Minnesota Department of Health
Office of Medical Cannabis

Request for Application for the Registration of Medical Cannabis Manufacturers

Publication Date:
September 5, 2014

Request for Application Response Deadline:
October 3, 2014

Any questions regarding the contents of this document should be directed to:
health.cannabis.RFA@state.mn.us

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Minnesota Department of Health
Office of Medical Cannabis
Request for Application for the Registration of Medical Cannabis Manufacturers

The Minnesota Department of Health ("MDH" or "Department") is requesting applications from parties interested in receiving a Medical Cannabis Manufacturer Registration.

Overview

On May 29, 2014 the Department became responsible for administering Minnesota's Medical Cannabis program with the enactment of Chapter 311 of the 2014 Minnesota Session Laws. This program allows a qualifying patient or caregiver who is registered with MDH to purchase medical cannabis from a manufacturer's distribution site for the palliative treatment of a patient's debilitating medical condition.

In accordance with Chapter 311, the Department is issuing this Request for Application ("RFA") for purposes of registering up to two Medical Cannabis Manufacturers.

Number of Manufacturers

MDH anticipates awarding two Manufacturer Registrations, one serving the portion of the state encompassed by Congressional Districts 1, 3, 5 and 7 (Service Area A), and the other serving Congressional Districts 2, 4, 6 and 8 (Service Area B).

The Manufacturers will be registered on a competitive basis based on an evaluation of the timely submitted responses to this RFA.

This RFA does not obligate the Department to register a Medical Cannabis manufacturer. The Department reserves the right to award fewer than two registrations if the Department concludes that an insufficient number of qualified applicants submitted a response prior to the deadline. In such an event, the Department may re-issue the RFA to solicit additional applications until two Manufacturer Registrations are awarded.

RFA Intent to Apply & Submission Deadline

RFA Intent to Apply

In order to efficiently manage the evaluation process and for an application to be considered an **Intent to Apply letter must be submitted** via email to health.cannabis.RFA@state.mn.us with the subject line "Medical Cannabis RFA Intent to Apply – *Manufacturer Name*" **by Friday, September 19, 2014 at 3 pm Central Daylight Time**. The Intent to Apply letter should contain the following information:

- Manufacturer's Name
- Names of the owner(s) and managing director(s) for the organization

- A name, telephone number and email address for responding to any questions that arise during the evaluation process
- Whether the Manufacturer requests a presentation

If an Intent to Apply letter is not **received** by MDH by **September 19th** then the RFA Response will NOT be accepted and considered.

How to Apply

It is recommended all potential applicants become familiar with Chapter 311 of the 2014 Minnesota Session Laws and the draft administrative rules governing manufacturer operations for the medical cannabis registry program (Revisor No. R-4272) that MDH intends to propose in early October and adopt by December 1, 2015 (http://www.health.state.mn.us/topics/cannabis/mfrrules.html). Applicants should use the definitions sections of those documents to assist in interpreting this RFA.

Each applicant must prepare comprehensive documents that respond to each item requested in this RFA.

All attachments, exhibits or other information produced in response to the RFA must include a label referencing the item number and subpart of this RFA to which it responds so that it is clear to the Department that all requested information is provided.

All application materials need to 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.

A complete application package must include:

1. An original and twenty paper copies of the RFA response, all of which must be single-sided and securely bound
2. A DVD, CD or USB drive containing an electronic version of your complete submission in a searchable PDF file format
3. A twenty thousand dollar ($20,000) non-refundable application fee in the form of a check, made out to:

   Minnesota Department of Health – OMC

The submittal of an application constitutes acceptance of the requirements, administrative stipulations, and all of the terms and conditions of this RFA.

All costs and expenses incurred in submitting an application in response to this RFA will be borne by the responder.

Response Deadline & Submission

For an application to be considered, a complete response to this RFA and the non-refundable application fee must be hand-delivered to MDH's offices (see address below) **on or before 3:00 pm Central Daylight Time on Friday, October 3, 2014. Mail, fax, and email applications will not be considered**.

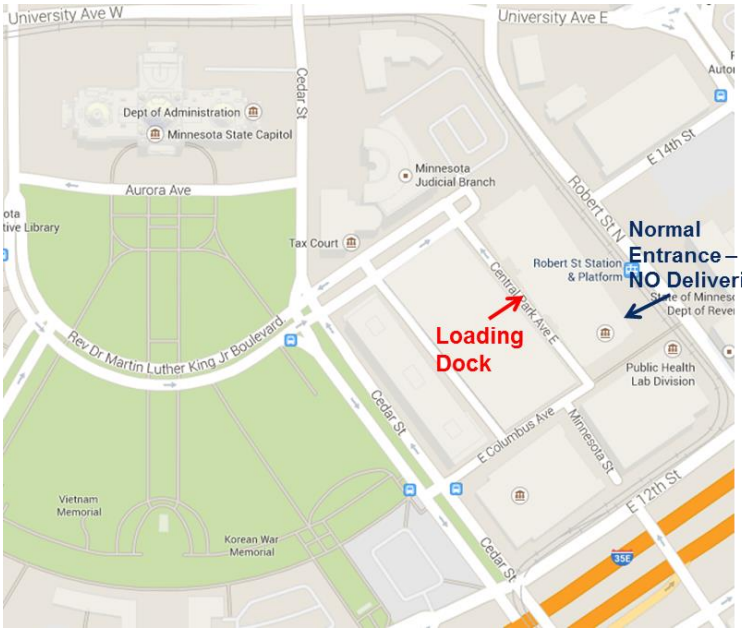
MDH will time-stamp each application upon its submission and the time-stamp shall serve as the official record of when the application was delivered to MDH. A MDH employee

will be available in between the hours of 10:00 am and 3:00 pm each business day beginning, **Monday, September 29, 2014 until Friday, October 3, 2014**. Applications will only be accepted during those hours.

All **RFA submissions to the Department must be given to a MDH employee and time-stamped at the time of delivery.** Application submissions should not be left unattended in the office or on a desk.

MDH RFA Delivery Address:
Attn: Jeff Smith – Loading Dock
Minnesota Department of Health
Office of Medical Cannabis
625 Robert Street North
St. Paul, MN 55155

Please Note: the Loading Dock for the O.L. Freeman building is located on the west side of the building which is accessible from Central Park Avenue East, St. Paul, MN (see map below).



It is the applicant's responsibility to allow sufficient time to address potential delays. **Sole responsibility rests with the applicant to ensure that their application is received and time-stamped on or before the submission deadline.**

Late applications will not be accepted.

