Director written objections or exceptions to the Proposed Decision, or written statements in support of all or part of the Proposed Decision, and briefs in support of their respective positions. It is therefore ordered as follows:

1. The appellant and the Department may submit initial briefs on or before October 10, 2022.

2. The appellant and the Department may submit responsive briefs on or before October 31, 2022.

The Director will not receive any new or additional evidence that was not presented as part of the administrative hearing before the ALJ.

Dated this 16th day of September, 2022.

IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Heather Adams (by email and local mail)

Iowa Department of Health and Human Services

CARL OLSEN, Appellant, v. IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	))))))))))	DIA Docket No. 22IDPH002 **RESPONDENT'S BRIEF IN SUPPORT OF PROPOSED DECISION**

COMES NOW Respondent, Iowa Department of Health and Human Services, and hereby provides the following Brief in Support of Proposed Decision.

TABLE OF CONTENTS

I. SUMMARY OF THE CASE

The Iowa Department of Health and Human Services ("Department")[1] administers the Medical Cannabidiol Act ("Act) contained at Iowa Code chapter 124E, which authorizes patients who suffer from debilitating medical conditions to possess and use medical cannabidiol upon receipt of a medical cannabidiol registration card ("registration card"). The Act requires – as a condition of obtaining a registration card – that an applicant obtain a written certification from a health care practitioner that the applicant suffers from a debilitating medical condition which qualifies for the use of medical cannabidiol. Iowa Code §§ 124E.3, 124E.4.

On November 24, 2021, Appellant Carl Olsen submitted an online application for a registration card to the Department. Department's Exhibit 2. Appellant's application did not contain the required health care practitioner certification form. Department's Exhibits 2 and 5, Testimony of Owen Parker. Appellant admits he does not have a debilitating medical condition as defined by the Act, and that he does not meet the requisite statutory qualifications to use medical cannabidiol for the legally authorized purposes. Department's Exhibit 5.

In lieu of submitting the health care practitioner certification form, Appellant

[1] Effective July 1, 2022, through July 1, 2023, the Iowa Department of Public Health (IDPH) and the Iowa Department of Human Services (DHS) shall be in a "transition period" as the agencies develop and implement transition plans to merge the agencies and become a new state agency, the Iowa Department of Health and Human Services (HHS). *See* HF 2578, H-8372, § 51. Throughout the transition period, HHS shall have and may exercise all legal powers and duties of IDPH as prescribed by law or rule in effect on July 1, 2022, including but not limited to those related to contested cases involving IDPH. All contested cases pending before IDPH "shall continue without change in status" before HHS and shall be governed by the laws and rules applicable to the contested case in effect on July 1, 2022. *See* HF 2578, H-8372, § 51.

submitted a personal "Declaration" describing his religious use of cannabis as a member of the Ethiopian Zion Coptic Church. Department's Exhibit 2, Testimony of Owen Parker. Owen Parker, Chief of the Bureau of Medical Cannabidiol within the Department, reviewed Appellant's application. Testimony of Owen Parker. Mr. Parker could not approve the application because it lacked the required health care practitioner certification form. Testimony of Owen Parker. Mr. Parker consulted with his supervisor, Sarah Reisetter, Deputy Director of the Department, who confirmed that he did not have any authority to approve the application. Testimony of Owen Parker. Mr. Parker denied Appellant's application and sent written notification regarding the denial to Appellant on January 7, 2022. Department's Exhibit 3, Testimony of Owen Parker. The denial letter provided information regarding Appellant's right to appeal the denial. Department's Exhibit 3. On January 20, 2022, Mr. Olsen filed a timely appeal. Department's Exhibit 4.

A contested case hearing was held on June 15, 2022. On August 11, 2022, the assigned administrative law judge issued a proposed decision following the contested case hearing ("Proposed Decision"). The Proposed Decision affirmed the Department's decision to deny Mr. Olsen's application for a registration card, finding the Department's denial to be correct under the express language of applicable laws and declining to rule on his constitutional claims due to lack of authority to decide constitutional issues. On August 31, 2022, Appellant filed a timely Request for Review by the Director pursuant to 641 Iowa Administrative Code 173.27. On September 16, 2022, the Director issued a briefing scheduling giving the parties an opportunity to address whether the Proposed Decision is correct as a matter of law. For the reasons stated below, the Proposed Decision is correct as a matter of law and the Director should affirm the Proposed Decision without

modification.

