

**Iowa Department of Public Health**

**Office of Medical Cannabidiol**

**Request for Proposals  
to License Medical Cannabidiol Manufacturers**

**REQUEST FOR PROPOSAL #58819009**

**Initial License Effective Period:  
July 1, 2018 – November 30, 2018**

**NOTICE: This RFP does not include any funding award**

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## **SECTION 1 – GENERAL AND ADMINISTRATIVE ISSUES**

### **1.01 Purpose and Overview**

The Medical Cannabidiol Act (2017 Iowa Acts House File 524), enacted on May 12, 2017, directed the Iowa Department of Public Health (“Department”) to implement and administer new [Iowa Code chapter 124E](#). This Act authorizes the Department to license up to two medical cannabidiol manufacturers in Iowa.

A Request for Proposals was released in October 2017 and resulted in the licensing of one manufacturer. The purpose of this Request for Proposals (RFP) #58819009 is to solicit applications that will enable the Department to select and license the most qualified applicant as the second medical cannabidiol manufacturer to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol in the State of Iowa.

### **Background**

According to the Medical Cannabidiol Act, the Department was required to license up to two medical cannabidiol manufacturers initially by December 1, 2017. The Department licensed MedPharm Iowa on December 1, 2017. With this RFP, the Department intends to license a second manufacturer by July 1, 2018. Thereafter, the Department intends to renew the manufacturer licenses each year by December 1, in accordance with applicable administrative rules unless a manufacturer relinquishes a license, there is a change in state law, or the license is revoked pursuant to Iowa Code chapter 124E or applicable administrative rules.

Applicants interested in obtaining a license to manufacture medical cannabidiol in Iowa must submit an application in response to this RFP. The Department expects an application to contain sufficient information to allow a thorough understanding of the applicant’s ability to meet the requirements of the RFP and to operate as a medical cannabidiol manufacturer in accordance with Iowa law and administrative rules. Refer to Section 2 for additional details about licensure requirements and the manufacturing of medical cannabidiol in Iowa.

### **1.02 Application Eligibility Requirements**

Current holders of manufacturing licenses in Iowa are not eligible to apply.

Applicants for this RFP must meet each of the following eligibility requirements to be considered.

- A. Applicants must be registered to do business in the state of Iowa (Secretary of State’s office) or have started the registration process. If an applicant is not registered to do business in the state of Iowa at the time of application, the applicant must provide evidence of submission of required materials to be registered to do business in the state of Iowa with the application.

→ A file stamped copy of the organization's articles of incorporation or certificate of organization would be sufficient as evidence of submission of required materials.

- B. All owners of the business entity must be disclosed; and all owners must not have a history of a conviction of a disqualifying felony offense (refer to section 1.03). An owner is defined as any person who owns any share of the manufacturing business.
- C. An applicant is required to maintain and provide to the Department, upon application, a current and valid email account for electronic communications with Department.

### **1.03 Background Investigation and National Criminal History Background Check Fees**

A medical cannabidiol manufacturer owner shall not have been convicted of a disqualifying felony offense. A 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). To be eligible for a license, all owners of applicant manufacturer business entities must submit information and pass/clear a background investigation and a national criminal history background check conducted by the Iowa Department of Public Safety. Owners or partners who are added after an application is submitted or after a license is issued must also pass/clear a background investigation and a national criminal history background check conducted by the Iowa Department of Public Safety to be added to a license.

A manufacturer owner may not be convicted of a disqualifying felony offense. If any owner of the applicant manufacturer has been convicted of a disqualifying felony offense, that manufacturer should not apply. If a violation is discovered, any pending or issued medical cannabidiol manufacturer license will be revoked and the applicant will have forfeited any fees submitted to the Department or to the Department of Public Safety.

Payment in the form of a cashier check written to the Department of Public Safety in the amount of \$10,000 per owner must be submitted immediately following the posting of the notice of intent to award the manufacturer license. These funds will serve as a deposit for the costs associated with the background investigation and national criminal history background check on each owner. Background investigation and national criminal history background check costs shall be deducted from the funds deposited. If background investigation and national criminal history background check fees exceed the funds deposited, the applicant shall submit additional funds as required by the Department of Public Safety. If the background investigation and national criminal history background check fees are less than the funds deposited, the Department of Public Safety may refund or retain the fees as mutually agreed with the manufacturer.

Instructions for the background investigations and national criminal history background checks that are required as part of the application will be sent to the successful applicant following the award of a manufacturer license. The applicant shall cause all waivers and fingerprinting to be executed by appropriate persons to effectuate the background investigations and checks. As a condition of application to this RFP, applicants shall submit

to the Department immediately upon request, the following items:

- Completed background investigation and national criminal history background check forms for each owner
- Fingerprint cards for each owner
- Releases necessary to conduct the background investigation and national criminal history background check

#### 1.04 Application Fees

As required by the Medical Cannabidiol Act, each entity (applicant) submitting an application for licensure as a medical cannabidiol manufacturer shall pay a nonrefundable application fee of seven thousand five hundred dollars (\$7,500) to the Department. Payment of this fee must be in the form of a cashier check made payable to the Iowa Department of Public Health and must be submitted with the application.

#### 1.05 Schedule of Important Dates (All times and dates listed are local Iowa time.)

The following dates are set forth for informational purposes. The Department reserves the right to change them.

EVENT	DATE
RFP Issued	April 11, 2018
<b>Intent to Apply Letter Due</b>	<b>May 16, 2018 by 4:00 p.m.</b>
Written Questions and Responses	
Round 1 Questions Due:	May 3, 2018
Responses Posted By:	May 10, 2018
Round 2 Questions Due:	May 17, 2018
Responses Posted By:	May 24, 2018
<b>Applications Due</b>	<b>May 31, 2018 by 4:00 p.m.</b>
Post Notice of Intent to License	June 29, 2018

- A. RFP Issued  
The Department will post the RFP on the Department website under Funding Opportunities at <http://idph.iowa.gov/> on the date referenced in the Event Date table above. The RFP will remain posted through the Applications Due date.

The RFP does not include any funding award.

- B. Intent to Apply Email Due – May 16, 2018, 4:00 p.m.  
**All potential applicants must submit an intent to apply email in compliance with this section, on or before the due date.** This requirement is a mandatory requirement and will **not** be subject to waiver as a minor deficiency. **Intent to Apply emails received by the Department after the stated due date and time will be rejected. If an Intent to Apply email is not received by the due date and time, the application will also be rejected.**

**Intent to Apply emails must be received by Stacey Hewitt at [Stacey.Hewitt@idph.iowa.gov](mailto:Stacey.Hewitt@idph.iowa.gov) by Wednesday May 16, 4:00 p.m. (local time), with the subject line “Medical Cannabidiol Manufacturer RFP Intent to Apply”.**

The Intent to Apply email must contain the following information:

1. The name of the business for which the application is being submitted.
2. The name(s) of the owner(s) of the business for which the application is being submitted.
3. The name, telephone number, and email address of the business representative who will act as point of contact for RFP purposes.