Terms and Conditions

Applicants may submit a modification to their RFA response, with an accompanying explanatory cover letter, at any time prior to the submission deadline. MDH may disqualify any applicant who:

- Fails to submit a complete response or
- Fails to pay the application fee prior to the submission deadline or
- Submits incomplete, false, inaccurate, unresponsive or misleading information in response to this RFA

The decision of MDH to disqualify an applicant or not award a Manufacturer Registration is final.

An applicant awarded a Manufacturer Registration shall operate in accordance with the representations made in its RFA submissions, or as modified upon mutual agreement with MDH.

Communications with the Department

All questions about the RFA or RFA process must be forwarded to MDH only **by email** at health.cannabis.RFA@state.mn.us with the subject line "Medical Cannabis RFA Question." Questions and answers of a substantive nature will be posted on the MDH website http://www.health.state.mn.us/topics/cannabis/mfrqa.html so that all applicants will have access to the same information. Questions received by the Department before Tuesday, September 23, 2014 will be answered. For questions received after Tuesday, September 23, 2014, the Department may not be able to respond prior to the Submission Deadline. Applicants are therefore, encouraged to identify and raise any questions to the Department's attention as soon as possible.

To ensure the proper and fair evaluation of all applications, other communications regarding this RFA including verbal, telephone, written or internet initiated by or on behalf of any applicant to any employee of the Department, other than questions submitted to health.cannabis.RFA@state.mn.us, are prohibited. **Any violation of this prohibition may result in the disqualification of the applicant.**

Data Practices

All materials submitted in response to this RFA will become property of MDH.

Data submitted during the application process are private data on individuals or nonpublic data as in Minnesota Statutes section 13.02 until the manufacturer is registered. Therefore, the Department will not be able to identify any applicant until the registration process is complete. Data on a manufacturer that is registered are public data, unless the data are trade secret or security information under Minnesota Statues section 13.37.

If a registration is awarded to an applicant, MDH may use or disclose the trade secret data to the extent provided by law. Any decision by the State to disclose information determined to be trade secret information will be made consistent with the Minnesota Government Data Practices Act (Minnesota Statutes chapter 13) and other relevant laws and regulations

If the Applicant submits information in response to this RFA that it believes to be trade secret information as defined by Minnesota Statutes section 13.37, and the Applicant does not want such data used or disclosed for any purpose other than the evaluation of this Proposal, the Applicant must:

A. Clearly mark every page of trade secret materials in its Proposal at the time the Proposal is submitted with the words "TRADE SECRET INFORMATION" in capitalized, underlined and bolded type that is at least 20 pt.; the State does not assume liability for the use or disclosure of unmarked or unclearly marked trade secret information;

B. Fill out and submit the attached "Trade Secret Information Notification Form", specifying the pages of the Proposal which are to be restricted and justifying the trade secret designation for each item. If no material is being designated as trade secret information, a statement of "None" should be listed on the form; and

C. Satisfies the statutory burden to justify any claim of trade secret information.

MDH reserves the right to reject a claim that any particular information in a response is trade secret information if it determines Applicant has not met the burden of establishing that the information constitutes a trade secret. MDH will not consider prices or costs submitted by the Applicant to be trade secret information under any circumstance. Use of generic trade secret language encompassing substantial portions of the proposal or simple assertions of trade secret interest without substantive explanation of the basis therefore will not be sufficient to warrant a trade secret designation. If certain information is found to constitute trade secret exception and information, the remainder of the Proposal will become public; in the event a data request is received for Proposal information, only the trade secret data will be removed and remain nonpublic.

The applicant must defend any action seeking release of the materials it believes to be trade secret information, and indemnify and hold harmless the State, its agents and employees, from any judgments awarded against the State in favor of the party requesting the materials, and any and all costs connected with that defense. This indemnification survives the State's award of a registration.

In submitting a response to this RFA, the Applicant agrees that this indemnification survives as long as the trade secret information is in the possession of MDH.

MDH is required to keep all the basic documents related to its contracts, for the manufacturers that are successfully registered this includes their RFA response documentation, for a minimum of six years after the end of the registration. Non-selected manufacturer's RFA Proposals will be kept by MDH for a minimum of one year after the award of the two registrations.

Application Content

The Department expects each application to contain information for the following sections to allow a thorough understanding of the applicant's ability to meet the needs and expectations of patients, MDH and the residents of the State of Minnesota. In each of the sections below, individual pieces of information will be requested. Each item must be responded to, if you do not have the information requested you must state that the information is not available rather than not address the item.

MANDATORY FORMS

- Application Checklist
- Regulatory Agency Authorization Form
- Notice of Proper Manufacturing Facility Zoning Form
- Owner and Managing Director Certification Statement Form

SCORED ELEMENTS

A. Business Overview and Plan
B. Facilities
C. Operations
D. Ownership & Financial Structure
E. Bonus Points
F. Conclusion

Applicants should understand the contents of Chapter 311—S.F.No.2470 and strive to provide complete explanations of how their firm has the experience, ability and financial resources to create and run a medical cannabis business pursuant to what is outline in the law.

Applications that do not contain a response for each requested item will be disqualified and not scored.

APPLICATION CHECKLIST

Applicant Name: _____

Application Date: _____

Service Area(s): A (odd # districts): ☐ B (even # districts): ☐

	Statutory Requirement	Yes	No
1	I certify I have read the provisions of Minn. Stat. §§152.22 – 152.37 and my application complies with all the statutory requirements	☐	☐
2	My proposal entails a plan that would accomplish supplying medical cannabis to patients by July 1, 2015	☐	☐
3	My proposal entails a plan that would begin distribution at four (4) distribution facilities supplying medical cannabis to patients by July 1, 2016	☐	☐
4	I certify I will contract with a laboratory, subject to the commissioner's approval of the laboratory and any additional requirements set by the commissioner, for purposes of testing medical cannabis manufactured by the medical cannabis manufacturer as to content, contamination, and consistency to verify the medical cannabis meets the requirements of Minn. Stat. §§152.22, subdivision 6	☐	☐
5	I certify I will document and make available on request the following operating documents:		
	a. Procedures for the oversight of the manufacturer and procedures to ensure accurate recordkeeping	☐	☐
	b. Procedures for the implementation of appropriate security measure to deter and prevent the theft of medical cannabis and unauthorized entrance into areas containing medical cannabis	☐	☐
6	My proposal would implement security requirements, including requirements for protection of each location by a fully operational security alarm system, facility access controls, perimeter intrusion detection systems and a personnel identification system	☐	☐
7	I certify our manufacturing facility will not share office space with, refer patients to a health care practitioner, or have any financial relationship with a health care practitioner	☐	☐
8	I certify that we will not permit any person to consume medical cannabis on the property of the manufacturing or distribution facilities	☐	☐

	Statutory Requirement	Yes	No
9	I acknowledge I am subject to reasonable inspection by the commissioner and his or her designates	☐	☐
10	I certify I will not employ any person who is under 21 years of age or who has been convicted of a disqualifying felony offense and that all employees and staff must submit to a criminal history records check and a full set of classifiable fingerprints prior to beginning work	☐	☐
11	I certify I will not operate in any location, whether for distribution or cultivation, harvesting, manufacturing, packaging, or processing, within 1,000 feet of a public or private school existing before the date of the manufacturer's registration	☐	☐
12	I certify that I will comply with reasonable restrictions set by the commissioner relating to signage, marketing, display, and advertising of medical cannabis	☐	☐

The undersigned attests that the applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the applicant organization to the statutory requirements.

