

## **License Medical Cannabidiol Manufacturers RFP #58821019 Score Tool**

Refer to the RFP Section 4 for details about the Application Review Process and Criteria. This document is an example and is a draft\* of the anticipated Score Tool for applications submitted under this RFP, and will be used to create the final review/score tool(s) for Phase I and Phase II review.

\*The Department reserves the right to change this document at its sole discretion.

### **Phase I: Technical Review**

Phase 1 Technical Review involves Department staff reviewing the application to ensure technical requirements are met. This includes, but is not limited to:

- Confirming that the applicant meets all Eligibility Requirements, listed below:
  - Registered to do Business in Iowa, with the submission of necessary documentation
  - Submission of Business Entity Ownership Disclosures (see Business Organization, Ownership, and Financial Structure Form)
  - Submission of the Intent to Apply Letter.
  - Submission of the Application Fee.
- Confirming submission of all Required Forms, including:
  - Medical Cannabidiol Manufacturer Application Certification and Conditions Form
  - Statutory Requirements Certification Form
  - Licensing/ Regulatory Authority Release Form
  - Proper Zoning Form
  - Owner Certification Form
- Reviewing that the contact information indicated in the Narrative Section: Business Organization, Ownership, and Financial Structure is complete and the organization is eligible; as well as verifying that the Applicant Information Organization Name field (for the Project Officer) matches the Legal Name of the Eligible Applicant identified in the Contact Information.
- Reviewing the applicant's responses to disclosure of any issues related to litigation (pending or threatened), contract defaults, or contract terminations as listed in the Narrative Section: Business Organization, Ownership, and Financial Structure.
- Reviewing the applicant's response to disclosure of any issues related to financial accountability as listed in the Narrative Section: Business Organization, Ownership, and Financial Structure.
- Ensuring that the Medical Cannabidiol Manufacturing Application Certification and Conditions Form is completed with all 'Yes' responses.
- Verifying that required forms are completed and information input into the forms appears to be appropriate (but not assessing content against requirements). For example, information is not just a 'place-holder.'

**Phase II: Review Committee**

Applications that have successfully met the requirements of Phase 1 Technical Review will be eligible to move forward to Phase II-Review Committee. Phase II will be completed by a review committee or committees established by the Department using a standard-format scoring tool. These are the Narrative Sections reviewers will assess in each application.

**Business Organization, Ownership, and Financial Structure**

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
<p>A. Contact Information: The applicant provides the general information about the applicant business entity including:</p> <ol style="list-style-type: none"> <li>1. Legal name of the eligible applicant</li> <li>2. Applicant legal address</li> <li>3. Applicant’s last 4 digits of federal tax ID number</li> <li>4. Applicant’s phone number, and</li> <li>5. The name of the Executive Director or CEO of the applicant organization. If the applicant is a board of health/board of supervisors, includes the name of the board’s authorized signatory.</li> </ol>	N/A - This information will not contribute to the application score				
<i>Comments:</i>					
<p>B. Business Structure: The applicant describes the Manufacturing business structure, for example, but not limited to, sole proprietorship, limited partnership, or C-corporation and provides the following as attachments/uploads (as applicable):</p> <ol style="list-style-type: none"> <li>1. Articles of incorporation</li> <li>2. Articles of association</li> <li>3. Charter</li> <li>4. By-laws</li> <li>5. Partnership agreement</li> <li>6. Any agreements between any two or more members of the applicant Manufacturing’s business that relate in any manner to the assets, property or profit of the applicant or</li> <li>7. Any other comparable documents that set forth the legal structure of the applicant or relate to the organization, management, or control of the applicant.</li> </ol>	1	2	3	4	5
<i>Comments:</i>					