**C. Written Questions and Responses**

Written questions related to the RFP must be submitted via electronic mail to [Stacey.Hewitt@idph.iowa.gov](mailto:Stacey.Hewitt@idph.iowa.gov) no later than the due dates specified for each round in the Event Date table above. If the question or comment pertains to a specific section of the RFP, the section and page must be referenced. Oral questions will not be accepted.

The Department will prepare written responses to all pertinent, timely and properly submitted questions according to the Event Date table above. Responses will be posted on the Department website under Funding Opportunities as a PDF document. The Department’s written responses will be considered part of the RFP.

It is the responsibility of the applicant to review written questions and responses to this RFP as posted on Department website under Funding Opportunities at <http://idph.iowa.gov/>.

**E. Applications Due – May 31, 2018, 4:00 p.m.**

**Applications must be received by Stacey Hewitt at the address below by 4:00 p.m. (local time) on May 31, 2018.** This requirement is a mandatory requirement and will **not** be subject to waiver as a minor deficiency.

All application information must be provided in the order and format established in the RFP, and clearly labeled with the RFP sections and subparts.

All application information must be typed in 12-point Times New Roman font, 1.5 line spacing, and 1-inch margins on each side. No portion of the application may be hand written except for documents that require signatures.

- Required materials, the original of which are not typed in 12-point Times New Roman font, such as floor plans and operating documents, may be submitted in the original format.

The complete application package must include:

1. One original and ten (10) paper copies of the application, inclusive of all required information, with each application single-sided and securely bound.

2. One CD containing an electronic version of the application, inclusive of all required information, in a searchable PDF file format, and one CD that contains a redacted copy of the application (if any) as described in section 1.24 of this RFP.
3. One cashier check made out to the Iowa Department of Public Health for \$7,500 as payment of the non-refundable application fee.

**Applications received by the Department after the stated due date and time will be rejected and not reviewed by the Department.**

Applications must be hand delivered or mailed to the Department to the attention of:

Stacey Hewitt, Contract Administrator  
Iowa Department of Public Health  
Lucas State Office Building - 6th Floor  
321 East Twelfth Street  
Des Moines, Iowa 50319-0075

Electronic mail and faxed copies of the application **will not** be accepted. Applicants who choose to mail applications must allow ample mail delivery time to ensure timely receipt of their applications by the Department. Postmarking by the due date will **not** substitute for actual receipt of the application by the Department. It is the applicant's responsibility to ensure that the application is date and time stamped as received by the Department prior to the deadline.

Any information submitted separately from the application will not be considered in the review process.

F. Notice of Intent to License

A Notice of Intent to Award a License will be posted for 10 business days on the Department website under Funding Opportunities at <http://idph.iowa.gov/> by 4:30 p.m. on the date specified in the Event Date table above. Applicants are solely responsible for reviewing the Notice of Intent to Award to determine their award status.

## 1.06 Inquiries

During the period following release of this RFP and during the period of evaluation, applicants should contact only Stacey Hewitt in the manner provided for in Section 1.05(C). Unauthorized contact regarding this RFP with other state employees or officials may result in disqualification. In no case shall verbal communications override written communications. Only written communications are binding on the Department.

The Department assumes no responsibility for representations made by its officers or employees unless such representations are specifically incorporated into the RFP.

Any verbal information provided by the applicant shall not be considered part of its application.

### **1.07 Amendments to the RFP**

The Department reserves the right to amend the RFP at any time. In the event the Department decides to amend, add to, or delete any part of this RFP, a written amendment will be posted on the Department website under Funding Opportunities. The applicant is advised to check the Department website periodically for amendments to this RFP. In the event an amendment occurs after the Funding Opportunity is closed and removed from the website, the Department will email the written amendment to the individual identified as the point of contact in the submitted intent to apply.

### **1.08 Open Competition**

No attempt shall be made by the applicant to induce any other person or firm to submit or not to submit an application for the purpose of restricting competition.

### **1.09 Withdrawal of Applications**

Applications may be withdrawn, modified and resubmitted at any time prior to the stated due date and time for the receipt of applications. An applicant desiring to withdraw an application shall submit notification via email to [Stacey.Hewitt@idph.iowa.gov](mailto:Stacey.Hewitt@idph.iowa.gov).

### **1.10 Acceptance of Terms and Conditions**

- A. An applicant's submission of an application constitutes acceptance of the terms, conditions, criteria and requirements set forth in the RFP and operates as a waiver of any and all objections to the contents of the RFP. By submitting an application, an applicant agrees that it will not bring any claim or have any cause of action against the Department or the State of Iowa based on the terms or conditions of the RFP or the award process.
- B. The Department reserves the right to accept or reject any exception taken by an applicant to the terms and conditions of this RFP. Should the successful applicant take exception to the terms and conditions required by the Department, the successful applicant's exceptions may be rejected and the Department may elect to terminate award to that applicant.

### **1.11 Costs of Application Preparation**

All costs of preparing the application are the sole responsibility of the applicant. The Department is not responsible for any costs incurred by the applicant which are related to the preparation or submission of the application or any other activities undertaken by the applicant related in any way to this RFP.

### **1.12 Multiple Applications**

An applicant may submit only one application.

An applicant may not be party to another application as an owner, investor, director, officer,

or employee.

### **1.13 Oral Presentation**

Applicants may be requested to make an oral presentation of the application. The determination of need for presentations and the location, order, and schedule of the presentations is at the sole discretion of the Department. If an oral presentation is required, applicants may clarify or elaborate on their applications, but may in no way change their original application.

### **1.14 Rejection of Applications/Cancellation of the RFP**

- A. The Department reserves the right to reject, in whole or in part, any or all applications, to advertise for new applications, to abandon the need for such services, and to cancel this RFP if it is in the best interests of the Department.
- B. Any application will be rejected outright and not evaluated for any of the following reasons:
  - 1. The applicant fails to submit via email the Intent to Apply by the date and time stated in Section 1.05.
  - 2. The applicant fails to deliver the application by the date and time stated in Section 1.05.
  - 3. The applicant is not an eligible applicant as defined in Section 1.02.
  - 4. An applicant submits more than one application.
  - 5. An application is submitted in a manner other than that specified in this RFP.
- C. Any application may be rejected outright and not evaluated for any of the following reasons:
  - 1. The applicant fails to include required information or fails to include sufficient information to determine whether an RFP requirement has been satisfied.
  - 2. The applicant fails to follow the application instructions or presents information requested by this RFP in a manner inconsistent with the instructions of the RFP.
  - 3. The applicant provides misleading or inaccurate answers.
  - 4. The applicant states that a mandatory requirement cannot be satisfied.
  - 5. The applicant's response materially changes a mandatory requirement.
  - 6. The applicant's response indicates inability to comply with a mandatory requirement of the Medical Cannabidiol Act, Iowa Code chapter 124E, 641 Iowa Administrative Code 154, or proposed administrative rules.
  - 7. The applicant's response limits the right of the Department.
  - 8. The applicant fails to respond to the Department's request for information, documents, or references.
  - 9. The applicant fails to include any signature, certification, authorization,

- or stipulation requested by this RFP.
10. The applicant initiates unauthorized contact regarding the RFP with a state employee or official.