_____ _____

Name – Signature Date

_____

Name - Printed

REGULATORY AGENCY AUTHORIZATION FORM

I/We, the undersigned applicant, hereby state as follows:

I/We have either applied for or are currently or have been previously licensed or authorized to produce or otherwise deal in the distribution of cannabis in any form, in the following states or jurisdictions and corresponding agency or authority:

State & Agency	Name of Licensee	License or Registration #

I/We hereby specifically grant the Minnesota Department of Health permission to contact the above listed states or jurisdictions and their licensing agency or authority to confirm the information contained in the application for a manufacturer registration. I/We hereby specifically grant permission to the above listed states or jurisdictions and their licensing agency or authority to release to the Minnesota Department of Health any and all information relating to the application, licensure or authorization to produce or otherwise deal in the distribution of cannabis in any form, including the following:

a. Any denial, suspension, revocation or other sanction of the application, license or authorization and
b. A copy of documentation so indicating; or
c. A statement that the applicant was so licensed or authorized and was never sanctioned.

The undersigned attests that the applicant organization will adhere to the statutory requirements listed above and that they have the authority to bind the applicant organization to the statutory requirements.

_____ _____

Name – Signature Date

_____

Name - Printed

NOTICE OF PROPER MANUFACTURING FACILITY ZONING FORM

TO BE COMPLETED BY APPLICANT		
1. NAME OF ENTITY APPLYING FOR A MEDICAL CANNABIS REGISTRATION		
2. ADDRESS OF THE PROPOSED MANUFACTURING LOCATION	3. DISTRICT	
4. CITY	5. COUNTY	6. ZIP CODE

CHECK ALL THAT APPLY		
There are no local zoning restrictions specific to a medical cannabis manufacturing facility at the identified location.	☐ Yes	☐ No
The location of the proposed medical cannabis dispensary is in compliance with local zoning restrictions for medical cannabis manufacturing.	☐ Yes	☐ No
The proposed manufacturing has duly filed a request to the appropriate local zoning authority to approve the specified location for a medical cannabis manufacturing. If a zoning request was filed but has not been approved, the zoning determination is expected to be issued in approximately _____ DAYS ☐ WEEKS ☐ MONTHS ☐ (check one)	☐ Yes	☐ No

TO BE COMPLETED BY AN AUTHORIZED REPRESENTATIVE OF THE LOCAL ZONING OFFICE

_____ _____
Title of the Authorized Zoning Representative Name of the Local Jurisdiction

_____ _____
Printed Name Telephone Number

_____
Signature/Date

Subscribed and sworn to before me this _____ day of _____, 20_____.

(SEAL) _____
Notary Public

OWNER AND MANAGING DIRECTOR CERTIFICATION STATEMENT FORM

This form is to be completed by each owner of the applicant company and its managing director.

MEDICAL CANNABIS OWNER AND MANAGING DIRECTOR CERTIFICATION STATEMENT FORM		
1. I certify that I have not held an ownership interest in a cannabis manufacturer or its equivalent in another state or territory of the United States that had the registration or license suspended, revoked, placed on probationary status or subject to disciplinary action.	☐ Yes	☐ No
2. I certify that I have not managed or served on the board of any business or not-for-profit that was convicted, fined, censured, or had a registration suspended or revoked in an administrative or judicial proceeding. If no, provide a brief explanation. _____ _____	☐ Yes	☐ No
3. Are you a party to any legal proceeding where damages, fines, or civil penalties may reasonably be expected to exceed $500,000 above any insurance coverage available to cover the claim? If yes, provide a brief explanation. _____ _____	☐ Yes	☐ No
4. I certify that I am not delinquent on the filing of state or federal taxes. If no, provide a brief explanation. _____ _____	☐ Yes	☐ No
5. If you have held a medical cannabis or medical marijuana license or registration in another State, have you been disciplined (including, but not limited to restricted, suspended, or terminated) by any State? If yes, provide a brief explanation. _____ _____	☐ Yes	☐ No
6. I certify that I have not been denied a professional license, privilege of taking an examination, or had a professional license or permit disciplined by a licensing authority in Minnesota or other state. If no, provide a brief explanation. _____ _____	☐ Yes	☐ No
Are you employed by the State of Minnesota? If no, skip next question.	☐ Yes	☐ No
If you are employed by the State, please state the name, agency and position. _____		

I acknowledge that as an applicant, I have actual notice that, notwithstanding any State law: • Cannabis is a prohibited Schedule I controlled substance under federal law; • Any activity not sanctioned by the Statute or the administrative rules may be a violation of State or federal law and could result in arrest, prosecution, conviction, or incarceration; • Use of medical cannabis may affect an individual's ability to receive federal or State licensure in other areas; • Use of medical cannabis, in tandem with other conduct, may be a violation of State or federal law and could result in arrest, prosecution, conviction, or incarceration;	☐ Yes	☐ No
I certify that I have not been charged with or have been convicted of a "disqualifying felony offense" as defined under Minnesota section 152.22, subdivision 3.	☐ Yes	☐ No
I certify my acknowledgment that application fees are non-refundable.	☐ Yes	☐ No
I acknowledge that in filing an application for registration and receiving a date and time stamped receipt, the following: a. The Department is vested with broad discretion to select the applicants to be awarded a registration; and b. The Department's decisions in selecting the applicants shall be final.	☐ Yes	☐ No

Dated this _____ day of _____, 2014

_____ _____

Signature of Owner / Managing Director Printed Name of Owner / Managing Director

Sworn to and subscribed before me on this _____ day of _____, 2014.

(SEAL) _____

Notary Public

A. BUSINESS OVERVIEW AND PLAN

Total Possible Points = 200

No longer than 15 pages, excluding copies of web templates, brochures, posters, etc.