II. APPLICABLE LAW

The Medical Cannabidiol Act, Iowa Code chapter 124E, provides the authority for the Department to issue registration cards to eligible patients and primary caregivers. The Act provides a list of the requirements that must be satisfied before the Department may issue a registration card to a patient, which includes that the applicant must 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. Iowa Code §§ 124E.4(1)(*c*), 124E.3; 641 IAC 154.3(1)"c". The Medical Cannabidiol Act solely authorizes the possession and use of medical cannabidiol for medical purposes: the Act does not reference any religion or religious use of medical cannabidiol and does not provide a mechanism for individuals to apply for a registration card for religious use.

III. ARGUMENT

A. The Department was required to deny Appellant's application for a registration card based on the undisputed facts and clear statutory requirements.

Based on the undisputed facts, Appellant's application for a registration card was properly denied because he (admittedly) failed to submit a written health care practitioner certification form. Appellant further admits that he does not have a "debilitating medical condition" as defined in Iowa Code section 124E.2(2) and 641 IAC 154.1. Under Iowa law, access to medical cannabidiol is restricted to individuals that have debilitating medical conditions. Based on the clear language of chapter 124E, and accompanying administrative rules, the Department was required to deny Appellant's application for a registration card because Appellant failed to meet the minimum requirements for issuance.

Appellant's post-hearing brief cites to other contexts in which the Department

provides for religious exemptions or waivers as support for his argument that the Department should recognize a religious exemption in this matter. This argument fails for three reasons. First, the examples cited by Appellant involve circumstances in which the Department recognizes a religious exemption to a generally applicable state requirement. In certain circumstances in which the legislature has imposed a mandated activity to protect public health – such as childhood screenings or immunizations – it has chosen to provide exemptions to the required activity if it conflicts with an individual's sincere religious beliefs. In contrast to the other examples provided by Appellant, Iowa's Medical Cannabidiol Act does not impose a requirement or obligation on all Iowans that would potentially educe a similar exemption process.[2]

Second, in each of the examples cited by Appellant – including dental and vision screening of children, blood lead testing of children, immunization of children, the placement of prophylactic solutions in the eyes of newborns, and specific courses of

[2] It is important to note that while the Iowa legislature has chosen to provide for religious exemptions to certain required screenings and immunizations, it is not constitutionally obligated to do so. For example, the states of California, Connecticut, Maine, Mississippi, New York, and West Virginia do not allow religious exemptions to childhood vaccinations and authorize exemptions only on medical grounds. Courts have consistently held that states are not required to include religious exemptions to generally applicable state requirements. *See, e.g., Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015) (holding state "could constitutionally require that all children be vaccinated in order to attend public school."); *Workman v. Mingo Cty. Bd. of Educ.*, 419 F. App'x 348, 353–54 (4th Cir. 2011) (finding state statute requiring school vaccinations does not unconstitutionally infringe the right to free exercise and that "this conclusion is buttressed by the opinions of numerous federal and state courts that have reached similar conclusions in comparable cases."); *Whitlow v. California*, 203 F. Supp. 3d 1079, 1084 (S.D. Cal. 2016) (holding "the Constitution does not require the provision of a religious exemption to vaccination requirements."); *McCarthy v. Boozman*, 212 F.Supp.2d 945, 948 (W.D. Ark. 2002) (finding it is "well settled that a state is not required to provide a religious exemption from its immunization program. The constitutional right to freely practice one's religion does not provide an exemption for parents seeking to avoid compulsory immunization for their school-aged children.")

medical treatment – the ability for the Department to authorize a religious exemption or waiver was expressly established by the legislature. In enacting the Medical Cannabidiol Act, the legislature did not include any provision that would authorize the Department to waive or exempt any of the statutory requirements to allow for the religious use of medical cannabidiol.