### **1.15 Restrictions on Gifts and Activities**

Iowa Code chapter 68B contains laws which restrict gifts which may be given to or received by state employees and requires certain individuals to disclose information concerning their activities with state government. Applicants are responsible for determining the applicability of this chapter to their activities and for complying with these requirements.

In addition, Iowa Code chapter 722 provides that it is a felony offense to bribe a public official.

### **1.16 Reference Checks**

The Department reserves the right to contact any reference to assist in the evaluation of the application, to verify information contained in the application, and to discuss the applicant's qualifications.

### **1.17 Criminal Background Checks**

The Department reserves the right to conduct background investigations and national criminal history background checks of the applicant, its officers, directors, managerial and supervisory personnel, clerical or support personnel, and contractors retained by the applicant.

The Department of Public Safety, on behalf of the Department, will conduct background investigations and national criminal history background checks of the applicant manufacturer business owner(s) and employees as described in Section 1.03 and Section 2. The applicant is responsible for the costs associated with the background investigations and national criminal history background checks as described in this RFP. Results of the background checks may be used in determining license awards.

### **1.18 Information from Other Sources**

The Department reserves the right to obtain and consider information from other sources concerning an applicant, including the applicant's product or services, personnel, and contractors, and the applicant's capability and performance under other Department contracts, other state contracts, and contracts or licenses with other states or private entities. The Department may use any of this information in evaluating an applicant's application.

### **1.19 Verification of Application Contents**

The Department reserves the right to verify the contents of an application submitted by an applicant. Misleading or inaccurate responses may result in rejection of the application pursuant to Section 1.14.

## **1.20 Litigation or Investigation Disclosure**

The applicant shall disclose any pending or threatened litigation, administrative, or regulatory proceedings or similar matters which could affect the ability of the applicant to manufacture medical cannabidiol. Failure to disclose such matters at the time of application may result in rejection of the application or in revocation of any license. This is a continuing disclosure requirement. Any such matter commencing after submission of an application or award of a license must be disclosed in a timely manner in a written statement to the Department.

## **1.21 RFP Application Clarification Process**

The Department may request clarification from applicants for the purpose of resolving ambiguities or questioning information presented in the application. Clarifications may occur throughout the application evaluation process. Requests for clarification will be issued to the applicant via email from [Stacey.Hewitt@idph.iowa.gov](mailto:Stacey.Hewitt@idph.iowa.gov). Clarification responses shall be in writing in the format provided by the Department and shall address only the information requested. Responses shall be submitted to the Department within the time stipulated at the time of the request. An applicant will not be permitted to modify or amend its application if contacted by the Department for this reason.

## **1.22 Waivers and Variances**

The Department reserves the right to waive or permit cure of non-material variances in the application's form and content providing such action is in the best interest of the Department. In the event the Department waives or permits cure of nonmaterial variances, such waiver or cure will not modify the RFP requirements or excuse the applicant from full compliance with RFP specifications or other legal requirements if the applicant is awarded a license. The determination of materiality is in the sole discretion of the Department.

## **1.23 Disposition of Applications**

All application submissions become the property of the Department.

If the Department awards a license to an applicant, the contents of all applications will be in the public domain at the conclusion of the selection process and will be open to inspection by interested parties subject to exceptions provided in Iowa Code chapter 22 or other provision of law and as stated in Section 1.24 of this RFP.

## **1.24 Public Records**

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.

All information submitted by an applicant will be treated as public information following the conclusion of the selection process unless the applicant properly requests that information be treated as confidential at the time the application is submitted.

Any request for confidential treatment of information must be included in a transmittal letter with the applicant's application. In addition, the applicant must enumerate the specific grounds in Iowa Code chapter 22 which support treatment of the material as confidential. The request for confidential treatment of information must also include the name, address, and telephone number of the person authorized by the applicant to respond to any inquiries by the Department concerning the confidential status of the materials.

Any application submitted which contains confidential information must be conspicuously marked as containing confidential information and must indicate which sections of the application should be treated as confidential. Identification of the entire application as confidential shall be deemed non-responsive and shall disqualify the applicant.

The applicant must submit one copy of the application from which the confidential information had been excised. The confidential material must be excised in such a way as to allow the public to determine the general nature of the material removed and to retain as much of the application as possible.

In the event Department receives a public request for application information marked confidential, written notice shall be given to the applicant seventy-two (72) hours prior to the release of the information to allow the applicant to seek injunctive relief pursuant to Iowa Code section 22.8. The information marked confidential shall be treated as confidential information to the extent such information is determined confidential under Iowa Code chapter 22 or other provisions of law by a court of competent jurisdiction.

The applicant's failure to request confidential treatment of material pursuant to this section and the relevant law will be deemed by the Department as a waiver of any right to confidentiality which the applicant may have had.

### **1.25 Copyrights**

By submitting an application, the applicant agrees that the Department may release the application for the purpose of facilitating the evaluation of the application or to respond to requests for public records. By submitting the application, the applicant consents to such release and warrants and represents that such release will not violate the rights of any third party. The Department shall have the right to use ideas or adaptations of ideas that are presented in the applications. In the event the applicant copyrights its application, the Department may reject the application as noncompliant.

### **1.26 Appeal of Rejection Decision**

The applicant's receipt of a rejection letter constitutes receipt of notification of the adverse decision per 641 Iowa Administrative Code chapter 176.8(1). Applicants may appeal the adverse decision only for a timely submitted application. The appeal shall be submitted in writing within ten business days of receipt of notification of the adverse decision. Appeals shall be submitted in writing, return receipt requested, to Stacey Hewitt, Contract Administrator, Division of Administration and Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Appeals must clearly and fully identify all issues being contested and demonstrate what procedures in the

RFP were not followed. In the event of an appeal, the Department will continue working with the successful applicant(s) pending the outcome of the appeal.

### **1.27 Appeal of Award Decision**

The posting of the Notice of Intent to Award a License on the Department website constitutes receipt of notification of the adverse decision per 641 Iowa Administrative Code Chapter 176.8(1). Applicants may appeal the adverse decision only for a timely submitted application. The appeal shall be submitted in writing within ten business days of receipt of notification of the adverse decision. Appeals shall be submitted in writing, return receipt requested, to Stacey Hewitt, Contract Administrator, Division of Administration and Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Appeals must clearly and fully identify all issues being contested and demonstrate what procedures in the RFP were not followed. In the event of an appeal, the Department will continue working with the successful applicant(s) pending the outcome of the appeal.

### **1.28 Definition of Contract**

Award of a license pursuant to this RFP does not constitute the making of a contract between the Department and the licensee.