C. Organizational Chart: The applicant provides a current organizational chart, including the names of persons holding each position, to the extent such positions have been filled.		1	2	3	4	5
<i>Comments:</i>						
D. Resumes: The applicant provides a resume of each person listed on the organizational chart setting out the individual's particular skills, education, experience or significant accomplishments that are relevant to the position.		1	2	3	4	5
<i>Comments:</i>						
E. Investors: The applicant provides a list of owners, their ownership percentage and financial investment for all investors. 1. Describes future financial investments and commitments per owner or investor and potential owners or investors. a. Provides the amount of future financial investment and the timeline the commitment is valid for. b. Each commitment is 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.		1	2	3	4	5
<i>Comments:</i>						
F. Compensation Agreements: The applicant provides 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.		1	2	3	4	5
<i>Comments:</i>						
G. Individual Criminal History and Civil Litigation: For all individuals listed in the organizational chart, investors, or individuals with compensation agreements with the applicant, the applicant provides a list of any criminal history and civil litigation (as a plaintiff or defendant) for all individuals.		1	2	3	4	5
<i>Comments:</i>						
H. Manufacturer Indebtedness Information: The applicant describes the nature, type, terms, covenants, and priorities of all outstanding bonds, loans, mortgages, trust		1	2	3	4	5

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 Manufacturing facility.						
<i>Comments:</i>						
<p>I. Financial Statements: The applicant provides the following for the applicant business:</p> <ol style="list-style-type: none"> <li>1. Audited financial statements for the previous three (3) years, which shall include, but not be limited to, an income statement, balance sheet, statement of retained earnings or owner 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. <ol style="list-style-type: none"> <li>a. If the audited financial statements are more than three months old, the applicant provides an affidavit indicating that there are no material changes subsequent to the most recently submitted financial statements.</li> <li>b. If the applicant was formed within the year preceding this application, provides certified financial statements for the period of time the applicant has been in existence and any pro forma financials used for business planning purposes.</li> </ol> </li> </ol>	1	2	3	4	5	
<i>Comments:</i>						
<p>J. Disclosure of Litigation: The applicant discloses any pending or threatened litigation, administrative, or regulatory proceedings or similar matters which could affect the ability of the applicant to perform the required services.</p> <ol style="list-style-type: none"> <li>1. Failure to disclose such matters at the time of application may result in rejection of the application or in termination of any subsequent contract. This is a continuing disclosure requirement. Any such matter commencing after submission of an application must be disclosed within 30 days in a written statement to the Department.</li> </ol>	1	2	3	4	5	
<i>Comments:</i>						
<p>K. Disclosure of Contract Default: Indicates whether the applicant or subcontractor has ever defaulted on a contract, includes:</p> <ol style="list-style-type: none"> <li>1. Name of Contract or subcontract</li> <li>2. Contact person's telephone number and email address</li> <li>3. A brief description of the incident</li> </ol>	1	2	3	4	5	

<i>Comments:</i>						
L. Disclosure of Terminated Contract: Indicates whether the applicant or subcontractor has ever terminated a contract, includes: 1. Name of Contract or subcontract 2. Contact person's telephone number and email address 3. A brief description of the incident	1	2	3	4	5	
<i>Comments:</i>						
M. Disclosure of Financial Accountability: The applicant discloses each irregularity (as applicable) of accounts maintained by the applicant discovered by the applicant's accounting firm, the applicant, or any other third party. Failure to disclose such matters, including the circumstances and disposition of the irregularities at the time of application may result in rejection of the application or in termination of any subsequent contract. This is a continuing disclosure requirement. Any matter commencing after submission of an application must be disclosed within 30 days in a written statement to the Department.	1	2	3	4	5	
<i>Comments:</i>						
N. Disclosure of Financial Accountability Contact Information: The applicant provides the name and contact information for the person the Department can contact regarding financial irregularities.	N/A - This information will not contribute to the application score					
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 10</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>50</b>					