1. Brief Summary

   Provide a brief summary of the applicant's qualifications, experience and industry knowledge relevant to the development and operation of a medical cannabis production facility.

2. A manufacturer shall operate in accordance with the business plan submitted to, and approved by, the Department as part of the application. Please provide a business plan that shows the following information:

   a. The applicant's expected production capacity, including any ability of the applicant to expand capacity within the approved manufacturing facility
   b. All Medical Cannabis products intended to be offered by the producer during the first year of operation and, for each product, provide a sample of the proposed label and identify the types of packaging
   c. Expected product pricing in each of the first 3 years of operations
   d. Expected number of customers in each of the first 3 years of operations

   Total Possible Points- up to 150

3. Marketing Plan

   Please provide a marketing plan that includes the following information:

   a. Any web templates and educational materials such as brochures, posters, or promotional items
   b. Expected outreach, media, events or promotional activities to communicate medical cannabis to physicians
   c. Expected outreach, media, events or promotional activities to communicate medical cannabis to patients and caregivers
   d. Any other advertising, media, events or promotional activities planned for any other audience

   Total Possible Points- up to 50

B. FACILITIES

Total Possible Points = 200

No longer than 25 pages, excluding copies of maps, blueprints, photos, etc.

1. Intended Service Area(s)

   Please identify whether the applicant is seeking to be registered for Service Area A (the portions of the state located in Congressional Districts 1, 3, 5 and 7) or Service Area B (the portions of the state located in Congressional Districts 2, 4, 6, and 8) or either. **Applicants may submit an application for more than one Service Area but all eight potential distribution sites will need to be identified.**

   If an applicant wants to use its manufacturing site as one of its distribution sites, that will be allowed if it is selected for the Service Area in which the manufacturing site is located. For example, if the manufacturing site is in Duluth (District 8) and the manufacturer selected for Service Area A (districts 1, 3, 5 & 7) it will NOT be allowed to use its manufacturing site as a distribution site. If, however, it is selected for Service Area B (districts 2, 4, 6 & 8) it will be allowed to have a distribution site at its manufacturing facility. The maximum number of distribution sites a manufacturer can have is four and all four must be within the Service Area district it is selected for.

   No one manufacturer will be awarded a registration in both Service Areas - a manufacturer is limited to serving only one Service Area.

   We recommend that applicants locate their distribution facilities for the 1st, 6th, 7th and 8th districts at least 30 miles away from the border of the seven county metro area (Anoka, Carver, Dakota, Hennepin, Ramsey, Scott and Washington counties) so as to ensure compliance with the statutory direction that "distribution facilities shall be located based on geographical need throughout the state to improve patient access."

2. Manufacturing Facility

   Please provide the following information:

   a. The location of the proposed manufacturing facility (it must be located in the State of Minnesota)
   b. Documents sufficient to establish that the applicant is authorized to conduct business in Minnesota; and that state and local building, fire and zoning requirements and all applicable local ordinances are met for the proposed location of the production facility. If documents to this effect do not exist yet, please indicate this but provide the information that does exist and the plan and timeline to finalize the documentation. All documentation must be provided to the Department by November 14, 2014 in order to be a registered manufacturer
   c. If support exists by a local government authority, include documentation indicating the support that exists

d. If the property is not owned by the applicant, provide a written statement from the property owner certifying that they have consented to the applicant operating a production facility on the premises and the duration of the actual or potential lease
e. Any signage, lettering, text and graphic materials that will be shown on the exterior of the proposed production facility
f. Photographs of the surrounding neighborhood and businesses within 500 feet of the manufacturer's property, sufficient to evaluate the proposed production facility's compatibility with commercial or residential structures already constructed, or under construction, within the surrounding area
g. A map that identifies all places used primarily for religious worship, public or private schools, convents, charitable institutions whether supported by private or public funds, hospital or veterans' homes, or any camp or military establishment that are within 1000 feet of the proposed production facility location
h. A site plan, drawn to scale, of the proposed production facility showing any 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 production facility
i. A blueprint or floor plan, drawn to scale, of the proposed production facility, which shows and identifies the following information:

    i. The location and square footage of the area where cannabis is to be grown
    ii. The square footage of the areas where cannabis is to be harvested
    iii. The square footage of the areas where the medical cannabis is to be produced and manufactured
    iv. The square footage of the areas where medical cannabis is to be packaged and labeled
    v. The square footage of the overall production facility
    vi. The square footage and location of areas to be used as storerooms or stockrooms
    vii. The location of toilet facilities
    viii. The location of all break rooms and personal belonging lockers
    ix. The locations of all areas that may contain medical cannabis or cannabis products that shows walls, partitions, counters and all areas of ingress and egress. Said diagram must also reflect all, propagation, vegetation, flowering, harvesting, testing, storage, manufacturing, packaging, and shipping areas.
    x. The locations of any business operations on the property that will not be related to the production and distribution of medical cannabis

NOTE: If documents to this effect do not exist yet, please indicate this but provide the information that does exist and the plan and timeline to finalize the documentation. All documentation must be provided for at least the first distribution facility to the Department by November 14, 2014 in order to be a registered manufacturer.

j. A site development and construction plan identifying the start date, duration of the construction and the completion date
k. Do you plan to begin manufacturer at a temporary site prior to your manufacturing facility described above being complete? If so, provide all of the information previously requested in subsection h, for the temporary site, in addition to the following:

    i. The estimated duration of activity at the temporary facility
    ii. What activities will be conducted in the temporary facility (e.g. propagation, vegetation, etc.)?
    iii. What security protocols will be used at that temporary facility

l. Explanation of how the manufacturing facility will be secured to minimize the potential for theft or diversion of cannabis plants, cultivation materials and byproducts
m. The process that the producer will take to ensure that access to the manufacturing facility premises will be limited only to employees and authorized personnel)
n. Any air treatment or other system that will be installed and used to reduce off-site odors)
o. Explanation of previous experience developing new manufacturing facilities