### **1.29 Construction of RFP**

This RFP shall be construed in light of pertinent legal requirements and the laws of the State of Iowa. Changes in applicable statutes and rules may affect the award process. Applicants are responsible for ascertaining the relevant legal requirements. Any and all litigation or actions commenced in connection with this RFP shall be brought in the appropriate Iowa forum.

## **SECTION 2 – DESCRIPTION OF APPLICATION AND LICENSE REQUIREMENTS**

The Iowa Medical Cannabidiol Act, requires the Department to select and license up to two medical cannabidiol manufacturers in Iowa. MedPharm Iowa was licensed on December 1, 2017. One additional medical cannabidiol manufacturer in Iowa may be licensed by the Department through this RFP. Applicants for this RFP are responsible for compliance with the Medical Cannabidiol Act, as well as all proposed and final administrative rules. The Act, the current administrative rules, and the proposed rules can be found at the links included in this RFP.

The Medical Cannabidiol Act allows a qualifying patient or primary caregiver who is registered with the Department to possess medical cannabidiol for the treatment of the patient's debilitating medical condition(s). (The Department's administrative rules pertaining to patients, primary caregivers, and debilitating medical conditions can be found at [641 IAC 154](#)).

Medical cannabidiol must be manufactured by a manufacturer licensed by the Department and must be purchased from a dispensary licensed by the Department. (The Department's implemented administrative rules pertaining to manufacturers and dispensaries can be found at [641 IAC 154](#), and proposed administrative rules can be found at [ARC 3707C](#)). Five dispensaries were licensed on April 1.

This section of the RFP describes minimum expectations of the medical cannabidiol manufacturer. Section 3 of this RFP details the requirements of the application content.

The selected manufacturer(s) will be expected to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol within this state consistent with the provisions of the Medical Cannabidiol Act, as well as the implemented and proposed administrative rules.

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 July 1, 2019.

### **License Effective Dates and Annual Fees**

The Department expects the initial license will be valid from July 1, 2018, through November 30, 2018.

The Department intends to renew the license annually unless a manufacturer relinquishes a 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 administrative rules.

Iowa Code section 124E.10 requires the Department to collect annual fees in an amount sufficient to regulate the medical cannabidiol manufacturers and dispensaries, to cover the cost of salaries for two agents of the Division of Criminal Investigation of the Department of Public Safety, and for other expenses that are necessary to administer

chapter 124E, including the costs of information technology systems. At this time, annual fees for Year 1 are payable by December 1, 2018, and are anticipated to be in the range of \$150,000 to \$200,000. This estimate is subject to revision based on changes in the law or any other factors that may impact the program budget.

### **License Effective Area**

A medical cannabidiol manufacturer license is effective for the entire state of Iowa.

### **Employee Background Checks and Fees**

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 and national criminal history background check conducted by the Division of Criminal Investigation of the Department of Public Safety.

Upon notice of license award, the licensed manufacturer will pay a deposit of \$200 per employee to the Department of Public Safety for background investigations and national criminal history background checks for every employee and every prospective employee of the manufacturer. Background investigation and national criminal history background check costs shall be deducted from the funds deposited. If the background investigation and national criminal history background check fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the Department of Public Safety. If the background investigation and national criminal history background check fees are less than the funds deposited, the Department of Public Safety may refund or retain the fees as mutually agreed with the manufacturer.

### **Manufacturing Minimum Requirements**

Please see the implemented administrative rules at [641 IAC 154](#), and the proposed administrative rules at [ARC 3707C](#) for manufacturing requirements.

### **Inspections and Product Standards**

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

The licensed medical cannabidiol manufacturer shall be required to contract with the State Hygienic Laboratory at the University of Iowa in Iowa City or an independent medical cannabidiol testing laboratory to perform testing of the medical cannabidiol produced by the manufacturer as to the content, contamination and consistency of the product. The Department shall require that the laboratory report testing results to the manufacturer in a manner described in the proposed administrative rules found at [ARC 3707C](#).

The cost of all laboratory testing shall be paid by the medical cannabidiol manufacturer.

## Data System Use

The Department is required to maintain a system of record for secure monitoring and tracking of *Cannabis* plant material inventory, manufacturing and production processes, and medical cannabidiol product inventory. The system is designed to alert the Department of potential diversion (tracking any inventory lost at any point from seed to sale) and to ensure public safety (tracking product sold to patients back to the plant level). The Department has contracted with BioMauris to develop and manage the Department's secure seed-to-sale tracking and inventory system.

A manufacturer may choose to enter data directly in to the Department's system or may use its own system. Any system used by a manufacturer must be capable of integrating with the Department's system so that all required data can be sent to and maintained by the Department. A manufacturer shall be responsible for any costs to integrate its system with the Department's. If a manufacturer's system is unable to send the appropriate data through an application programming interface (API), the data must be provided through an upload process or through direct entry into the Department's system. The system will also generate all transport manifests between manufacturers, dispensaries, and laboratories.

## **SECTION 3 – APPLICATION FORMAT AND CONTENT**

This section of the RFP prescribes the format and content of the application and is designed to facilitate the submission of an application that is easy to understand, review, and evaluate. The applicant is solely responsible for including all information requested throughout this RFP in the submitted application. Failure to adhere to these requirements and application content may result in rejection of the application.

This RFP includes forms that the applicant must download and complete (from the Department website under Funding Opportunities), and provides direction for the applicant to obtain other documents or write narrative responses.

### **3.01 Technical Requirements**

A. Applications must be typewritten and follow the format delineated herein.

<b>Aspect</b>	<b>Requirement</b>
Length	Page limitations apply only to the narrative portions of the RFP, refer to Section 3.02C. Narrative will be limited to 200 pages. This limitation excludes Mandatory Certification Forms, Operating Procedures, Floor Plans, and any other document required or suggested.
Font size	Applications must be typed using a 12-point font Times New Roman. Applications must include required forms. Mandatory Certification Forms, tables, operating documents, figures or maps may be submitted in original format. No portion of the application may be hand written except for documents that require signatures. Handwritten applications will not be accepted.
Margins	Must be a minimum of one inch on all sides.
Spacing	Application must be single-sided. Must be 1.5 spacing, except for Mandatory Certification Forms provided by the Department.
Header or Footer and Pagination	Preferred: Insert a header or footer that identifies the applicant name, page number. All pages should be sequentially numbered (1, 2, 3...) at the top right corner of each page, including the cover page, maps, charts, budget pages, tables, and appendices or attachments; and beginning after the Mandatory Certification Forms.
Copies	Submit one (1) original application, signed Cover Page and ten (10) copies, one (1) CD that contains the content of the entire application, inclusive of all information and in searchable PDF file format, and one (1) CD that contains a redacted copy of the application (if any) provided under section 1.24 of this RFP.
Mandatory Certification Forms	The forms listed in Section 3.02 Mandatory Certification Forms must be completed and signed as directed.
Binding	The original and each copy must be securely bound.