## Manufacturing Facility

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
A. Location: The applicant specifies the physical location of the proposed Manufacturing facility. This must include city and county and, if known, the specific street address.	1	2	3	4	5
<i>Comments:</i>					
B. Location Authorization: The applicant provides 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.	1	2	3	4	5
<i>Comments:</i>					
C. Location Support/Dissent: The applicant provides documentation of any support or dissent by a local government authority for the proposed Manufacturing facility location.	1	2	3	4	5
<i>Comments:</i>					
D. Hiring/Background Checks: The applicant describes how the Manufacturer will vet potential employees and inform the Department of potential new hires to initiate required background investigation and national criminal history background checks.	1	2	3	4	5
<i>Comments:</i>					
E. Ownership: The applicant provides documentation that the proposed Manufacturing facility location is owned by the applicant. If not owned by the applicant, provides 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.	1	2	3	4	5
<i>Comments:</i>					
F. Displayed Graphics: The applicant describes signage, lettering, text and graphic materials that will be shown on the exterior of the Manufacturing facility.	1	2	3	4	5
<i>Comments:</i>					
G. Site Plan: The applicant provides a site plan, drawn to scale, of the proposed Manufacturing facility showing perimeter fencing as well as all streets, property	1	2	3	4	5

lines, buildings, parking areas, and outdoor areas, if applicable, that are within a 500-foot radius of the Manufacturing facility.						
<i>Comments:</i>						
H. Site Blueprint: The applicant provides 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 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. 3. The square footage and location of areas to be used as storerooms or stockrooms, if not included above. 4. The location of all break rooms and employee lockers or storage areas for personal belongings. 5. The locations of any business operations on the property that will not be related to the dispensing of medical cannabidiol. 6. All points of entrance and exit at the dispensing facility.		1	2	3	4	5
<i>Comments:</i>						
I. All points of entrance and exit at the manufacturing facility.		1	2	3	4	5
<i>Comments:</i>						
J. Construction Plan: The applicant provides a site development and construction (or conversion) plan identifying the construction start date, duration, and completion date.		1	2	3	4	5
<i>Comments:</i>						
K. Describe any air treatment system or other means to reduce odors released from the facility.		1	2	3	4	5
<i>Comments:</i>						
L. Explain previous experience with developing secure and/or regulated manufacturing facilities.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
		<i>Multiple by Weight of 15</i>				

<b>Recommended Section Score</b>	
<b>Maximum Potential Score</b>	<b>75</b>

## Security Requirements

Items to be Assessed	Individual Criteria Scoring					
	1	2	3	4	5	
A. Provide a plan to meet the restricted access requirements of 641 IAC 154.18(1) to 154.18(2).		1	2	3	4	5
<i>Comments:</i>						
B. Provide a plan to meet the perimeter intrusion detection system requirement of 641 IAC 154.18(3), including a floor plan noting the location of all cameras. Describe 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.		1	2	3	4	5
<i>Comments:</i>						
C. Provide a plan to meet the security alarm system requirements of 641 IAC 154.18(4).		1	2	3	4	5
<i>Comments:</i>						
D. Provide a plan to meet the personnel identification system requirements of 641 IAC 154.18(5).		1	2	3	4	5
<i>Comments:</i>						
E. Security Contractors: The applicant provides the names and addresses of any contractors hired or planned to provide security.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section!						
	<i>Multiple by Weight 10</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>50</b>					

## Personnel Background and Training

Items to be Assessed	Individual Criteria Scoring					
	1	2	3	4	5	
A. Staffing: 1. Provides a proposed staffing chart when the licensed Manufacturing is at full capacity.		1	2	3	4	5
<i>Comments:</i>						
2. Provides position descriptions that include descriptions of required qualifications and technical expertise for each position. Describes how the business will recruit qualified employees.		1	2	3	4	5
<i>Comments:</i>						
3. Describe the desired qualifications of and the number of employees to be involved in extraction, refinement, and production of medical cannabidiol.		1	2	3	4	5
<i>Comments:</i>						
B. Resumes: Provide the resume and experience of any staff that have been hired/retained to fill positions on the proposed staffing chart. Indicate the position each staff member will fill.		1	2	3	4	5
<i>Comments:</i>						
C. Consultants: Provide a list of consultants that will be used for education and training of employees, if applicable.		1	2	3	4	5
<i>Comments:</i>						
D. Employee Security and Safety Training: Describe how the business will train employees on security and safety.		1	2	3	4	5
<i>Comments:</i>						
E. Employee Policy and Regulation Training: Describe how the business will train employees on company policies, administrative rules, and applicable laws.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						