Total Possible Points- up to 150

3. Distribution Facilities

Please provide the following information specific to each of the proposed distribution facilities:

a. The location of the proposed distribution facilities (it must be located in the State of Minnesota) and the date each facility will be operational. As a reminder, one distribution facility in each Service Area must be operational by July 1, 2015 with all four in each Service Area being operational by July 1, 2016.
b. Documents sufficient to establish that state and local building, fire and zoning requirements and all applicable local ordinances are met for the proposed location of the distribution facilities. If documents to this effect do not exist yet, please indicate this but provide the information that does exist and the plan and timeline to finalize the documentation. All documentation must be provided for at least the first distribution facility to the Department by November 14, 2014 in order to be a registered manufacturer.
c. If support exists by a local government authority, include documentation indicating the support that exists

d. If the properties are not owned by the applicant, provide a written statement from the property owner certifying that they have consented to the applicant operating a distribution facility on the premises and the duration of the actual or potential lease
e. If the applicant intends to locate any of the distribution facilities in anything other than a physical retail space dedicated only to medical cannabis, provide a description of the other activities at the location as well as any agreements with the existing business owners.
f. Any signage, lettering, text and graphic materials that will be shown on the exterior of any distribution facilities
g. Photographs of the surrounding neighborhood and businesses within 500 feet of the distribution facility, sufficient to evaluate the proposed facility's compatibility with commercial or residential structures already constructed, or under construction, within the surrounding area
h. A map that identifies all places used primarily for religious worship, public or private schools, convents, charitable institutions, whether supported by private or public funds, hospital or veterans' homes, or any camp or military establishment that are within 1000 feet of the proposed distribution facility location
i. A site plan, drawn to scale, of the proposed distribution facilities showing all streets, property lines, buildings, parking areas, and outdoor areas, if applicable, that are within a 500 foot radius of the distribution facility
j. A blueprint or floor plan, drawn to scale, of the proposed distribution facility, which shows and identifies the following information:

    i. The square footage of the overall distribution facility
    ii. The location and square footage of the area where cannabis is to be sold
    iii. The location of the safes or vaults that are used to store medical cannabis
    iv. The square footage and location of areas to be used as storerooms or stockrooms
    v. The location of toilet facilities
    vi. The location of all break rooms and personal belonging lockers
    vii. The locations of any business operations on the property that will not be related to the production and distribution of medical cannabis

    NOTE: If documents to this effect do not exist yet, please indicate this but provide the information that does exist and the plan and timeline to finalize the documentation. All documentation must be provided for at least the first distribution facility to the Department by November 14, 2014 in order to be a registered manufacturer.

k. A site development and construction plan identifying the start date, duration of the construction and the completion date)
l. Explanation of how the distribution facilities will be secured to minimize the potential for theft or diversion of medical cannabis products both usable and expired)

m. The process that the manufacturer will take to ensure that access to the distribution facility premises will be limited only to employees and patients and caregivers
n. Explanation of how the distribution facilities will be made to be a safe environment of employees working in and around the facilities
o. Explanation of previous experience developing new product distribution sites)

Total Possible Points- up to 50

C. OPERATIONS

Total Possible Points = 400

No longer than 150 pages

1. General

   Please provide the following information for all operations and facilities:

   a. Describe the training that will be provided to all staff
   b. Describe how you will ensure that employees and staff are at least 21 years of age and have not been convicted of a disqualifying felony offense
   c. Describe the process for any employee to report the suspected or confirmed diversion of medical cannabis plants, in process product and finished product

   Total Possible Points- up to 20

2. Cultivation

   Please provide the following information specific to the cultivation methods:

   a. Describe the experience of the applicant in agriculture required to produce pharmaceutical grade cannabis. For purposes of this response, you may include the experience of any person employed by the applicant, including the person's name and position with the applicant.
   b. A detailed description of the applicant's cultivation process, with a focus on minimizing the risk of exposure to contaminants
   c. Describe the cultivation methods that are expected to be employed, including the growing medium and the approach to cultivate consistent medical cannabis
   d. Describe the documentation of a plant or batches of plants through the growing process to allow for product traceability to support product recalls or notifications in the event an issue is found with a plant or batch of plants
   e. Describe the protocol that will be employed if a fungal or pest outbreak were to occur to both address the issue and resume / restart cultivation
   f. Describe the expected usage of any chemicals including fertilizers, fungicides, herbicides, insecticides including the conditions or protocols in which such chemical would be utilized
   g. Describe the documentation and record keeping of the use of any chemicals
   h. Describe how any applied chemicals (fertilizers, pesticides, etc.) will be controlled from becoming part of the final product or how the final product will meet FDA standards for those chemicals
   i. Describe who will be certified to apply pesticides at the manufacturing facility and how they will be reviewed to ensure that all licenses and recertification requirements are met according to Minnesota Pesticide Laws (Minnesota Statutes Chapter 18B) as well as FDA and EPA regulations

j. If the manufacturer proposes to grow organically, it should provide a detailed explanation of what standards it intends to comply with. (For example, will the applicant use the standards from the USDA National Organic Program Handbook? http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5096778)
k. Explain how the cultivation operations will be made to be a safe environment of employees working in and around the facilities
l. Explain the expected resource usage and disposal of power and water any other resources necessary for cultivation
m. Describe the planned method for disposal of cultivation waste including the growing medium, excess fertilizers and pesticides and plant matter that becomes unusable due to fungal or pest infestations
n. Describe the expected hours of operation of the cultivation operations
o. Describe the maximum and minimum number of staff expected to be working in the cultivation operations at any one time
p. Describe the experience expectations of staff and whether you expect the staff to be full time employees or part time employees or contractors
q. Describe the training that will be provided to cultivation staff
r. To the extent known, provide a list of expected cultivation staff (employees or contractors) and their qualifications

Total Possible Points- up to 100

3. Refining

Please provide the following information specific to refining of plant cannabis:

a. Describe the experience of the applicant in creating acceptable forms of statutorily defined forms of medical cannabis. For purposes of this response, you may include the experience of any person employed by the applicant, including the person's name and position with the applicant. In particular, cite any experience the applicant may have in turning raw plant material into medication.
b. Describe the extraction method that will be employed to extract the active ingredients from the cannabis plant to produce the medical cannabis oil and liquids. Explain how the process ensures that no residual solvents will remain in the finished product and how the work environment will be made safe for employees.
c. A detailed description of protocol and computer systems used for turning the raw plant into acceptable medical cannabis, including:

    i. The equipment the applicant will be using in its manufacturing protocol, including any policies or procedures relating to cleaning and maintenance
    ii. Calculation of yield process
    iii. Sampling and testing of in-process materials and drug products
    iv. Controls and testing of microbiological contamination
    v. Sampling and testing of final products
    vi. Packaging and labeling process, including type of container, label used and information contained on the label. Describe the types of child safety packaging you will use for each product sold

vii. Stability testing and process for determining expiration dates
viii. Timeline of production process
ix. Record keeping process