Finally, while the Department does have a general process for requesting waivers, the Department cannot waive a provision of law that is specifically mandated by statute. Iowa Code § 17A.9A(2)(*c*); 641 IAC 178. Because the requirement for a written health care practitioner certification form is mandated by the Act, the Department would lack authority to approve a request for waiver if Appellant submitted such a request.

B. The Director cannot decide Appellant's constitutional challenges to the Medical Cannabidiol Act.

Appellant argues the Director should rule on his constitutional challenge to Iowa Code chapter 124E. The Department disagrees. While it is necessary for Appellant to raise his constitutional challenge at the agency level in order to preserve it for judicial review, the agency lacks authority to rule on Appellant's constitutional challenge to the statute. *Endress v. Iowa Dep't of Human Servs.*, 944 N.W.2d 71, 83 (Iowa 2020) (stating "It is true DHS's final decision preserved Endress's constitutional arguments for judicial review. This is because DHS lacked authority to decide her constitutional issues. Moreover, Endress is required to raise constitutional issues at the agency level, even though the agency lacks the authority to decide the issues, in order to preserve the constitutional issues for judicial review."). Under the separation of powers doctrine, the judiciary is the branch of government responsible for determining the constitutionality of legislation. *ABC Disposal Sys., Inc. v. Dep't of Natural Res.*, 681 N.W.2d 596, 605 (Iowa

2004) (stating "We will not give any deference to the view of the agency with respect to the constitutionality of a statute or administrative rule, because it is exclusively up to the judiciary to determine the constitutionality of legislation and rules enacted by the other branches of the government."). Therefore, a final decision in this appeal need only note Appellant's constitutional argument, but need not rule on the constitutionality of Iowa's Medical Cannabidiol Act.

Appellant's post-hearing brief references the recent district court ruling in *Olsen v. Iowa Department of Public Health*, which dismissed the case due to Appellant's failure to exhaust administrative remedies. CVCV062566 (Polk Co. District Court, May 3, 2022). The ruling does not state that the agency can or should rule on his constitutional challenge. Rather, it states "Mr. Olsen's constitution claims could be fully adjudicated and the declaratory relief he seeks obtained through a judicial review proceeding under chapter 17A." *Id.* at 6–7. It then directs him to "seek relief through Chapter 17A proceedings, after his administrative remedies have been exhausted." *Id.* at 7. The requirement for Appellant to complete the administrative process prior to seeking judicial review does not equate to a requirement for the agency to rule on his constitutional challenge.

Appellant's Request for Review by Director quotes *Shell Oil v. Bair*, 417 N.W.2d 425 (Iowa 1987) for the proposition that an agency must rule on constitutional claims. However, the quoted language does not state that an agency must rule on constitutional challenges to statutes. Rather, the Court indicates the appropriate proceeding in which to develop a factual record is the proceeding before the agency. The Court further speculates that because many facial constitutional challenges will be joined by as-applied constitutional challenges, the development of a factual record before the agency will ultimately aid a

reviewing district court. Appellant has failed to cite to a case that indicates an agency must rule on a constitutional challenge to a statute if presented in an administrative proceeding. In this case, a factual record was developed at the contested case hearing, which will serve as the factual basis upon which a potential reviewing court can consider Appellant's constitutional claims should he file a petition for judicial review challenging the final agency action in this matter.

The Proposed Decision correctly declined to issue separate and distinct rulings regarding Appellant's constitutional challenges. The Administrative Law Judge properly found:

> [I]t is well-settled that an administrative agency lacks authority to decide constitutional issues. And although Olsen was required to raise the issues in this forum to preserve them for judicial review, no deference is afforded the agency's opinion regarding the constitutionality of a rule or statute. The Iowa Supreme Court has expressly emphasized: "We will not give any deference to the view of the agency with respect to constitutionality of a statute or administrative rule, because it is exclusively up to the judiciary to determine the constitutionality of legislation and rules enacted by the other branches of the government." Accordingly, the merits of Olsen's First Amendment claim are appropriately left for the district court. Proposed Decision, p. 3, citations omitted.

The issues listed in paragraph 12 of Appellant's Request for Review by Director all pertain to his constitutional challenges to the Act. The Director therefore should not modify the Proposed Decision to address these constitutional issues, and the Proposed Decision should be affirmed in its entirety.