B. Promotional materials or items other than required by this RFP will not be considered during the review process.

C. Any information or materials submitted separately from the application will not be considered in the review process.

## 3.02 Application Content

### A. Cover Page

This form identifies the applicant's legal name and contact information. Applicant must download this form posted separately and complete the required form following these instructions:

- Applicant – Provide the legal name of the applicant entity. This must be the entity associated with the Federal Identification (ID) number per the Internal Revenue Service (IRS). If the entity operates under another name as a “d/b/a” (doing business as), please include that in the legal name.
- IRS # – Provide the applicants **last four digits** of the federal identification number.
- Conditions/Signature – The person authorized to legally obligate the applicant must sign and date in non-black ink to certify that the applicant is in agreement with the conditions listed.

### B. Mandatory Certification Forms

Mandatory forms are required. An application that does not include the mandatory forms listed below will be rejected during the technical review and not reviewed.

Applicants must download each form, print, sign and include it with the application. Refer to the forms posted separately, but with this RFP, in section 5.

The Mandatory Certification Forms include:

1. Statutory Requirements Certification Form
2. Licensing Regulatory Authority Release Form
3. Proper Zoning Form
4. Owner Certification Form

The content of mandatory forms will be considered in evaluating applications.

#### 1. Statutory Requirements Certification Form

This form certifies that the applicant is knowledgeable of and will comply with all statutory requirements applicable to RFP #58819009.

By signing the form, the person completing the form attests that he/she is authorized to provide such information and to bind the applicant.

Further, signing the form means the applicant answers yes to each statement, except as specifically noted. For any statement for which the answer is no, answer no immediately after that statement and provide a brief explanation.

## **2. Licensing Regulatory Authority Release Form**

This form certifies that the applicant is providing the Department with all requested regulatory agency information and authorizes the Department to contact the listed agencies for the purposes of RFP #58819009.

By signing the form, the person completing the form attests that he/she is authorized to provide such information and to bind the applicant manufacturer.

Further, signing the form means the applicant answers yes to each statement, except as specifically noted. For any statement for which the answer is no, answer no immediately after that statement and provide a brief explanation.

## **3. Proper Zoning Form**

This form certifies that the applicant is providing the Department with requested zoning information and notarized verification of zoning information for the purposes of RFP #58819009.

By signing the form, the person completing the form attests that he/she is authorized to provide such information and to bind the applicant manufacturer.

Further, signing the form means the applicant answers yes to each statement, except as specifically noted. For any statement for which the answer is no, answer no immediately after that statement and provide a brief explanation.

## **4. Owner Certification Form**

This form certifies that each applicant manufacturer owner is providing the Department with requested business and professional information and acknowledges State and Federal law for the purposes of RFP #58819009.

By signing this form, each applicant manufacturer owner attests that he/she is authorized to provide such information and to bind the applicant manufacturer with his/her responses.

Further, signing the form means the applicant answers yes to each statement, except as specifically noted. For any statement for which the answer is no, answer no immediately after that statement and provide a brief explanation.

## **C. Narrative Sections**

The Department expects an application to fully address the contents of every narrative section and to contain sufficient information to allow a thorough understanding of the applicant's ability to meet the requirements of the RFP and to operate as a medical cannabidiol manufacturer, in accordance with Iowa law and regulations. As outlined in Section 3.01 Technical Requirements, narrative response are limited to 200 pages. This page limit does not include Mandatory Certification Forms, Operating Procedures, Floor

Plans, and any other document required or suggested.

The narrative sections listed below are required:

1. Business Overview and Plan
2. Manufacturer Operations
3. Security Requirements
4. Advertising and Marketing
5. Packaging and Labeling
6. Transportation of Medical Cannabidiol and Plant Material
7. Disposal of Medical Cannabidiol and Plant Material
8. Record-keeping Requirements
9. Production Requirements
10. Quality Assurance and Control
11. Supply and Inventory
12. Ownership and Financial Structure

Applicants may be required to submit additional documents within each narrative section of the application, for example, a table of organization, operating documents, or other information to fully be responsive to each section. Applicant shall incorporate the necessary documents in the correct place in the application.

Narrative sections will be considered in evaluating applications.

**1. Narrative: Business Overview and Plan**

a. Summary

Provide a brief summary of the applicant manufacturer's qualifications, experience, and industry knowledge relevant to the development and operation of a medical cannabidiol manufacturing business in Iowa.

b. Business Plan

- (1) Describe the steps and anticipated timeframes for becoming operational as a manufacturer and having medical cannabidiol available at dispensaries by July 1, 2019.
- (2) Describe the proposed production capacity by July 1, 2019, and in the second and third year of operation. Include a description of the ability to expand capacity in the future.
- (3) Give a summary of the business continuity plan should there be a loss of power or other natural or man-made event that precludes manufacturing at the site for a period of time, keeping in mind that manufacturers are limited to a single physical location.
- (4) Describe the forms and quantity of medical cannabidiol (i.e., products) that will be manufactured during the first year of

operation (i.e., available July 1, 2019), and any forms and quantities of products that are likely to be developed in the second and third year of operation. All forms must be consistent with 641 IAC 154.14, as amended by ARC 3707C.

- (5) Describe planned product pricing for each of the first three years of operation.

## 2. Narrative: Manufacturer Facility

- a. Specify the physical location of the proposed manufacturing facility.
- b. Provide documentation sufficient to establish that the applicant is authorized to conduct business in the State of Iowa; and that state and local building, fire, and zoning requirements and all applicable local ordinances are or will be met for the proposed location of the manufacturing facility. Documentation may include blueprints, equipment specifications, or statements from local officials, etc. that state and local building, fire, and zoning requirements and applicable local ordinances will be met if the manufacturer completes construction and operates as proposed in the application.
- c. Provide documentation of any support by a local government authority for the proposed manufacturing facility location.
- d. Describe how the manufacturer will inform the Department of potential new hires to initiate required background investigation and national criminal history background checks.
- e. Provide documentation that the proposed manufacturing facility location is owned by the applicant. If not owned by the applicant, provide a written statement from the property owner certifying that the property owner has consented to the applicant operating a manufacturing facility at that location and the duration of the actual or planned lease.
- f. Describe signage, lettering, text and graphic materials that will be shown on the exterior of the manufacturing facility.
- g. Provide a site plan, drawn to scale, of the proposed manufacturing facility showing perimeter fencing as well as all streets, property lines, buildings, parking areas, and outdoor areas, if applicable, that are within a 500-foot radius of the manufacturing facility.
- h. Provide a blueprint or floor plan, drawn to scale, of the proposed manufacturing facility, which shows and identifies the following information:
  - (1) The square footage of the overall manufacturing facility.
  - (2) The locations and square footage of all areas that may contain *Cannabis* or medical cannabidiol with descriptions of the activities to occur in the spaces. The diagram should include walls, partitions, counters and all areas of ingress and egress. Said diagram must also reflect all cultivation, propagation, harvest, extraction, refinement, testing, storage, packaging and labeling, and transportation areas.
  - (3) The square footage and location of areas to be used as storerooms or stockrooms, if not included above.

