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

Gerd W. Clabaugh, MPA
Director

Kim Reynolds
Governor

Adam Gregg
Lt. Governor

Iowa Department of Public Health
Office of Medical Cannabidiol
REQUEST FOR PROPOSAL # 58818014
To License Medical Cannabidiol Manufacturers

Written Questions and Response Document

Round 1: Written Questions and Responses for the time period of 10/5/17-10/12/17
Posted: 10/19/17

Q1. If there are other owners or partners added to my business after the formal application is submitted and I am selected as one of the two manufacturers, will there be an opportunity to amend the license and add them to it?

A1. Yes, owners or partners may be added to a license or application for a license at any time after a license has been issued. Please notify the department and follow the department's instructions for submission of $10,000/ additional owner to the Iowa Department of Public Safety for a background investigation and national criminal history background check. The new owner or partner must satisfactorily pass these background checks to be added to a license.

Q2. We have the following question related to: **6) The locations of any business operations on the property that will not be related to the production and distribution of medical cannabidiol.** What is the proper zoning for dispensing? Searched Iowa code 124E but haven't seen that it exists.

A2. The department presumes commercial zoning is required for dispensing businesses. Applicants should check with local zoning authorities where a proposed dispensary might be located for a definitive response to this question.

Q3. Section 1.03 (page 2) – In order to determine the payments that must be submitted for the background checks and national criminal history checks, what is the definition of an owner of an applicant manufacturer? Will the $10,000 deposit be required for any owner, regardless of the share his or her equity comprises of the total ownership?

A3. For the purposes of the RFP, an owner is any person who owns any share of the manufacturing business.

Q4. Section 1.03 (page 2) – Will the results of the background investigation be shared with the applicant?

A4. No.

Q5. Section 1.03 (page 2) – In the event owners have already submitted background checks, fingerprints, etc. to national registries, will the owners still be required to obtain new background checks and submit new fingerprints?

A5. Yes.

Q6. Section 1.05, Part B. (page 3) – In the event there are additional owners added to the business after the delivery of the Intent to Apply Letter but before submission of the applicant's proposal, will the Department require the Intent to Apply Letter to be amended? If so, in what form should such an amendment be submitted?

A6. At the time of submission of the application, please follow the instructions in Section 1.05 E and any supplemental instructions from the department for background investigations of each business owner as defined in A3. You do not need to amend your letter of intent.

Q7. Section 3.01, Part A. (page 14) – The page length requirement refers the applicant to Section 3.03. However, the RFP does not contain a Section 3.03. What is the content of Section 3.03?

A7. See Amendment 2 striking Section 3.03 and referring instead to Section 3.02C.

Q8. Section 3.01, part A. (page 14) – Forms provided by the Department have been provided in font Arial and with different spacing requirements than the rest of the application. This section specifically exempts the Department's forms from the spacing requirements, but does not specify whether the Department's forms should be converted to 12-point font Times New Roman. Should applicants submit the Department's forms in their original format, or should each Department form be converted to 12-point font Times New Roman?

A8. See 1.05 (E) - "Required materials, the originals 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 font." You may use the original format of the forms.

Q9. Section 3.01, part A. (page 14) – With respect to the header or footer and pagination, should an applicant insert the header or footer and the page number on the forms provided by the Department? For those forms provided by the Department for which a signature is required, how should the applicant insert a header or footer and properly paginate those documents, especially considering that some pages may be executed before or after final pagination is established?

A9. The forms provided by the Department can be submitted without additional headers, footers or pagination.

Q10. Section 3.02, Part C., Narrative Section 1, part b., point (3) (page 17) – An applicant is required to provide a summary of its business continuity plan. Typically, that type of plan would involve a second physical location in the event something happened at the first physical location. Is the Department contemplating allowing a second physical location for an applicant, even if this location is only to be used in the event of a loss of power or other natural or man-made event that precludes manufacturing at the site for

a period of time? Or instead, should this plan assume that a licensed manufacturer will still be limited to one physical location?

A10. The applicant should assume that a licensed manufacturer is limited to one physical location.

Q11. Section 3.02, Part C., Narrative Section 1, part b., point (4) (page 17) – This section asks applicants to "describe the forms and quantity of medical cannabidiol (i.e., products) that will be manufactured during the first year of operation (i.e., available December 1, 2018), and any forms and quantities of products that are likely to be developed in the second and third year of operation." Proposed administrative subrule 154.15, however, states that "form and quantity" means "the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine." In addition, proposed administrative subrule 154.17(2) provides that a manufacturer shall not, among other things, "sell medical cannabidiol in any form or quantity other than those approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine." Will the Department provide the permitted forms and quantities before October 30, 2017, when the application is due? In the event that the permitted forms and quantities are not available, will an applicant be able to amend its application once available to describe how it plans to manufacture the forms and quantities that are permitted? Will a manufacturer be disqualified or lose points for answering the question with forms or quantities that are not eventually approved?