C. Even if the Director were to rule on Appellant's constitutional challenges, the Act is constitutional.

The Free Exercise Clause of the First Amendment, applicable to the States under the Fourteenth Amendment, provides that "Congress shall make no law . . . prohibiting the free exercise" of religion. *Fulton v. City of Philadelphia, Pennsylvania*, 141 S. Ct. 1868,

1876 (2021). The Free Exercise Clause, however, "does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes).'" *Employment Div. v. Smith*, 494 U.S. 872, 879 (1990) (quoting *United States v. Lee*, 455 U.S.252, 263 (1982) (Stevens, J., concurring)). The analysis of a free exercise claim begins with a determination of whether or not the challenged law is a neutral law of general applicability governed by *Smith*.

The Iowa Supreme Court has followed a three-step framework for analyzing whether a law is a neutral law of general applicability. *See Mitchell Cnty. v. Zimmerman*, 810 N.W.2d 1, 9–11 (Iowa 2012). First, a court considers whether the law is facially neutral. *Id.* at 9. If a law is facially neutral, a court next considers whether the law is operationally neutral. *Id.* at 10. If a law is operationally neutral, a court finally considers whether the law is generally applicable. *Id.* at 11.

If a court finds the challenged law satisfies all three of these tests, then *Smith* governs and the free exercise claim must fail. *Id.* at 8–9. If a court finds the challenged law fails any of these three tests, then the court must analyze whether the challenged law can pass constitutional muster under a strict scrutiny analysis. *Id.* A law can survive strict scrutiny if it advances interests of the highest order and is narrowly tailored to achieve those interests. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993). The Free Exercise Clause does not prohibit a state from enforcing a regulatory law that is both neutral and generally applicable. *Mitchell Cnty.*, 810 N.W.2d at 8.

The specific laws that prohibit Appellant from engaging in the sacramental use of marijuana are Iowa Code section 124.204(4)(*m*), which places marijuana in Schedule I of

the Iowa Controlled Substances Act, and Iowa Code section 124.401, which establishes criminal penalties for the unlawful possession of marijuana. Pursuant to Iowa Code chapter 124E, the legislature has authorized Iowans with specific debilitating medical conditions to legally access medical cannabidiol. Medical cannabidiol falls under the definition of marijuana in Iowa Code section 124.101(20), and is therefore a Schedule I controlled substance; however, Iowa Code section 124E.12 provides an affirmative defense to criminal prosecution for the charge of unlawful possession of marijuana to a patient in possession of medical cannabidiol with a valid registration card. In addition, Iowa Code section 124.401(5) 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 chapter 124E." The laws cited herein are the pertinent laws to analyze in evaluating neutrality and general applicability.

"The most basic requirement of neutrality is 'that a law not discriminate on its face.'" *Mitchell Cnty.*, 810 N.W.2d at 9 (quoting *Lukumi*, 508 U.S. at 533). "'A law lacks facial neutrality if it refers to a religious practice without a secular meaning discernable from the language or context." *Id.* The laws governing marijuana in Iowa are indisputably facially neutral – they do not reference religion in any way.

Appellant argues that Iowa Code chapter 124 is not neutral towards religion because of the statutory exemption for the religious use of peyote. However, this specific argument is barred by the doctrine of *res judicata*. The doctrine of *res judicata* includes both the doctrines of claim preclusion and issue preclusion. *Winnebago Indus., Inc. v. Haverly*, 727 N.W.2d 567, 571–72 (Iowa 2007). Under the doctrine of issue preclusion (also known as

collateral estoppel), once a court has decided an issue of law or fact necessary to its judgment, the same issue cannot be re-litigated in a subsequent proceeding. *Id.* at 571. Issue preclusion serves the important dual purposes of protecting parties from "the vexation of relitigating identical issues with identical parties…and to further the interest of judicial economy and efficiency by preventing unnecessary litigation." *Id.* at 572.

Our Supreme Court follows a four-factor test to determine if the issue preclusion doctrine applies to bar re-litigation of an issue – namely, the court will review whether:

1) the issue determined in the prior action is identical to the present issue;
2) the issue was raised and litigated in the prior action;
3) the issue was material and relevant to the disposition in the prior action; and
4) the determination made of the issue in the prior action was necessary and essential to that resulting judgment.