d. Explain the intended plan to store, devitalize propagating parts (seeds) and dispose of plant materials left-over after the resources for development of medical cannabis products have been extracted.
e. Describe your expected process and interactions with the certified laboratory responsible for testing the accuracy of the final medical cannabis products. Include expected frequency and volume of testing such as how and when you will select samples for laboratory testing, what type of testing you will request from a laboratory, and how you will use this information for best practices. Please include a description of timelines and transportation methods
f. Explain how the applicant will limit employee exposure to potentially unsafe chemicals or other unsafe conditions
g. Describe the method of documentation of a plant and plant extract through the manufacturing process to allow for product traceability to support product recalls or notifications in the event an issue is found with a plant, batch of plants or plant extract
h. Describe the process to collect, review, analyzes and determine needed actions when adverse event information is discovered
i. A detailed description of the controls the applicant will have over the components of the medication and any product containers
j. Describe the expected hours of operation of the refining operations
k. Describe the maximum and minimum number of staff expected to be working in the refining operations at any one time
l. Describe the experience expectations of staff and whether you expect the staff to be full time employees or part time employees or contractors
m. Describe the training that will be provided to refining staff
n. To the extent known, provide a list of expected refining staff (employees or contractors) and their qualifications

Total Possible Points- up to100

4. Distribution

Please provide the following information:

a. Describe the experience of the applicant in providing care or service to patients and caregivers. In addition, describe any experience in managing the product inventory of high value and potential risk for diversion.
b. Describe the computer systems, tools and information that will be provided to distribution site pharmacists to provide patient and caregiver guidance on medical cannabis products and dosages for their conditions

c. Describe the computer systems, tools and information that will be provided to distribution site pharmacists to provide patients and caregivers information on potential drug interactions and side affects
d. Describe the processes and training that will be provided to distribution site staff and pharmacists if they suspect a patient or caregiver is diverting medical cannabis
e. Describe the computer systems, tools, information and training that will be provided to distribution site staff and pharmacists regarding documentation and notification of MDH of adverse events potentially attributable to medical cannabis
f. Describe the process for handling medical cannabis within the distribution site to minimize the opportunity for theft or diversion
g. Describe the process for accepting new product into distribution site inventory
h. Describe the expected days and hours of operation of each of the distribution sites
i. Describe the maximum and minimum number of staff expected to be working in each distribution site at any one time
j. Describe the experience expectations of staff and whether you expect the staff to be full time employees or part time employees or contractors
k. Describe the training that will be provided to distribution site staff
l. To the extent known, provide a list of expected distribution site staff (employees or contractors) and their qualifications

Total Possible Points-up to 50

5. Transportation

Please provide the following information:

a. Describe the experience of the applicant in transporting product of high value and potential risk for diversion.
b. A detailed description of the proposed method of transportation of medical cannabis products including the following:

    i. The frequency expected of medical cannabis transport from the manufacturing facility to each of the distribution sites
    ii. Explain how you intend to comply with the requirements identified in the draft Manufacturer Rules for transportation of medical cannabis.
    iii. The types of vehicles used to transport the medical cannabis
    iv. The containers the medical cannabis will be stored in during transportation
    v. The number of employees expected to be engaged for transportation activities
    vi. The process that should be followed if an emergency (traffic accident, extreme weather, etc.) occurs during transport
    vii. The process that should be followed if the transportation staff determines medical cannabis is missing, whether misplaced or intentionally diverted

c. A description of the proposed method to minimize the risk of diversion or theft of medical cannabis during its transport from the manufacturing site to the distribution sites

d. To the extent known, provide a list of all expected transportation staff (employees or contractors) and their qualifications

Total Possible Points-up to 25

6. Inventory Management

Please provide the following information:

Describe the processes and computer systems that will be utilized to manage medical cannabis inputs (including plant matter, chemicals, machinery, etc.) and final product inventory (at all locations including when the final product is in transport). Include the real-time processes to document inventory as well as the schedule and processes to audit the accuracy of inventory.

Total Possible Points- up to 20

7. Technology Usage

Please provide the following information:

Provide a high level description and diagram of the computer systems that will be utilized to manage all of the medical cannabis operations from cultivation to manufacturing to distribution

Total Possible Points- up to10

8. Security Plan

Please provide the following information:

a. All measures employed to provide physical security of the manufacturing facility
b. Identify all points of entrance and exit at the manufacturing facility.
c. Provide all measures installed to limit access to all restricted entry areas identified on the floor plan
d. Provide the name and address of any outside contractors hired to provide security
e. Provide the design of the surveillance system that will be installed at the facility. This must include the location of all cameras on a floor plan of the facility
f. Provide the storage capabilities for the onsite retention of historical recordings
g. Should the Minnesota Department of Health request a real time feed of the manufacturing and distribution facilities, describe what capacity and ability the manufacturer has to provide that ability

Total Possible Points- up to 50

9. Disaster Recovery and Continuity Planning

   Please provide the following information:

   In the event a situation disrupts the cultivation, manufacturing or ability to distribute medical cannabis whether due to weather, equipment or product malfunction or any other circumstances, explain the steps and timeline to resume operations and minimize the potential impact to patients

   Total Possible Points- up to 20

D. OWNERSHIP AND FINANCIAL STRUCTURE

Total Possible Points = 200

All applicants must provide the following documents:

1. Specify the type of business structure the applicant will have (e.g. sole proprietorship, limited partnership, C-corporation). Include the articles of incorporation; articles of association; charter; by-laws; partnership agreement; any agreements between any two or more members of the applying organization 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.

2. Current organizational charts that include position descriptions and the names and resumes of persons holding each position to the extent such positions have been filled.

3. The resumes 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.

4. Copies of all compensation agreements with investors, board members, directors, owners, officers, other management. For purposes of this RFA, 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;

5. A listing of any criminal history and civil litigation (as a plaintiff or defendant) for all individuals identified in items 2, 3 and 4 above.

6. A description of 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 production facility (cultivation and manufacturing) and distribution facilities.

7. 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 please 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;

8. A list of owners, their ownership percentage and financial investment for all investors.

9. Future financial investments and commitments per owner or investor and potential owners or investors. Provide the amount of future financial investment and the time horizon the commitment is valid for. 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 it does please indicate the percentage of their net worth it represents.

E. BONUS POINTS

Total Possible Points = 100, 10 points available for each category

Applicants may provide information related to any or all of the categories below with their application. Should the applicant be awarded a registration from the Department, their commitments in a bonus category shall become a condition of their registration. If a violation of a condition occurs, it may be deemed a material breach and the Department may assess a penalty or seek suspension or revocation of the registration.

1. **Patient Services Plan** (no longer than three pages): Describe any plans you have to support patient health care needs. For example, describe whether and how you would implement patient specific care programs, support for a phone line to address questions or concerns, or collection of patient and caregiver feedback on the medical cannabis products and services provided.