Average Score for Section	
	<i>Multiple by Weight of 10</i>
<b>Recommended Section Score</b>	
<b>Maximum Potential Score</b>	<b>50</b>

## Cultivation

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
<p>A. Applicant Experience</p> <p>1. Describe the applicant's experience designing, building and operating controlled growth environments. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.</p>					
<i>Comments:</i>					
<p>2. Describe the applicant's experience growing cannabis or other agricultural/horticultural crops.</p>					
<i>Comments:</i>					
<p>B. Cultivation Plan - Facility Diagram</p> <p>1. Provide a labeled diagram of all areas of the proposed facility where cultivation activities will take place, including:</p> <ul style="list-style-type: none"> <li>i. Articles of association</li> <li>ii. Propagation</li> <li>iii. Transplanting</li> <li>iv. Vegetative Plant Growth</li> <li>v. Flowering Plant Growth</li> <li>vi. Post-harvest processing and storage</li> <li>vii. Waste/Compost processing and storage</li> <li>viii. Water/Irrigation layout</li> <li>ix. Fertilizer and other crop input mixing areas</li> </ul>					
<i>Comments:</i>					
<p>C. Cultivation Plan - Operations and Management</p> <p>1. Controlled Environments: Describe the controlled growth</p>					

environments, systems, and automation that will be used to cultivate <i>Cannabis</i> from seed or cutting to harvest.						
<i>Comments:</i>						
2. Crop Inputs:		1	2	3	4	5
i. Indicate the growing media that will be used to grow plants from cutting to harvest.						
<i>Comments:</i>						
ii. Indicate what crop inputs will likely be used from propagation to harvest of <i>Cannabis</i> plants, and describe 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. Note that the Iowa Department of Agriculture and Land Stewardship (IDALS) has not approved any pesticides for use on <i>Cannabis</i> . 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.		1	2	3	4	5
<i>Comments:</i>						
iii. 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.		1	2	3	4	5
<i>Comments:</i>						
iv. Describe biosecurity measures to minimize contamination consistent with 641 IAC 154.25(1).		1	2	3	4	5
<i>Comments:</i>						
v. Describe the protocol to be used if a fungal or pest outbreak were to occur to both address the issue and resume/restart cultivation.		1	2	3	4	5
<i>Comments:</i>						

3. Harvest: Describe the harvest and post-harvest procedures that will be used to prepare plant material for extraction.		1	2	3	4	5
<i>Comments:</i>						
D. Waste 1. Describe the processes for disposing of any medical cannabidiol waste generated during the cultivation and harvest of cannabis plants at the manufacturing facility in accordance with 154.23(2).		1	2	3	4	5
<i>Comments:</i>						
2. Describe the processes for disposing of any hazardous waste generated during the cultivation of cannabis plants at the manufacturing facility in accordance with 641 IAC 154.23(4). Include the disposal procedure of any mercury, heavy metal, or halogen-containing lights, if applicable.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 15</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>75</b>					