Id.

Appellant's argument that Iowa Code chapter 124 is not neutral due to the peyote exemption has been rejected several times, including by the Eighth Circuit in a prior case initiated by Appellant. *Olsen v. Mukasey*, 541 F.3d 827 (8th Cir. 2008). In *Olsen v. Mukasey*, Appellant argued "the [Controlled Substances Acts] are not generally applicable because they exempt the use of alcohol and tobacco, certain research and medical uses of marijuana, and the sacramental use of peyote." *Id.* at 832. In response to this argument, the Eighth Circuit held "[g]eneral applicability does not mean absolute universality . . . [e]xceptions do not negate that the CSAs are generally applicable." *Id.* Ultimately, the Eighth Circuit held that Olsen's "free exercise claim—alone or hybrid—is barred by collateral estoppel." *Id.* (Based on the fact that his free exercise claim had been previously denied by courts in *State v. Olsen*, 315 N.W.2d 1 (Iowa 1982); *U.S. v. Rush*, 738 F.2d 497

(1st Cir. 1984); and *Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458 (D.C. Cir. 1989)). The decision in *Olsen v. Mukasey* clearly satisfies each of the four elements necessary to invoke issue preclusion. Consequently, in light of the above case law and the doctrine of res judicata, Appellant's arguments on this issue are barred and any reviewing body should find that Iowa's Controlled Substances Act is facially neutral towards religion and is constitutional despite the exemption for peyote. *See also McBride v. Shawnee County*, 71 F.Supp.2d 1098 (D. Kansas 1999).

Appellant has not asserted, and would have no basis to assert, that Iowa's Medical Cannabidiol Act is not facially neutral. There are no references to religion or any specific religious practices in Iowa Code chapter 124E. Clearly, Iowa Code chapter 124E is facially neutral. Based on issue preclusion and a plain reading of chapter 124E, the pertinent laws are all facially neutral.

To determine operational neutrality, a court must "look beyond the language" to determine whether there is a religious practice being targeted for discriminatory treatment. *Mitchell Cnty.*, 810 N.W.2d at 10. Appellant does not allege, and has never alleged in prior cases, that laws placing marijuana in Schedule I were passed to target the religious practices of the members of the Ethiopian Zion Coptic Church. This stands in sharp contrast to the ordinances at issue in *Lukumi*, wherein the City of Hialeah passed ordinances to prohibit religious animal sacrifice by members of the Santeria church. 508 U.S. at 527–28. Although the ordinances themselves did not explicitly reference religion or the Santeria church, the record overwhelming established that the city council members passed the ordinances specifically to prevent religious animal sacrifice by church members. The Supreme Court held that a facially neutral law is not neutral if the objective of the law

is to infringe on certain practices due to religious motivation. *Id.* at 533.

Given that Iowa, along with the federal government and the remaining 49 states, enacted laws classifying marijuana as a Schedule I controlled substance to prevent drug abuse and promote the public health – and not to hinder the religious practices of the Ethiopian Zion Coptic Church – there can be no dispute that the laws are operationally neutral.

> A law fails the general applicability requirement if it burdens a category of religiously motivated conduct but exempts or does not reach a substantial category of conduct that is not religiously motivated and that undermines the purposes of the law to at least the same degree as the covered conduct that is religiously motivated.

Mitchell Cnty., 810 N.W.2d at 13 (quoting *Blackhawk v. Pennsylvania*, 381 F.3d 202, 209 (3rd Cir. 2004)). "[F]ederal courts have generally found laws to be neutral and generally applicable when the exceptions, even if multiple, are consistent with the law's asserted general purpose." *Id*. The purpose of classifying marijuana as a Schedule I controlled substance was to prevent drug abuse and protect the public health. *See* Iowa Code § 124.201 (setting forth the factors to consider in making scheduling recommendations); *State v. Olsen*, 315 N.W.2d 1, 8–9 (Iowa 1982). This purpose applies universally to the numerous controlled substances listed in the five schedules set forth in chapter 124.