A11. It is not anticipated that the permitted forms of medical cannabidiol will be made available before the applications are due. Applicants should propose the forms and quantities that they deem appropriate given the debilitating medical conditions that have been approved in HF 524 and the production methods that they are proposing to use. Applicants will not be penalized if a form or quantity that they included is not recommended by the Medical Cannabidiol Board and adopted by the Board of Medicine, provided that the applicant's proposed form(s) and quantity(ies) is/are reasonable given the approved debilitating conditions.

Q12. Section 3.02, Part C., Narrative Section 3 (page 19) – Will the information provided for the Security Requirements be kept confidential automatically, given its sensitive nature, or must an applicant specifically mark it confidential as provided for in Section 1.24 (page 9) of the RFP?

A12. As stated in Section 1.24, 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. Please refer to Section 1.24 for full instructions.

Q13. Section 3.02, Part C., Narrative Section 3, part a. (page 19) – An applicant must provide a plan to meet the restricted access requirements in proposed administrative subrule 154.18(2). With respect to logs of visitors to the restricted access areas, does the Department contemplate that each visitor should have a unique visitor badge? Is it expected that an applicant will be required to sign each visitor in and out of each restricted access area each time?

A13. As described in proposed administrative subrule 154.18(1), the only requirements are that visitors sign manifests, wear badges that are visible at all times, and identify them as visitors. Each visitor should have a badge. Visitors should be treated similarly to personnel in proposed administrative subparagraph 154.18(2)“a”(4). Written manifests should be used to track movement of visitors in and out of each restricted area every time a visitor enters or leaves a restricted area.

Q14. Section 3.02, Part C., Narrative Section 3, part b. (page 19) – An applicant must provide a plan to meet the security alarm system requirements of proposed administrative subrule 154.18(3)a. For purposes of this proposed administrative subrule, is a network camera considered closed-circuit TV?

A14. A closed-circuit TV system is required, but applicants may also go beyond this with other systems like a network IP camera system. A network camera is not considered to be closed-circuit TV.

Q15. Section 3.02, Part C., Narrative Section 3, part d. (page 19) – An applicant must provide a plan to meet the personnel identification system requires in proposed administrative subrule 154.18(5). With respect to this rule, does the Department have a requirement for how long an identification card should be valid before it would expire and need to be reissued?

A15. No, there is no requirement for how long an identification card should be valid before it expires.

Q16. Section 3.02, Part C., Narrative Section 5, part c. (page 19) – This section requires an applicant to explain how it will comply with proposed administrative subrule 154.21(3). Proposed administrative subrule 154.21(3)a.(9) states that the Department will provide a universal warning symbol. Will this universal warning symbol be made available to applicants before the application is due October 30, 2017? If not, how should an applicant address this section in its response to the RPF with respect to this subpart of the proposed administrative subrule?

A16. The symbol will not be made available before October 30, 2017, but applicants should reserve a space no smaller than 0.75 inches wide by 0.5 inches high on a label for the warning symbol.

Q17. Section 3.02, Part C., Narrative Section 7 (page 20) – In this narrative (and in other places throughout the RFP), an applicant must describe how it will dispose of medical cannabidiol and plant material. Will a waste facility be licensed or otherwise approved by the Department for disposing of medical cannabidiol in a manner which renders it unusable, pursuant to proposed administrative subrule 154.23(2)? Will a waste facility be licensed or otherwise approved by the Department for disposing of plant material by composting, pursuant to proposed administrative subrule 154.23(2)? Or, instead, will the manufacturer be responsible for rending medical cannabidiol unusable and composting plant material before transporting it to a waste facility? Additionally, will the manufacturer be required to submit proof that the biomass has been deactivated before it can be sent to a waste facility? What type of testing is the Department contemplating? Will there be a detection limit set by the Department before the release of the waste material? Does the waste material need to be sent to the approved laboratory to prove that it is deactivated? Could a manufacturer use bleach or another similar product to deactivate this material? If so, would the Department contemplate a change to the proposed rules?

A17. The applicant should describe the selected waste disposal site or sites in the application, but the Department will not be licensing any specific sites. The manufacturer will be responsible for disposing

of medical cannabidiol and for composting plant material waste. No proof of biomass deactivation or testing is required, but the Department may inspect the process used to render plant material unusable and unrecognizable. As described in proposed administrative subrule 154.23(2), bleach is not an acceptable method of rendering the plant material unusable.