## Extraction

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
<p>A. Applicant Experience</p> <p>1. Describe the applicant's experience related to cannabis extraction. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.</p>	1	2	3	4	5
<i>Comments:</i>					
<p>B. Extraction Plan: Facility Diagram</p> <p>1. Provide a labeled diagram of the areas of the proposed facility where all cannabis extraction activities will take place, including:</p> <ul style="list-style-type: none"> <li>i. The location of extraction and refinement equipment.</li> <li>ii. Storage areas of all cannabis and cannabis extracts.</li> </ul>	1	2	3	4	5
<i>Comments:</i>					
<p>C. Extraction Plan: Operations and Management</p> <p>1. Extraction Methods: Describe the method(s) that will be employed to extract the active ingredients from the <i>Cannabis</i> plant to produce cannabis extracts and concentrates. Include a description of the equipment that will be used in extraction and refinement.</p>	1	2	3	4	5
<i>Comments:</i>					
<p>2. Solvents: Indicate any solvents that will be used in the extraction and refinement of cannabis.</p> <ul style="list-style-type: none"> <li>i. Describe the process for disclosing solvents to the Department pursuant to IAC 641:154.24(4)c.</li> </ul> <p>3. Describe the processes used to ensure the safe removal of any processing solvents from cannabis extracts, if applicable.</p>	1	2	3	4	5
<i>Comments:</i>					
<p>4. Describe how cannabis extracts will be stored.</p>	1	2	3	4	5
<i>Comments:</i>					
<p>D. Waste:</p> <p>1. Describe the processes for disposing of medical cannabidiol waste</p>	1	2	3	4	5

and plant material waste generated during cannabis extraction and refinement in accordance with 154.23(2).						
<i>Comments:</i>						
2. Indicate any hazardous material waste that will be generated during the extraction and refinement of cannabis, and describe the processes for disposing of the waste in accordance with 641 IAC 154.23(4).		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 15</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>75</b>					

### Medical Cannabidiol Product Formulation & Manufacturing

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
A. Applicant Experience					
a. Describe the applicant's experience related to formulating medical cannabidiol products from cannabis extracts. Include the experience of any person employed by or consulting with the applicant, including the person's name and position/work description.	1	2	3	4	5
<i>Comments:</i>					
B. Product Formulation and Packaging Facility Diagram					
a. Provide a labeled diagram of all areas of the proposed facility where all medical cannabidiol products will be formulated from cannabis extracts, including:	1	2	3	4	5
i. The location of equipment used to formulate medical cannabidiol products.					
ii. Secure storage areas of all in-process medical cannabidiol and finished medical cannabidiol products.					
iii. Storage areas of any product ingredients.					
<i>Comments:</i>					

C. Proposed Products Plan a. Describe the medical cannabidiol products that will be produced at the licensed manufacturing facility. Product forms are limited to those indicated in 641 IAC 154.14 as amended by ARC5082c.		1	2	3	4	5
<i>Comments:</i>						
D. Product Formulation & Manufacturing Plan a. Describe all additives, excipients, flavorings, or other products that will be used in producing medical cannabidiol.		1	2	3	4	5
<i>Comments:</i>						
b. Describe procedures for ensuring that the cannabinoid content of manufactured medical cannabidiol products will be homogenous.		1	2	3	4	5
<i>Comments:</i>						
c. Describe how all general sanitation requirements in 641 IAC 154.25(4) will be met.		1	2	3	4	5
<i>Comments:</i>						
E. Product Packaging and Labeling Plan a. Describe procedures for packaging and labeling final medical cannabidiol products in compliance with 641 IAC 154.21.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
		<i>Multiple by Weight of 20</i>				
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>		<b>100</b>				

### Quality Assurance and Control

Items to be Assessed	Individual Criteria Scoring					
	1	2	3	4	5	
A. Describe the elements of the quality control program, consistent with 641 IAC 154.26, 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		1	2	3	4	5