Appellant is specifically requesting a lawful right to purchase, possess, and use medical cannabidiol for religious purposes in accordance with Iowa Code chapter 124E. Admittedly, Iowa Code chapter 124E does provide an exception to the general law that marijuana is illegal. But it does not follow that the laws making marijuana illegal are not generally applicable. Iowa's Medical Cannabidiol Act provides for controlled access to a

controlled substance for medical use. This highly regulated access to medical cannabidiol is similar to the familiar concept of patient access to controlled substances through a prescription authorized by a health care practitioner.

As previously stated, Iowa's Controlled Substances Act establishes criminal penalties for the possession of a controlled substance. Iowa Code § 124.401. But chapter 124 also makes it lawful for an individual to possess a controlled substance if prescribed or furnished by a licensed health care professional for a legitimate medical purpose. Iowa Code § 124.401(5). For example, the possession of hydrocodone, a controlled substance, is illegal for someone who does not have a prescription for it, while the possession of hydrocodone is legal for someone who has a valid prescription. This disparity exists because a licensed health care professional has determined that a patient under their care has a medical need for hydrocodone. The prescribing of controlled substances occurs in a highly regulated environment, with regulation by the federal Drug Enforcement Administration, the Iowa Board of Pharmacy, and the various licensing boards established under Iowa Code chapter 147 that license health care practitioners with prescriptive authority.

Iowa's Medical Cannabidiol Act – the "exception" cited by Appellant – is analogous to the allowance in chapter 124 for access to controlled substances via prescription for a medical reason. Neither chapter 124 nor chapter 124E establish a system of government assessment of individual exemptions. Rather, they establish the allowance for medical use of controlled substances as authorized (either through a prescription in chapter 124 or a written certification of a debilitating medical condition in chapter 124E) by a patient's health care provider. This medical allowance is categorically unique. It allows health care

providers to authorize treatment of medical conditions using controlled substances. Chapter 124E does not authorize use of medical cannabidiol outside of a medical context in which a health care practitioner diagnoses, or affirms a diagnosis for, a patient with a debilitating medical condition and provides the patient with explanatory information about the "therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment." Iowa Code § 124E.3. Use of a controlled substance for medical treatment does not undermine the goals of the Controlled Substances Act to prevent drug abuse and protect the public health. Society has recognized that tightly controlled access to controlled substances is a cornerstone of medical care. Because of the nature of this excepted category of use, the laws prohibiting the use of marijuana outside of the medical context remain generally applicable and the State can refuse to extend access to medical cannabidiol to individuals with a religious hardship. A contrary finding would allow a person to seek access to any controlled substance of their choosing, including opioids that have led to the ongoing opioid epidemic, for religious use.

Because the laws making controlled substances, including marijuana, illegal except for medical purposes are neutral and generally applicable, they "need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." *Lukumi*, 508 U.S. at 531. The Free Exercise Clause does not relieve someone of obligation to comply with a valid and neutral law of general applicability. *Smith*, 494 U.S. at 879–80. Therefore, there is no basis to declare Iowa Code chapter 124 or 124E unconstitutional as Appellant urges.

Even a contrary finding would not necessarily result in a mandate for the Department to issue Appellant a registration card. Based on the record established at the contested

case hearing, Appellant has not demonstrated how access to medical cannabidiol – as that term is defined in Iowa Code section 124E.2(10) and 641 IAC 154.1 – would allow him to practice his religion consistent with the beliefs of the Ethiopian Zion Coptic Church. Specifically, Appellant has indicated through testimony at hearing and in prior litigation that his religious use primarily entails smoking marijuana – a practice expressly prohibited by the Act. Iowa Code § 124E.17.

IV. CONCLUSION

The Proposed Decision should be AFFIRMED without modification.

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

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Filed with the Director electronically via email to William.Sales@ag.iowa.gov

Copy to:

Colin Murphy
ATTORNEY FOR APPELLANT
ccmurphy@grllaw.com

Proof of Service

The undersigned certifies that the foregoing instrument was served upon Attorney for Appellant by delivery in the following manner on the 10th day of October, 2022.