2. **Employee Working Standards** (no longer than three pages): Describe any plans you have to provide a quality working environment for your employees, including, but not limited to, environmental standards, codes of conduct, healthcare benefits, educational benefits, retirement benefits, and wage standards.

3. **Workforce Diversity** (no longer than three pages): Provide a detailed description of any plans you have to address compliance with equal opportunity standards and recruitment and retention of under-represented populations.

4. **Compassionate Need Plan** (no longer than three pages): Provide a detailed description of any compassionate need program you intend to offer to assist those who may not have the financial resources to purchase medical cannabis at list prices. Include in your response:
   - The protocols for determining which patients will qualify for the program;
   - The discounts available to patients eligible for the compassionate need program;
   - The names of any other organizations, if any, with which you intend to partner or coordinate in connection with the compassionate need program, including any manufacturer's distribution site facility applicant; and
   - Any other information you think may be helpful to the Department in evaluating your compassionate need program.

5. **Research Plan** (no longer than three pages): Provide a detailed description of any plan you have to conduct research on relevant combinations of cannabinoids, dosage levels, extraction methods, cultivation methods with particular emphasis on the relationship of those research subjects to the treatment of qualifying conditions.

6. **Substance Abuse Prevention Plan** (no longer than three pages): Provide a detailed description of any plans you will undertake to combat potential abuse of medical cannabis, such as a proposed monthly limit for patients. The plan can

include the extent to which you will partner, or otherwise work, with existing substance abuse programs.

7. **Environmental Plan** (no longer than three pages): Provide a detailed description of any plans you will take to reduce the ecological footprint of your production facility and other business operations such as plans to use renewable energy sources.

8. **Health Equity** (no longer than three pages): Provide a detailed description of any plans you will take to reduce health disparities such as translation of patient information, increased employee health literary, contracting practices.

9. **Community Engagement** (no longer than three pages): Provide a detailed description of any plans you will take to make a difference in the civic life of the communities in which you will do business, including participation in community service, volunteering, support for employee engagement in the community.

10. **Other** (no longer than three pages): Provide a detailed description of any other planned activity you will take that you believe would be of interest to the selection committee. Identify items not currently captured in any of the previous questions.

F. CONCLUSION

No longer than 3 pages

Provide a brief summary of why the applicant feels their application and proposal is the best choice for the State of Minnesota. In addition the conclusion should include the following:

1. The name, telephone number and email address for whoever will be responsible for responding to any questions that arise during the evaluation process.
2. Signatures of the owners and managing director(s) for the organization.

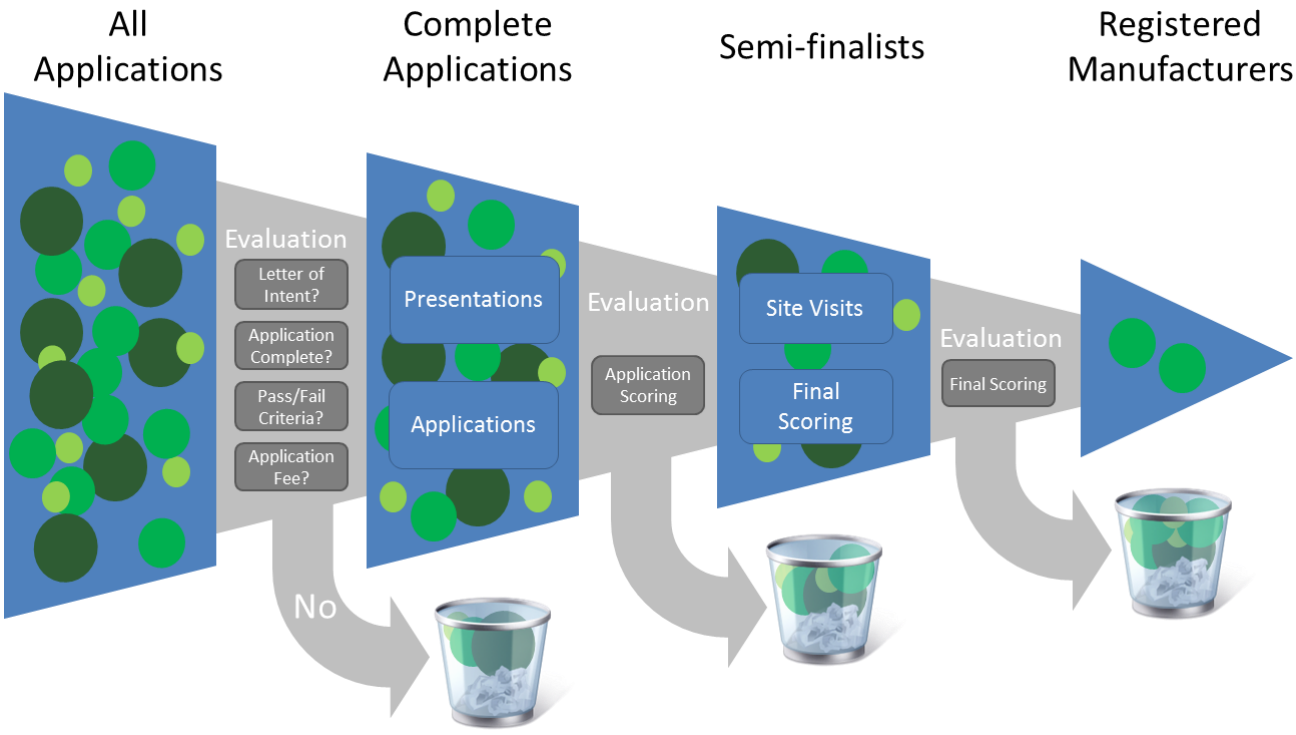
Evaluation and Selection Procedures

Overview & Timeline

The Department will conduct a comprehensive, fair, and impartial evaluation of all applications received in response to this RFA. This review will involve the following process:

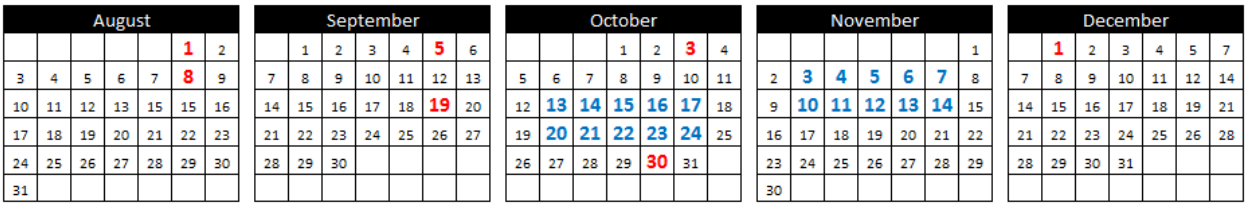
1. Intent to Apply Letter Submission
2. Application Completeness and Pass/Fail Criteria Evaluation
3. Application Evaluation
   a. Review of Applications
   b. Presentations – Optional
   c. Scoring of Applications
4. Selection of Semi-finalists
5. Site Visits
6. Selection of 2 Manufacturers

Below is a graphical depiction of the process and the points during the process that some applicants will be eliminated from consideration.