laboratory testing and stability testing, including the person's name and position.					
<i>Comments:</i>					
B. Describe any onsite testing equipment that will be used to perform internal QA prior to transferring samples of concentrate (pesticides, metals, solvents) or finished products (microbiological impurities, potency) to a laboratory.	1	2	3	4	5
<i>Comments:</i>					
C. Sampling: Describe medical cannabidiol sampling procedures consistent with 641 IAC 154.26(2), including: <ol style="list-style-type: none"> <li>1. Sampling protocols;</li> <li>2. Documentation;</li> <li>3. Labeling; and</li> <li>4. Retention of results.</li> </ol>	1	2	3	4	5
<i>Comments:</i>					
D. Describe the testing procedures consistent with 641 IAC 154.26(3) and 154.72, 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.	1	2	3	4	5
<i>Comments:</i>					
E. Describe how the stability testing procedures detailed in 641 IAC 154.26(4) will be met. Include a description of: <ol style="list-style-type: none"> <li>1. Procedures for stability testing of each product type and determination of storage conditions;</li> <li>2. Plans to involve dispensaries in shelf-life and product expiration date studies;</li> <li>3. Intervals for testing; and</li> <li>4. Timeline for the development of the stability testing program.</li> </ol>	1	2	3	4	5
<i>Comments:</i>					
F. Describe the procedures for reserving samples from each lot consistent with 641 IAC 154.26(5).	1	2	3	4	5
<i>Comments:</i>					
G. Describe the procedures for disposal of substandard medical cannabidiol products consistent with 641 IAC 154.26(7).	1	2	3	4	5
<i>Comments:</i>					
H. Describe the process to collect, review, analyze and determine actions needed	1	2	3	4	5

when information on adverse events from patients using the medical cannabidiol is discovered.						
<i>Comments:</i>						
I. Iowa Code Chapter 124E does not allow manufacturers to have access to patient and primary caregiver information. Given this limitation, describe recall and market withdrawal procedures consistent with 641 IAC 154.26(8). Include a description of: <ol style="list-style-type: none"> <li>1. The factors that would make a recall or market withdrawal necessary;</li> <li>2. The personnel who would be responsible for overseeing the recall or market withdrawal; and</li> <li>3. How the manufacturer will work with the Department to notify affected parties, including a projected timeline for the process.</li> </ol>						
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section	<i>Multiple by Weight of 20</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>100</b>					

### Packaging and Labeling

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
A. Describe planned medical cannabidiol packaging consistent with 641 IAC 154.21(1).	1	2	3	4	5
<i>Comments:</i>					
B. Describe the intended medical cannabidiol trade names consistent with 641 IAC 154.21(2).	1	2	3	4	5
<i>Comments:</i>					
C. Describe medical cannabidiol package labeling consistent with 641 IAC 154.21(3), 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 universal symbol for THC.	1	2	3	4	5
<i>Comments:</i>					

Total Individual Criteria Scores					
Average Score for Section					
	<i>Multiple by Weight of 5</i>				
<b>Recommended Section Score</b>					
<b>Maximum Potential Score</b>	<b>25</b>				

## Transportation

Items to be Assessed	Individual Criteria Scoring					
A. Describe any experience in transporting products of high value with potential risk for diversion.		1	2	3	4	5
<i>Comments:</i>						
B. Describe how medical cannabidiol will be transported to and from dispensaries and the laboratory consistent with 641 IAC 154.22 and 154.71(2). Include the following in the narrative: <ul style="list-style-type: none"> <li>1. The frequency of medical cannabidiol transport to each location;</li> <li>2. The frequency of collection of waste medical cannabidiol from dispensaries and the laboratory consistent with 641 IAC 154.23(1);</li> </ul>		1	2	3	4	5
<i>Comments:</i>						
3. Proposed methods for minimizing the risk of diversion or theft of medical cannabidiol during transport; and. 4. Describe the vehicle that will be used for the transportation of medical cannabidiol.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 5</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>25</b>					

## Disposal

Individual Criteria Scoring
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Items to be Assessed	1	2	3	4	5
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).	1	2	3	4	5
<i>Comments:</i>					
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).	1	2	3	4	5
<i>Comments:</i>					
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.	1	2	3	4	5
<i>Comments:</i>					
Total Individual Criteria Scores					
Average Score for Section	<i>Multiple by Weight of 5</i>				
<b>Recommended Section Score</b>					
<b>Maximum Potential Score</b>	<b>25</b>				