___ U.S. Mail
___ Hand Delivery
___ Federal Express
__X__ Electronically
___FAX
___Overnight
___Other

Signature: */s/ Josie Bollman*

Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building
Des Moines, Iowa 50319

CARL OLSEN, Appellant, vs. IOWA DEPARTMENT OF PUBLIC HEALTH, Respondent.	Docket No. ***22IDPH0002*** ***REPLY TO RESPONDENT'S BRIEF IN SUPPORT OF PROPOSED DECISION***

COMES NOW Appellant Carl Olsen, through counsel, Colin Murphy, and for the Reply to Respondent's Brief in Support of Proposed Decision states:

1. On page 10, Respondent claims that "[m]edical cannabidiol falls under the definition of marijuana in Iowa Code section 124.101(20), and is therefore a Schedule I controlled substance" for purposes of evaluating neutrality and general applicability.
2. As an extract of marijuana, it is correct to say that medical cannabidiol fits within the definition of marijuana. *See* Iowa Code § 124.101(20) (2022) ("Marijuana means all parts of the plants of the genus Cannabis . . . the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols.") However, medical cannabidiol is not a Schedule I controlled substance under Iowa Code chapter 124. Schedule I controlled substances have "no accepted medical use in treatment" or "lack[] accepted safety for use in treatment under medical supervision." *See* Iowa Code § 124.203(1)(b) (2022). Rather, the substance should be considered an *exception*

to chapter 124 that takes it outside the context of controlled substances, which is why it is found instead in chapter 124E.

3. The Eighth Circuit notes that "collateral estoppel does not apply if the controlling facts or legal principles have changed significantly since Olsen's prior judgments." *Olsen v. Mukasey*, 541 F.3d 827, 831 (8th Cir. 2008). Both the controlling facts and legal principles have not remained substantially static since that ruling. The possession and use of marijuana is no longer prohibited across the board here once the Iowa legislature carved out a secular exception from chapter 124 in 2017. Appellant's current argument – that chapters 124 and 124E are underinclusive - may rhyme with the prior cases, but it does not repeat.

WHEREFORE, Appellant respectfully requests the Director reverse the Department's denial of his application for a medical cannabidiol registration card.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on October 31, 2022

By:
- ☐ U.S. Mail
- ☐ Hand Delivered
- ☐ Certified Mail
- ☐ FAX
- ☐ Overnight Courier
- ☒ Electronic Mail

Signature: Colin Murphy

THE IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

CARL OLSEN, Appellant, vs. Iowa Department of Health and Human Services, Respondent.	DIA NO. 22IDPH0002 **DIRECTOR'S FINAL ORDER**

FINAL DECISION

After review of the record, the **PROPOSED** DECISION you received dated August 11th, 2022 is **ADOPTED** as the **FINAL DECISION.**

DISCUSSION

In the proposed decision dated August 11th, 2022, the Judge Affirmed the determination of the Iowa Department of Public Health (IDPH)* to deny the Appellant, Carl Olsen, a medical cannabidiol registration card. IDPH administers the Iowa medical cannabidiol program and issues registration cards to qualified patients allowing them to obtain and use medical cannabidiol for strictly limited medical purposes. Iowa Code 124E, The Medical Cannabidiol Act, governs all aspects of the permissible medical use of cannabidiol from the grant of authority to the IDPH to administer the program including the licensure and/ or registration of manufacturers, dispensaries, and persons seeking the ability to purchase it.

As listed in Iowa Code section 124E.4 titled "Medical cannabidiol registration card," the requirements for issuance of a medical cannabidiol card are that the person must be

eighteen years of age or older and a permanent resident of Iowa; the person must submit a written certification signed by a health care practitioner confirming the person is suffering from one of the debilitating medical conditions listed in Iowa Code section 124E.2(2); the person must submit an application containing his or her own full name, date of birth, address and phone number, the health care practitioner's full name, address and phone number, a caregiver's full name, address, date of birth and phone number (if any); and a copy of the person's valid photo identification. Persons applying for registration cards must also pay a processing fee.

