January 4, 2015

Mass Wellspring, Inc.
P.O. Box 1087
Waltham, MA 02454-1087

Re: Request for Information

This letter is to inform you that the Department of Public Health (“Department”) has reviewed Mass Wellspring, Inc.’s Management and Operations Profile (Application 1 of 1). The Management and Operations Profile requires the following information before the Department may complete its evaluation:

1. In response to Question E.29, the applicant refers to “105CMR725.E.1 & E.2.” This citation is unclear. Applicant must resubmit a completed response to Question E.29 that identifies the correct section of the Regulations.

2. In response to Question E.32, the applicant refers to, “247CMR Board of Regist. in Pharmacy.” This citation is unclear. Applicant must resubmit a completed response to Question E.32 that identifies a specific section of the Board of Registration in Pharmacy Regulations.

3. In response to Question E.34, applicant states that they will explain the following to patients and caregivers, “...driving/operating machinery while using marijuana is prohibited by law.” Pursuant to 105 CMR 725.105(K)(2) an RMD’s educational material must include, “A warning that when under the influence of marijuana, driving is prohibited by M.G.L. c. 90, s.24, and machinery should not be operated.” Applicant must resubmit a complete response to Question E.34 that demonstrates compliance with 105 CMR 725.105(K)(2).

4. In response to Question E.36, applicant states, “Mass Wellspring will provide free or reduced cost medicine to any patient that is a recipient of MassHealth, or Supplemental Security Income, and [emphasis added] whose income does not exceed the following sliding provide scale, determined by using the Federal Poverty Level (FPL), adjusted for family size.” 105 CMR 725.004 defines “Verified Financial Hardship” to mean “that an individual is a recipient of MassHealth, or
Supplemental Security Income, or [emphasis added] the individual’s income does not exceed 300% of the federal poverty level, adjusted for family size.” Applicant must resubmit a completed response to Question E.36 that complies with the definition of Verified Financial Hardship.

5. Also in response to Question E.36, within the sliding price scale, it is unclear whether “FPL 100%”, “FPL 200%” and, “FPL 300%” refer to ranges in income, or whether this is referring to those patients whose income falls exactly at 100% FPL, 200% FPL, or 300% FPL. Please resubmit a completed response to Question E.36 that explains the percentages.

6. Also in response to Question E.36, it is also not clear the amount of free marijuana the applicant intends to provide to patients who are under the age of 18, over the age of 65, or veterans. Please resubmit a completed response to Question E.36 that includes this information.

If the applicant has been requested to resubmit their response to a question, please do so using the page on the application form for that particular question, and include an initialed attestation at the bottom of the page. The applicant need not resubmit the entire application and may submit only the page for the particular question that needs to be submitted.

Please remember to type all responses in the information or materials resubmitted to the Department, other than any required signatures, as well as include the name of the Applicant Non-Profit Corporation and the number of the application (e.g., Application 1 of 1) at the top of each page of the resubmitted information or materials.

Please resubmit the additional or revised information as outlined above, via U.S. mail or hand-delivery, to:

Department of Public Health
Medical Use of Marijuana Program
RMD Applications
99 Chauncy Street, 11th Floor
Boston, MA 02111

Upon receipt, the Department will review the information and will notify the applicant if it is invited to submit a Siting Profile or if further information is required before the applicant may proceed.

If you have questions or need assistance, you may contact the Department at 617-660-5370 or RMDapplication@state.ma.us.

Sincerely,

Eric Sheehan, J.D.
Interim Bureau Director
Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health
29. Provide a summary of the RM D's operating procedures for quality control and testing of product for potential contaminants.

Cultivation/post-harvest areas will be maintained in clean, sanitary conditions and kept at constant temperature and humidity to ensure a healthful environment.
Personnel will wear protective gloves and hairnets while handling plants and products.
We will cure Cannabis for four to six weeks, depending on the strains, to produce a better quality Cannabis.
Only OMRI certified organic pesticides, or beneficial predator insects, will be used as preventatives, not for treatment of contaminated plants.
Plants in all life-stages and products will be subject to rigorous continual monitoring and inspections or signs of mold, disease, and pests. Pursuant to 105CMR725.105(C)(2), we will contract with an ISO17025-accredited, third-party and independent lab to test for, at minimum, cannabinoid profile, and contaminants, including mold, mildew, heavy metals, plant-growth regulators, and the presence of non-organic pesticides.
Testing will be conducted at a frequency determined by DPH. Any plants found with mold or other contaminants will be quarantined and destroyed immediately.
The certified results of each test will be reported on all product labels pursuant to 105CMR725.105(E)(2), whether they fall below DPH established limits or not.
MIPs will be manufactured with certified (tested and approved) cannabis and labeled according to 105CMR725.105(E)(1) and (3). The company will maintain the results of all testing for at least a year.
32. Provide a summary of the RMD's operating procedures for dispensing of marijuana for medical use.
34. Provide a summary of the RMD's plans for providing patient education.

Information relayed between staff and patients/caregivers is strictly confidential. We will discuss terminology, strains and effects of various forms of marijuana with the patient/caregiver and assist in selecting a medication. Discussions will include: usages and dosages, highlighting the safest methods; emphasize starting with the smallest amount of medicine and titrating to effect; amounts allowed by law; maintaining a log recording the effects of the strain, amount/frequency of dosing to quantify individual patient needs; and potential side-effects, withdrawal, abuse and abuse prevention/treatment programs. We will warn that: marijuana has not been analyzed or approved by the FDA; there is limited information on side effects; there may be health risks associated with its use; it may not be appropriate for children; it must be stored in a locked cabinet; when under the influence of marijuana, driving is prohibited by M.G.L. c. 90, s. 24 and machinery should not be operated; patients may not distribute marijuana to others; and any unused, excess or contaminated product must be returned to the RMD. We will demonstrate delivery options (i.e. vaporizers/MIPs) and explain the benefits/risks of each delivery mode. We will provide free educational material in a variety of languages and for the hearing/visually impaired reiterating the discussed information, abuse prevention and ways to contact our dispensary. We will host a website with information on research/regulations.
36. Provide a summary of the RMD's policies and procedures for the provision of marijuana for medical use to registered qualifying patients with verified financial hardship without charge or at less than the following sliding price scale:

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Medicine per Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPL 100% or less</td>
<td>3.5g per week = Free. Additional medicine per week = 50% discount.</td>
</tr>
<tr>
<td>FPL 200% or less</td>
<td>3.5g per week = 75% discount. Add'l medicine per week = 30% discount.</td>
</tr>
<tr>
<td>FPL 300% or less</td>
<td>3.5g per week = 50% discount; Add'l medicine per week = 20% discount.</td>
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</tbody>
</table>

Patients will submit an application, with MassHealth, SSI and/or income verification documentation attached, for review. Patients' privacy will be maintained at all times and retained records remain confidential per HIPAA guidelines. Patients will need to reconfirm their Verified Financial Hardship every six months.

Mass Wellspring will also have a Pay It Forward Program whereby registered patients/caregivers, local businesses, health care organizations, and the general public can donate funds that will be used to assist patients with Verified Financial Hardship. Donations may be anonymous.

All forms and further details regarding qualifying for Verified Financial Hardship and the Pay It Forward Program will be available on Mass Wellspring's website.