- (4) The location of pesticide, fungicide, and fertilizer storage, mixing, and cleanup areas, including equipment storage and cleanup.
- (5) The location of all break rooms, employee lockers, and employee shower facilities (for those applying pesticides or other crop inputs).
- (6) The locations of any business operations on the property that will not be related to the production and distribution of medical cannabidiol.
- (7) All points of entrance and exit at the manufacturing facility.
- i. Provide a site development and construction (or conversion) plan identifying the construction start date, duration, and completion date.
- j. Describe any air treatment system or other means to reduce odors released from the facility.
- k. Explain previous experience with developing new manufacturing facilities.

**3. Narrative: Security Requirements**

- a. Provide a plan to meet the restricted access requirements of 641 IAC 154.18(1) to 154.18(2).
- b. Provide a plan to meet the perimeter intrusion detection system requirement of 641 IAC 154.18(3), including a floor plan noting location of all cameras, and including a description of the storage capabilities for the onsite retention of historical recordings. Note that network cameras do not meet the definition of a closed-circuit TV system, but they may be used in addition to closed-circuit TV systems.
- c. Provide a plan to meet the security alarm system requirements of 641 IAC 154.18(4).
- d. Provide a plan to meet the personnel identification system requirements of 641 IAC 154.18(5).
- e. Provide the names and addresses of any contractors hired or planned to provide security.

**4. Narrative: Advertising and Marketing**

- a. Describe planned marketing and advertising activities consistent with 641 IAC 154.20(1), including templates for manufacturer displays, signs, website pages, and educational materials.
- b. Describe other marketing and advertising activities consistent with 641 IAC 154.20(2) intended to be conducted in the first year.
- c. Describe how interior displays of medical cannabidiol, signs and other exhibits will be arranged to prevent viewing from outside the manufacturing facility consistent with 641 IAC 154.20(3).

**5. Narrative: Packaging and Labeling**

- a. Describe planned medical cannabidiol packaging consistent

- with 641 IAC 154.21(1).
- b. Describe the intended medical cannabidiol trade names consistent with 641 IAC 154.21(2).
  - c. Describe medical cannabidiol package labeling consistent with 641 IAC 154.21(3), as amended by ARC 3707C, including a sample label template for each type of product proposed. A space no smaller than 0.75 inches wide by 0.5 inches high should be reserved on the label for the Department's warning symbol. The symbol will be made available at a later time.

**6. Narrative: Transportation of Medical Cannabidiol and Plant Material**

- a. Describe experience in transporting product of high value with potential risk for diversion.
- b. Describe how medical cannabidiol will be transported to and from dispensaries, the laboratory, and a waste facility consistent with 641 IAC 154.22 and proposed administrative rule 154.71(2) (see ARC 3707C). Include the following in the narrative:
  - (1) The frequency of medical cannabidiol transport to each location.
  - (2) The frequency of collection of waste medical cannabidiol from dispensaries and the laboratory consistent with 641 IAC 154.23(1).
  - (3) The location of the waste facility.
  - (4) Proposed methods for minimizing the risk of diversion or theft of medical cannabidiol during transport.
  - (5) The manifest or tracking system to be used in the event that the secure sales and inventory system is not operational.
- c. Describe how *Cannabis* plant material will be transported to a waste disposal site consistent with 641 IAC 154.22. Include the following in the narrative
  - (1) The frequency of transport to the waste facility.
  - (2) The location of the waste facility.
  - (3) Proposed methods for minimizing the risk of diversion or theft of *Cannabis* plant material during transport.
  - (4) The manifest or tracking system to be used in the event that the secure sales and inventory system is not operational.

**7. Narrative: Disposal of Medical Cannabidiol and Plant Material**

- a. Describe the process for collecting and documenting medical cannabidiol that has been returned from patients and dispensaries as detailed in 641 IAC 154.23(1).
- b. Describe how medical cannabidiol and plant material waste will be stored and disposed of consistent with 641 IAC 154.23(2). Include estimates of the amount of waste products that will need to be stored and disposed of. Describe the waste disposal site or sites (these are not licensed by the Department).

- c. Describe the process for disposal of liquid and chemical waste consistent with 641 IAC 154.23(3). Include estimates of the amount of liquid and chemical waste that will need to be disposed of and the location of the waste facility.

## **8. Narrative: Record-keeping Requirements**

- a. Describe how the record-keeping requirements in 641 IAC 154.24 will be met, including how and where each type of record will be stored.
- b. Describe contingency plans in the event that the Department's secure sales and inventory tracking system is not operational.

## **9. Narrative: Production Requirements**

- a. Describe the process for hiring of, qualifications of, and training for employees involved in the cultivation of *Cannabis*.
- b. Describe the process to assure that all employees are age 18 or older and have not been convicted of a disqualifying felony offense.
- c. Describe the applicant's experience in controlled growth environments and agricultural and/or horticultural crops. Include the experience of any person employed by or consulting with the applicant, including the person's name and position.
- d. Describe the number, experience, and training of staff who will be producing medical cannabidiol, including the extraction, refinement, and production of medical cannabidiol. Describe the qualifications of and the number of employees to be involved in extraction, refinement, and production of medical cannabidiol. Describe the experience of any person employed by the applicant who has expertise in these areas, including the person's name and position. Describe any experience the applicant may have in turning *Cannabis* into medical cannabidiol.
- e. Describe the controlled growth environment, systems, and automation that will be used to cultivate *Cannabis* from seed or cutting to harvest.
- f. Describe the expected hours of operation of the cultivation operations, the number of staff expected to be working in the cultivation operations at any one time, and the total number of full-time and part-time employees or contractors.
- g. Describe the proposed propagation, cultivation, and harvesting procedures, including biosecurity measures to minimize contamination consistent with 641 IAC 154.25(1).
- h. Describe any media that will be used to grow plants from cutting to harvest. Describe what crop inputs will likely be used from propagation to harvest of *Cannabis* plants, and how these will be applied and recorded, consistent with 641 IAC 154.25(2). Crop inputs include, but are not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments. If the

applicant manufacturer proposes to grow organically, specify the standards with which it intends to comply. (For example, standards from the USDA National Organic Program Handbook, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5096778>). Note that the Iowa Department of Agriculture and Land Stewardship (IDALS) has not approved any pesticides for use on *Cannabis*. See Iowa Code chapter 206 and 21 IAC chapters 44 and 45 for state law and regulations governing application and use of pesticides. State laws and regulations on the use of fertilizers can be found in Iowa Code chapter 200 and 21 IAC chapter 43 and 44.