There is no argument in this case about whether the Appellant filled out the appropriate IDPH-approved application or whether he paid the processing fee in full as required by the statute. There is no concern as to whether he provided his full name, birthdate, residential address, and phone number as required by the statute. The determinative issue is that the Appellant did not provide a certification from a health care practitioner indicating he is suffering with a qualifying debilitating medical condition at the time he submitted his application for a medical cannabidiol registration card. The Appellant does not claim to suffer from one of the debilitating medical conditions listed in Iowa Code section 124E.2(2).

Iowa Code chapter 124E uses a specific term when referring to applicants for registration cards. The term "applicant," is not used; not "candidate"; not "person". Instead, the term "patient" is used. Specifically, 124E.4(1) is subtitled "Issuance to a patient" and in all subsequent references to the person who is applying for the card, the term used is "patient." Though not defined within the statute, Merriam-Webster defines "patient" as "an individual awaiting or under medical care and treatment." The statutory

requirement for registration card applications to include a certification from the patient's health care practitioner indicating that the patient is suffering from one of the statutorily enumerated debilitating medical conditions is a measure which serves to reduce surreptitious attempts to obtain a medical cannabidiol registration card. This requirement reflects a clear desire by lawmakers to narrowly tailor access to medical cannabidiol registration cards. The statute does not include a provision providing the IDPH with authority to waive the health care practitioner certification requirement.

The Appellant cites constitutional claims of Free Exercise and Due Process to support his request for a medical cannabidiol registration card. His application did not include a certification of a debilitating medical condition from his health care practitioner, however, it did include a "Declaration," citing a religious, rather than medical need, for the card. The Appellant is a member of the Ethiopian Zion Coptic Church, which considers cannabis use to be part of its religious doctrine. The Appellant's association with the church is long standing and not in question; nor is the claim that his church does, in fact, adhere to a belief involving sacramental use of cannabis.

FINDINGS OF FACT

The Director ADOPTS the Findings of Fact contained in the Proposed Decision and incorporates them herein by reference.

CONCLUSIONS OF LAW

The Director ADOPTS the Conclusions of Law contained in the Proposed Decision and incorporates them herein by reference.

ORDER

The ORDER of the Proposed Decision is AFFIRMED and ADOPTED. As stated therein, the Constitutional Claims of the Appellant will not be resolved by the IDPH, or through this administrative appeal, and have been preserved for Review by the District Court.

The department is directed to implement the directions contained in the Proposed Decision.

Please call (515) 229-8156 if you have any questions with regard to this decision.

Under the provisions of Section 17A.19, Code of Iowa, you may file an appeal to the District Court in Polk County or in your county within thirty days of the date of this **FINAL DECISION** if you are dissatisfied with the decision. Within ten days after the filing of a petition for judicial review a copy of the petition shall be mailed to:

Kelly Garcia, Director
Department of Health and Human Services, Fifth Floor
1305 East Walnut
Des Moines, Iowa 50319-0114

Dated this 17th day of January, 2023, Des Moines, IA

IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES

Kelly Garcia

Kelly Garcia

Director

KG/SR/WS

cc:

Carl Olsen, Appellant

Colin Murphy, Attorney for Appellant

William Sales, AAG

Laura Steffensmeier, AAG

Sarah Reisetter, IDPH

Owen Parker, IDPH

DIA ALJ – Carla Hamborg

*Effective July 1, 2022, through July 1, 2023, the Iowa Department of Public Health (IDPH) and the Iowa Department of Human Services (DHS) shall be in a transition period as the agencies develop and implement transition plans to merge the agencies and become a new state agency, the Iowa Department of Health and Human Services (Iowa HHS). For purposes of this Agreement throughout the transition period, "Agency" or "Department" or "IDPH" means either IDPH or Iowa HHS. Throughout the transition period, IDPH and Iowa HHS shall have and may exercise all legal powers and duties of IDPH, including executing all contractual rights and obligations.

Effective July 1, 2023, the Iowa Department of Public Health (IDPH) and the Iowa Department of Human Services shall merge and become the Iowa Department of Health and Human Services (Iowa HHS). For purposes of this Agreement on and after July 1, 2023, "Agency" or "Department" or "IDPH" means Iowa HHS. On and after July 1, 2023, Iowa HHS shall have and may exercise all legal powers and duties of the former IDPH, including executing all contractual rights and obligations.