## Record-keeping Requirements

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
Manufacturing licensees are required to input inventory and sales data into the Department's Secure Sales and Inventory Tracking System via an Application Programming Interface (API). The details for integrating with the Department's system are referenced in the IDPH Integration MFG API guide V.6.0 and State API Validation Process v.1.0, which are included as an attachments in Section 5 - Attachments. The applicant must complete multiple sections and include the following:					
A. Manufacturing Software Section: Indicate the software that will be used to manage manufacturing inventory for cultivation, extraction, product formulation, finished products, testing, and transfers to and from a laboratory and dispensaries. Describe the applicant's experience using the software in a regulated cannabis program.	1	2	3	4	5

<i>Comments:</i>						
B. Technical Specification Section: The applicant describes the technical specifications around the POS software's API capabilities and technology stack.	1	2	3	4	5	
<i>Comments:</i>						
C. Integration Section: Describe the plans for integrating the manufacturing software with the Department's Secure Sales and Inventory Tracking System, including: required customization, testing, ongoing technical support, and Service Level Agreements (SLAs). Describe the plans for validating that the selected manufacturing software passes all of the required test cases as outlined in the State API Validation Process v.1.0 document, which is provided in Section 5 - Attachments.	1	2	3	4	5	
<i>Comments:</i>						
D. Record-Keeping Requirements Section: In the narrative field, describe how the record-keeping requirements in administrative rule 154.24 will be met, including how and where each type of record will be stored.	1	2	3	4	5	
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 20</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>100</b>					

## Supply and Inventory

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
A. Describe the procedures for ensuring a reliable and ongoing supply of medical cannabidiol to the dispensaries consistent with 641 IAC 154.27.	1	2	3	4	5
<i>Comments:</i>					
B. Describe the Inventory controls and procedures that will be used to prevent and detect diversion, theft, or loss in a timely manner consistent with 641 IAC 154.27(2), include:	1	2	3	4	5

a. The process for any employee to report the suspected or confirmed diversion of <i>Cannabis</i> plants, medical cannabidiol or medical cannabidiol waste;						
b. Record-keeping systems for maintaining a real-time record of the inventory of plant material and medical cannabidiol;						
c. The personnel roles/duties used to maintain inventory control; and						
d. The scope and schedule for periodic physical inventory count.						
<i>Comments:</i>						
C. Describe the procedures for inventory of medical cannabidiol waste and plant material waste consistent with 641 IAC 154.27(4), including the personnel, record-keeping, and schedule of the physical inventory counts.		1	2	3	4	5
<i>Comments:</i>						
D. Describe procedures for inventory reconciliation consistent with 641 IAC 154.27(5), including the personnel involved and the schedule for the inventory reconciliation.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
		<i>Multiple by Weight of 15</i>				
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>						<b>75</b>

## Business Overview and Plan

Items to be Assessed	Individual Criteria Scoring				
	1	2	3	4	5
A. Provide an analysis of the strengths, weaknesses, opportunities, and threats associated with the proposed business and explain how the applicant intends for the business to become successful.	1	2	3	4	5
<i>Comments:</i>					
B. Has a market analysis been completed for the business? If yes, provide.	1	2	3	4	5
<i>Comments:</i>					

C. Describe the steps and anticipated timeframes for becoming operational as a manufacturer and having medical cannabidiol available at dispensaries by July 1, 2021, including but not limited to: onset of cultivation, date of first harvest, onset of extraction and product formulation, delivery of samples to a laboratory, delivery of final products to dispensaries.		1	2	3	4	5
<i>Comments:</i>						
D. Describe the proposed production capacity by July 1, 2021, and in the second and third year of operation. Include a description of the ability to expand capacity to meet future demand. Production capacity includes cultivation, extraction, and final product production.		1	2	3	4	5
<i>Comments:</i>						
E. Outline the anticipated product release dates of the proposed products indicated in #7, Medical Cannabidiol Product Formulation & Manufacturing.		1	2	3	4	5
<i>Comments:</i>						
F. Describe how the business will set pricing, initially and thereafter, based on supply and demand.		1	2	3	4	5
<i>Comments:</i>						
G. Describe the estimated monthly revenues and expenses for the business in the first 2 years of operation, including factoring in testing costs as provided in Section 5 - Attachments. What are the estimates based on?		1	2	3	4	5
<i>Comments:</i>						
H. Describe the financial plan for the business. Specifically address financing if FDIC banks and NCUA insured credit unions do not provide loans or financing to the legal cannabis industry and how you will complete financial transactions.		1	2	3	4	5
<i>Comments:</i>						
I. 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.		1	2	3	4	5
<i>Comments:</i>						
J. Describe how the business will contribute to maintaining competitiveness in Iowa's medical cannabidiol program.		1	2	3	4	5
<i>Comments:</i>						