- i. Describe any data systems other than the department's secure sales and inventory tracking system that will be used to collect plant, cultivation, inventory, and production information.
- j. Describe the protocol to be used if a fungal or pest outbreak were to occur to both address the issue and resume/restart cultivation.
- k. Describe who will be certified to apply pesticides, fungicides, or other insecticidal agents at the manufacturing facility and how the credentials will be reviewed to ensure that all licenses and recertification requirements are met according to Iowa pesticide laws and regulations (Iowa Code chapter 206, and 21 Iowa Administrative Code chapters 44 and 45) as well as FDA and EPA regulations.
- l. Describe the process for propagating and tracking individual plants and assigning them to batches consistent with 641 IAC 154.25(2).
- m. Describe the method that will be employed to extract the active ingredients from the *Cannabis* plant to produce the medical cannabidiol, where the extractions will occur, and what solvents will be used in the extraction process. Explain how the process ensures that no residual solvents, if any solvents are used, will remain in the finished product, and how the work environment will be made safe for employees. Include a description of the protocols and equipment that will be used in extraction, refinement, and production of medical cannabidiol products. Describe the method of ensuring product traceability from plant and batch to medical cannabidiol product through the extraction and refinement process to the final product.
- n. Describe the hours of operation for extraction, refinement, and production of medical cannabidiol.
- o. Describe how all production requirements of 641 IAC 154.25(3) will be met.
- p. Describe how all general sanitation requirements in 641 IAC 154.25(4) will be met.
- q. Describe all additives, excipients, flavorings, or other products that will be used in producing medical cannabidiol.
- r. Describe how medical cannabidiol and *Cannabis* plant material

will be stored, consistent with 641 IAC 154.25(5).

## 10. Narrative: Quality Assurance and Control

- a. Describe the elements of the quality control program, consistent with 641 IAC 154.26, as amended by ARC 3707C, including the qualifications of staff involved in sampling, laboratory testing, and determining product purity and stability. Include the experience and credentials of any person employed by the applicant who has expertise in laboratory testing and stability testing, including the person's name and position.
- b. Describe medical cannabidiol sampling procedures consistent with 641 IAC 154.26(2), including:
  - (1) Sampling protocols;
  - (2) Documentation;
  - (3) Labeling; and
  - (4) Retention of results.
- c. Name the laboratory that will be used to conduct testing consistent with 641 IAC 154.26, as amended by ARC 3707C. If the selected laboratory is not the State Hygienic Laboratory at the University of Iowa, provide evidence that the laboratory is or will be accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, has a controlled substance registration certificate from the Drug Enforcement Administration of the US Department of Justice, and a certificate of registration from the Iowa Board of Pharmacy.
- d. Describe the testing procedures consistent with 641 IAC 154.26(3), as amended by ARC 3707C, and proposed administrative rule 154.72 (see ARC 3707C), including expected frequency and volume of testing; the type of testing that will be requested; protocols for samples that fail to meet acceptance criteria; and procedures for documenting test results, assessments, and destruction of failed product lots.
- e. Describe how the stability testing procedures detailed in 641 IAC 154.26(4), as amended by ARC 3707C, will be met. Include a description of:
  - (1) Procedures for stability testing of each product type and determination of storage conditions;
  - (2) Plans to involve dispensaries in shelf-life and product expiration date studies;
  - (3) Intervals for testing; and
  - (4) Timeline for the development of the stability testing program.
- f. Describe the procedures for reserving samples from each lot consistent with 641 IAC 154.26(5).
- g. Describe the procedures for disposal of substandard medical cannabidiol product consistent with 641 IAC 154.26(7).
- h. Describe the process to collect, review, analyze and determine actions needed when information on adverse events from patients using the medical cannabidiol is discovered.

- i. Iowa Code Chapter 124E does not allow manufacturers to have access to patient and primary caregiver names. Given this limitation, describe recall and market withdrawal procedures consistent with 641 IAC 154.26(8). Include a description of:
  - (1) The factors that would make a recall or market withdrawal necessary;
  - (2) The personnel who would be responsible for overseeing the recall or market withdrawal; and
  - (3) How the manufacturer will work with the Department to notify affected parties, including a projected timeline for the process.

## 11. Narrative: Supply and Inventory

- a. Describe the procedures for ensuring a reliable and ongoing supply of medical cannabidiol to the dispensaries consistent with 641 IAC 154.27. Include a description of:
  - (1) Inventory controls and procedures to prevent and detect diversion, theft, or loss in a timely manner;
  - (2) The process for any employee to report the suspected or confirmed diversion of *Cannabis* plants at any point in the manufacturing process;
  - (3) Systems for maintaining a real-time record of the inventory of plant material and medical cannabidiol should the Department's secure sales and inventory tracking system be inoperable;
  - (4) The personnel who will conduct inventory and the schedule for the inventory.
- b. Describe the procedures for inventory of medical cannabidiol waste and plant material waste consistent with 641 IAC 154.27(4), including the personnel involved and the schedule for the inventory.
- c. Describe procedures for inventory reconciliation consistent with 641 IAC 154.27(5), including the personnel involved and the schedule for the inventory reconciliation.

## 12. Narrative: Ownership and Financial Structure

- a. Describe the applicant manufacturer's business structure, for example, but not limited to, sole proprietorship, limited partnership, or C-corporation. Provide (as applicable):
  - Articles of incorporation
  - Articles of association
  - Charter
  - By-laws
  - Partnership agreement
  - Any agreements between any two or more members of the applicant manufacturer's business that relate in any manner to the assets, property or profit of the applicant or
  - Any other comparable documents that set forth the legal structure of the applicant or relate to the organization,

- management, or control of the applicant.
- b. Provide current organizational charts that include position descriptions and the names of persons holding each position, to the extent such positions have been filled.
  - c. Provide the resume of each person listed on the organizational chart setting out the employee's particular skills, education, experience or significant accomplishments that are relevant to the position.
  - d. Provide copies of all compensation agreements with investors, board members, directors, owners, officers, and other management. For purposes of this RFP, a compensation agreement includes any agreement that provides, or will provide, a benefit to the recipient whether in the form of salary, wages, commissions, fees, stock options, interest, bonuses or otherwise.
  - e. Provide a list of any criminal history and civil litigation (as a plaintiff or defendant) for all individuals identified in items b, c, and d above. Criminal history shall include arrests, deferred judgments, deferred sentences, and convictions. Minor traffic-related offenses do not need to be included.
  - f. Describe the nature, type, terms, covenants, and priorities of all outstanding bonds, loans, mortgages, trust deeds, pledges, lines of credit, notes, debentures, or other forms of indebtedness issued or executed, or to be issued or executed, in connection with the opening or operating of the proposed manufacturer.
  - g. Provide audited financial statements for the previous three (3) fiscal years, which shall include, but not be limited to, an income statement, balance sheet, statement of retained earnings or owners' equity, statement of cash flows, and all notes to such statements and related financial schedules, prepared in accordance with generally accepted accounting principles, along with the accompanying independent auditor's report.
    - If the audited financial statements are more than three months old, provide an affidavit indicating that there are no material changes subsequent to the most recently submitted financial statements.
    - If the applicant was formed within the year preceding this application, provide certified financial statements for the period of time the applicant has been in existence and any pro forma financials used for business planning purposes.
  - h. Provide a list of owners, their ownership percentage and financial investment for all investors.
  - i. Describe future financial investments and commitments per owner or investor and potential owners or investors.
    - (1) Provide the amount of future financial investment and the timeline the commitment is valid for.
    - (2) Each commitment should be accompanied by a letter certified by a Certified Public Accountant (CPA) verifying that the commitment by each owner (or potential owner) does not exceed 50% of their

personal net worth.