The evaluation process will occur over the following timeline:

- Draft RFA Published – August 1, 2014
- Manufacturer Interested Parties Conference – August 8, 2014
- RFA Published – September 5, 2014
- Intent to Apply Due Date – September 19, 2014
- RFA Due Date – October 3, 2014
- Prospective Manufacturer Presentations – October 13 – 24, 2014
- Semi-finalists Named – October 30, 2014
- Semi-finalist Site Visits – November 3 – 14, 2014
- 2 Finalists Selected – November 17 – 26, 2014
- 2 Manufacturers Registered – December 1, 2014



Application Completeness and Pass/Fail Criteria

All applications will be assessed to determine whether they meet the mandatory qualification criteria set forth below. **Be aware**: with the exception of the bonus categories, all requested items are mandatory unless the request indicates otherwise. If an applicant has no experience or plan relative to a specific area, the applicant's RFA response document should clearly indicate so. Providing no response at all may be grounds for disqualification prior to the review and scoring of the application.

MDH, however, reserves the right to waive minor irregularities or to request clarifications, modifications or amendments to an application, providing such application substantially complies with the RFA.

Mandatory Qualification Criteria

The Department will only review and score applications that:

- Are preceded by an Intent to Apply letter submitted prior to its due date (September 19, 2014)
- Are submitted on or before the submission deadline with the application fee
- Fully respond to all mandatory items in the RFA
- Do not contain significant inconsistencies or inaccuracies
- Include the appropriate number of copies (20), plus a DVD, CD or USB drive with a searchable PDF copy of the complete submission
- Contain all required signatures and contact information
- Successfully Pass all Pass/Fail Criteria:
    - Applicant has secured or provisionally secured (letter from current property owner is sufficient) ownership or lease agreements for the manufacturing facility and at least one distribution site

- Applicant has experience cultivating plants
- Applicant has experience in commercial manufacturing of pharmaceuticals, medical products or food products
- Applicant has previous business ownership and management experience
- Applicant has experience owning or managing a business that required 24 hour security monitoring

If an application response meets all of the above criteria then it will proceed to the next level of evaluation.

Evaluation Criteria

The evaluation of applications that meet the mandatory qualification criteria will proceed to be scored by the Evaluation Committee. The application response will be reviewed and scored according to the quality of its responses to the requirements set out in the RFA.

While a maximum score of 1000 is possible (1100 if all Bonus Points are included), proposals must achieve a minimum score of 750 points to be considered for an award of a Manufacturer Registration. If an insufficient number of applications obtain a score of at least 750 to award one or both of the Manufacturer Registrations, the Department may request modifications from applicants whose scores are close to 750, as determined by the Department, so as to render the applications acceptable. Alternately, if the Department determines that sufficient modifications cannot be made to raise enough applications to an acceptable level, in either or both Service Areas, the Department may re-issue the RFA.

The number of points in each Application Section (below) is the maximum number of points that may be awarded for each of the corresponding components of the RFA. For each category, the applicant's score will be based on the totality of the response to the corresponding RFA section.

Application Section	Points Available
Business Overview and Plan	200
Facilities	200
Operations	400
Financial Organization & Structure	200
Total	1000
Bonus Points (10 points each)	100
Total + Potential Bonus Points	1100

In conducting its evaluation of each of the criteria, the Department may conduct interviews, contact references, conduct background checks, contact state regulators in any other

state(s) where the applicant, applicant's investors or others associated with the applicant have engaged in, or sought to be engaged in, the state's medical cannabis program. If the applicant has not engaged in medical cannabis programs in other states the Department may conduct the same activities outlined above of other related businesses associated with the applicant or the applicant's investors or key personnel.

Presentations

As part of the evaluation process, the applicant or the Department may request a 90 minute in-person or video conference presentation to the Evaluation Committee. The presentations will not be scored separately. They will be used to inform each of the Application Section scoring areas noted previously.

Please specify in your application whether you want to make such a presentation. If the applicant chooses not to exercise this option the Department will review the application and determine if the Department wants to require a presentation by the applicant.

Depending on the number of applications we receive and in an effort to ensure the process is able to be completed in a timely manner, the Department reserves the right to narrow the number of applicants invited to provide a presentation to the Evaluation Committee.

Semi-finalist Selection

After the Presentations and Application scoring are complete the Evaluation Committee will select up to two Semi-finalists from each service area to proceed in the evaluation process. The Semi-finalists will be identified based on receiving one of the two highest scores in their self-identified service area.

Semi-finalist Site Visits

Once the Semi-finalists have been determined the Department will request a site visit of the applicant's existing (or previous) cultivation, manufacturing and/or distribution operations as evidence of their expertise.

Please indicate in your application the existing operations that would serve as your site visit location including the address and a contact to arrange for a potential site visit. If the applicant has no current operations a site visit of the prospective manufacturing and distribution locations can serve as an alternative but may not be scored as high due to the lack of demonstrable experience.

Final Selection

After completing the site visits the full Evaluation Committee will review the semi-finalist application scores and information collected during the site visits. The Evaluation Committee shall rank the semi-finalist in each Service Area according to the score totals. The highest score in each service area that meets the minimum score threshold will be identified as Finalists and will be presented to the Commissioner for his review and decision on whether to proceed to the process of securing Manufacturer Registrations.

If a registration agreement is unable to be secured by November 24, 2014 the Department may engage with the second highest scoring Semi-finalist applicant for the Service Area in registration.

If the highest ranked applicants in both service areas have overlapping investors, directors, owners, officers or other high-level employees, the Department may award the Manufacturer Registration to the next highest ranked applicant in one of the service areas without such an overlap.

If the applicant submits an application for each Service Area and is the highest applicant for both Service Areas, the Department shall give the applicant the option to select which Service Area it wishes to be registered for.

Upon selecting the successful applications, the Department shall notify all applicants of their status in writing. The Department's decision to award or not award a registration to an applicant shall be final.