K. Describe how the dispensary business will contribute to social equity within Iowa's medical cannabidiol program.		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 30</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>150</b>					

### Advertising and Marketing

Items to be Assessed	Individual Criteria Scoring					
	1	2	3	4	5	
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.		1	2	3	4	5
<i>Comments:</i>						
B. Describe other marketing and advertising activities consistent with 641 IAC 154.20(2) intended to be conducted in the first year.		1	2	3	4	5
<i>Comments:</i>						
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).		1	2	3	4	5
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight 5</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>25</b>					

## Operating Documents

Items to be Assessed:	Individual Criteria Scoring				
	1	2	3	4	5
Attach a copy of each of the following operating documents, consistent with 641 IAC 154.17(1). Applicants must include 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;	1	2	3	4	5
<i>Comments:</i>					
B. The methods of planting, harvesting, drying, and storing <i>cannabis</i> ;	1	2	3	4	5
<i>Comments:</i>					
C. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;	1	2	3	4	5
<i>Comments:</i>					
D. The disposal methods for all waste materials;	1	2	3	4	5
<i>Comments:</i>					
E. Employee training methods for the specific phases of production and who (or what position) will be responsible for oversight of the training;	1	2	3	4	5
<i>Comments:</i>					
F. Biosecurity measures used in the production and manufacturing of medical cannabidiol;	1	2	3	4	5
<i>Comments:</i>					
G. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;	1	2	3	4	5
<i>Comments:</i>					
H. Sampling strategy and quality testing for labeling purposes and product expiration	1	2	3	4	5

date determination;						
<i>Comments:</i>						
I. Medical cannabidiol packaging and labeling procedures;						
<i>Comments:</i>						
J. Procedures for mandatory (i.e., recall) and voluntary (i.e., market withdrawal) of medical cannabidiol;						
<i>Comments:</i>						
K. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;						
<i>Comments:</i>						
L. A business continuity plan;						
<i>Comments:</i>						
M. Records relating to all transport activities;						
<i>Comments:</i>						
N. Handling, storage, application, and disposal of pesticides, fertilizers, and other crop inputs;						
<i>Comments:</i>						
O. Oversight of all personnel and phases of manufacturing and production of cannabidiol (including a table of organization);						

<i>Comments:</i>						
P. Procedures to ensure accurate recordkeeping; and						
<i>Comments:</i>						
Q. 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.						
<i>Comments:</i>						
Total Individual Criteria Scores						
Average Score for Section						
	<i>Multiple by Weight of 30</i>					
<b>Recommended Section Score</b>						
<b>Maximum Potential Score</b>	<b>150</b>					

Applicant: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_

### Reviewer Suggested Scoring Summary

<b>Narrative Sections</b>	<b>Reviewer Suggested Score</b>	<b>Total Possible</b>
1. Business Organization, Ownership, and Financial Structure		50
2. Manufacturing Facility		75
3. Security Requirements		50
4. Personnel Background and Training		50
5. Cultivation		75
6. Extraction		75
7. Medical Cannabidiol Product Formulation and Manufacturing		100
8. Quality Assurance and Control		100
9. Packaging and Labeling		75
10. Transportation		25
11. Disposal		25
12. Record-keeping Requirements		100
13. Supply and Inventory		25
14. Business Overview and Plan		125
15. Advertising and Marketing		25
16. Operating Documents		75
<b>Reviewer's Suggested Total Score</b>		<b>1,000</b>