Q18. Section 3.02, Part C., Narrative Section 7, part b. (page 20) – Concentrated product, out-of-specification product, and other final forms may not be suitable for composting. Does the Department have any requirements for what a manufacturer must do before disposing of medical cannabidiol waste at a waste facility, pursuant to proposed administrative subrule 154.23(2)? Is the manufacturer or the waste facility responsible for rending the medical cannabidiol waste unusable?

A18. Per proposed administrative subrule 154.23(2), paragraph a, the manufacturer must dispose of medical cannabidiol waste at a waste facility according to federal and state law, and in a manner that renders it unusable. The manufacturer is responsible for rendering the medical cannabidiol waste unusable.

Q19. Section 3.02, Part C., Narrative Section 8, part b. (page 20) – Does the Department have an update on the status of its secure sales and inventory tracking system? Before investing capital into a system, it would be useful to know how long a manufacturer may need to provide its own secure sales and inventory tracking system.

A19. The Department anticipates using a competitive bid process to procure a secure sales and inventory tracking system with a goal of having a system procured by March 15, 2018, and intends to have the system available for use by manufacturers by June 1, 2018. Manufacturers are not required to procure electronic systems prior to that time, and may use written manifest systems to manage inventory from seed to distribution of medical cannabidiol until the secure sales and inventory tracking system becomes available.

Q20. Section 3.02, Part C., Narrative Section 10, part c. (page 22) – Will the State Hygienic Lab at the University of Iowa be up and running with validated methods such that an applicant can reliably count on it as the manufacturer's laboratory of choice? If so, when will the State Hygienic Lab have an offering for services provided, the cost for such services, and its anticipated turnaround time for its work? What is the contingency in the event that the State Hygienic Lab is not prepared to serve as the laboratory?

A20. Yes, the State Hygienic Laboratory at the University of Iowa will work with any licensed manufacturer to conduct testing. They anticipate being ready to test in early Spring 2018. The Department will define the minimum testing required in proposed laboratory testing administrative rules for potency, pesticides, microbiology, and metals. The proposed laboratory testing administrative rules are still in the process of being drafted. Other testing should also be available based on the needs of the manufacturer and Department. Test cost will be determined, in part, through partnership with the manufacturer. Turnaround times will be determined in partnership with the manufacturer.

Q21. Section 3.02, Part C., Narrative Section 10, part c. (page 22) – What other laboratories, if any, have been approved by the Department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol? If none, does the Department expect to approve any laboratories besides the State Hygienic Lab?

A21. The proposed administrative rule 154.15 includes the following definition of a laboratory: "*"Laboratory"* means the state hygienic laboratory at the university of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with 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, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol." A manufacturer proposing to use a laboratory other than the State Hygienic Laboratory at the University of Iowa should demonstrate in their application that the proposed laboratory meets the definition in the proposed administrative rules for accreditation, registration with the drug enforcement administration of the department of justice, and registration with the Iowa Board of Pharmacy.

Q22. Section 3.02, Part C., Narrative Section 10, part i. (page 23) – Will a manufacturer be provided patient information in order to a recall? Will the Department's secure sales and inventory tracking system connect the manufacturer to the dispensary's information, or will the dispensary or the Department provide the necessary patient information directly to the manufacturer?

A22. HF524 does not allow the Department to release the names of patients and caregivers to manufacturers in the event of a recall or market withdrawal. Applicants should describe procedures that involve working with the Department to notify affected parties of a recall or market withdrawal.

Q23. Section 3.02, Part C., Narrative Section 12, part e. (page 24) – This section notes that criminal history must be provided for "all individuals identified in items 2, 3, and 4 above". To what items do those numbers refer? For which individuals must this information be submitted?

A23. See Amendment #2. This information should be provided for individuals identified in b, c, and d of Narrative Section 12.

Q24. Section 3.02, Part C., Narrative Section 12, part e. (page 24) – To what extent does the Department contemplate an applicant will provide criminal history for certain individuals as required by the RFP? Is criminal history limited to convictions? Are minor issues, such as traffic tickets, expected to be included? Will the Department provide more clarity as to the criminal history that must be included, and for what period of time?

A24. Criminal history needs to include all criminal history information, including arrests, deferred judgments, deferred sentences, and convictions. All criminal history records need to be provided, including juvenile records. Minor traffic related offenses do not need to be included.

Q25. Section 4.01, part B. (page 27) – Who will be on the reviewing committee for Phase II of the Review Process?

A25. The Department is still working on finalizing the review team.

Q26. Will the Department require an applicant to disclose to employees or contractors that cannabis remains a federally illegal product?

A26. The Department does not require an applicant to disclose to employees or contractors that *Cannabis* remains a federally illegal product.