- If such commitment exceeds 50% of an owner or potential owner's personal net worth, indicate the percentage of that person's net worth that the commitment represents.

**D. Operating Documents**

Attach a copy of each of the following operating documents, consistent with 641 IAC 154.17(1):

1. Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:
  - a. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;
  - b. The methods of planting, harvesting, drying, and storing *Cannabis*;
  - c. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;
  - d. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;
  - e. The disposal methods for all waste materials;
  - f. Employee training methods for the specific phases of production and who (or what position) will be responsible for oversight of the training;
  - g. Biosecurity measures used in the production and manufacturing of medical cannabidiol;
  - h. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;
  - i. Sampling strategy and quality testing for labeling purposes and product expiration date determination;
  - j. Medical cannabidiol packaging and labeling procedures;
  - k. Procedures for mandatory (i.e., recall) and voluntary (i.e., market withdrawal) of medical cannabidiol;
  - l. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;
  - m. A business continuity plan;
  - n. Records relating to all transport activities;
  - o. Handling, storage, application, and disposal of pesticides, fertilizers, and other crop inputs;
  - p. Oversight of all personnel and phases of manufacturing and production of cannabidiol (including a table of organization).
2. Procedures to ensure accurate recordkeeping.
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.

## **SECTION 4 – APPLICATION REVIEW PROCESS AND CRITERIA**

### **4.01 Overview of Review Process**

Review and evaluation of applications submitted under this RFP will be conducted in three phases.

A. Phase I – Technical Review

The first phase will involve a preliminary review by Department staff of an applicant's compliance with the mandatory requirements to include but not limited to: eligibility, application fee check, certifications, and application content for submitted applications. Applications which fail to satisfy technical requirements or application content may be rejected and eliminated from the application review. The Department will notify an applicant of a rejection that occurs during Phase I of the review process. The Department reserves the right to waive minor variances at the sole discretion of the Department.

B. Phase II – Review Committee

Applications determined to be compliant with technical requirements and application content will be accepted for the second phase of evaluation, which shall be completed by a review committee established by the Department.

The review committee will initially evaluate applications and score in accordance with a point system. Each committee member will review the applications and the evaluation criteria outlined in this chapter and assign a point total for each criteria.

The Department reserves the right to solicit information from subject matter experts who may provide information to the review committee members about particular components of the RFP, the manufacturing requirements, and/or the applications received.

Once the applications have been evaluated and scored by individual committee members, the entire committee will meet to discuss the applications and arrive at the final scoring. Any individual scores may be adjusted at this point based upon discussion.

If an applicant is requested to make an oral presentation of the application pursuant to Section 1.13, the committee members may consider the oral presentation of the applicant in determining the points awarded.

The final score will be assigned as a consensus score from the committee members and the applications will then be ranked based on the final scores. In the event applications receive an equal number of points, the Department staff may solicit additional input and recommendations from the review committee.

- C. Phase III – Department Review and Award  
The third phase will be a final review. The Department will consider the submitted applications and the review committee’s score and recommendations.

The Department may also consider geographical location, budget information, any information received pursuant to Section 1.16 - 1.22 of the RFP, and any other information received during the award process. The Department reserves the right not to award a license to the applicant with the highest committee consensus score.

#### **4.02 Scoring of Applications**

A maximum of 1,000 points may be awarded to each application. A minimum score of 600 points or greater is required for the application to be considered for award of a license. Applications scoring less than the minimum score will be rejected.

Accepted applications will be evaluated based on the following criteria:

- A. All parts of each section are included and addressed.
- B. Descriptions and detail are clear, organized, and understandable.
- C. Descriptions are responsive to the intent of the RFP objectives.
- D. The overall ability of the applicant, as judged by the evaluation committee, to successfully meet the RFP, administrative rules, and statutory requirements within the proposed schedule.

Points will be assigned for each item listed as follows:

- 5 Applicant’s application or capability is exceptional and exceeds expectations for this criterion.
- 4 Applicant’s application or capability is superior and slightly exceeds expectations for this criterion.
- 3 Applicant’s application or capability is satisfactory and meets expectations for this criterion.
- 2 Applicant’s application or capability is unsatisfactory and contains numerous deficiencies for this criterion.
- 1 Applicant’s application or capability is not acceptable or applicable for this criterion.

The maximum points to be awarded for each application section are as follows:

<b>Application Form</b>	<b>Weight</b>	<b>Potential Maximum Score</b>
Cover Page	N/A - Required	N/A
Application Fee to Department	N/A - Required	N/A
Background Investigation and National Criminal History Background Check Fee to Department of Public Safety	N/A - Required	N/A
Statutory Requirements Certification Form	N/A - Required	N/A
Regulatory Agency Authorization Form	N/A - Required	N/A
Proper Zoning Form	N/A - Required	N/A
Owner Certification Form	N/A - Required	N/A
Business Overview and Plan	20	100
Manufacturer Facility	15	75
Security Requirements	10	50
Advertising and Marketing	10	50
Packaging and Labeling	10	50
Transportation of Medical Cannabidiol and Plant Material	10	50
Disposal of Medical Cannabidiol and Plant Material	10	50
Record-keeping Requirements	10	50
Production Requirements		
Employee Experience and Qualifications	5	25
Cultivation	20	100
Extraction and Production	20	100
Quality Assurance and Control	15	75
Supply and Inventory	5	25
Ownership and Financial Structure	25	125
Operating Documents	15	75
<b>Total Maximum Points:</b>		<b>1,000</b>

## SECTION 5 – REQUIRED FORMS

These forms are posted as separate files on the Department website under Funding Opportunities. Applicants must download these forms and include them in the application as outlined in Section 3 of this RFP. Applicant may not modify the language contained within the forms and shall only input information as requested of this RFP.

- Cover Page
- Statutory Requirements Certification Form
- Licensing/Regulatory Authority Release Form
- Proper Zoning Form
- Owner Certification Form

## SECTION 6 – LINKS

Implemented Medical Cannabidiol Manufacturer administrative rules ([641 IAC 154](#))

[21 Iowa Administrative Code chapter 43](#) – Fertilizers and Agricultural Lime

[21 Iowa Administrative Code chapter 44](#) – On-site Containment of Pesticides, Fertilizers, and Soil Conditioners

[Iowa Code chapter 200](#) – Fertilizers and Soil Conditioners

[21 Iowa Administrative Code chapter 45](#) – Pesticides

[Iowa Code chapter 206](#) – Pesticides

Medical Cannabidiol Act ([Iowa Code chapter 124E](#))

Proposed Medical Cannabidiol Manufacturer administrative rules ([ARC 3707C](#))

Standards from the [USDA National Organic Program Handbook](#)