THE REGISTRATION AND OPERATION OF A MEDICAL MARIJUANA COMPASSION CENTER IN THE STATE OF DELAWARE

FOR

DIVISION OF PUBLIC HEALTH

Date Due: April 8, 2014
11:00AM

ADDENDUM # 3

Please Note:

THE ATTACHED SHEETS HEREBY BECOME A PART OF THE ABOVE MENTIONED BID.

Responses to questions addressed at the pre-bid meeting on January 31, 2014 are attached.

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The Registration and Operation of a medical Marijuana Compassion Center in the State of Delaware

Pre-bid Meeting Questions

January 31, 2014

Question 1: My question is about the employees or agents of the compassion center, is there a residency requirement for employees of the compassion center?

DHSS Response: Yes, DHSS is expecting them to be Delaware state resident.

Question 2: Everyone who works there needs to be a Delaware resident, ok. Is home delivery allowed for patients who are unable to travel to the center?

DHSS Response: DHSS put the caregiver program in place for that very reason. I will work with the contractor to define the travel and security plan was before I could commit to something like that. Not saying it is completely out of bounds, it would have to be why we are not using a caregiver and why we are doing home delivery. So yes, it is something we can look at if a strong transportation plan is in place.

Question 3: Will a copy of the sign in sheet be made available online?

DHSS Response: It will be on the same website as you see on the RFP. It will be a link, an attachment right below the RFP, on that website. Will have that posted by the end of today. If not, by Monday. Subsequently, the Deputy Attorney General (DAG) advised it should not be posted due to the Confidentiality portion of the law. As a result, the sign in sheet is not posted.

DHSS Response: That is why it is important for anyone who has not signed in to do so.

DHSS Response: If you don’t sign in you can’t bid.

Question 4: Has DHSS confirmed that Charlie Oberly is going to adhere to the president’s directive not to prosecute medical marijuana dispensaries approved under state law and complying with state law?
DHSS Response: The State of Delaware makes no representations with respect to federal prosecution priorities. Applicants are referred to the U.S. Department of Justice guidance to all US attorneys regarding marijuana enforcement under the Controlled Substances Act (CSA) dated August 29, 2013, and are advised to seek their own legal advice with respect to all matters of compliance with federal and state law. Selection as a vendor by the State of Delaware does not provide any immunity or legal defense on matters of federal law, including any civil or criminal violation of the CSA.

**Statement from Program Participant (Patient) 5:** Want to bring up a few things. We are going to need different amounts of different strains. Most compassion centers carry between, 13 to 30 different strains. With our 150 plant limit they will have to know that they will have to do staggered planting, so as not to have shortages.

**DHSS Response:** The varieties of strains that are going to be produced will be a business decision by the compassion center. The Department will not force the compassion center to produce something, a product, that is not going to be sellable or there is no demand for. The Department will use that information as an element of scoring of the variety of products the compassion center will be willing to sell. Of course edibles are off the table. So we did consider that when we set up the RFP.

**Statement from Program Participant (Patient) 6:** Do they also know if the product prices are staggered pricing rate by salary? There was an amendment passed where the price of cannabis will be based on your yearly salary. Thank you for your time and I am glad to see a lot of people here.

**DHSS Response:** When evaluating compassion center applications, the Department is required by law to consider the applicant’s plan for making medical marijuana available on an affordable basis to certain lower-income patients.

**Question 7:** Do you require as evidence of zoning compliance, do you require a letter from the county or municipality or can it be a letter form an attorney?

**DHSS Response:** The Department would like a letter from the municipality, saying that they are going to allow operation of a Compassion Center to happen. The Department wouldn’t want you put in a position where you plan on having the compassion center there and then it is not allowed by a municipality. They had some of those problems in New Jersey.
Question 8: If in the future Governor Markell approves addition compassion centers in DE will the RFP process be opened back up or is there going to be any priority given to the initial vendors selected.

DHSS Response: What I think you are asking is would I go to the second person on the list and then the third.

DHSS Response: Once this RFP is closed and the selection is made and the contract is issued this particular RFP endeavor has concluded. Anything forth coming after that would be a new RFP and a new selection would be made.

Question 9: Two Questions, one concerning bidder references. The gentleman referred to the word “must” and in there it says the names and phone numbers of at least 3 organization’s agencies for who the vendor carried out a similar project “must” be included. If you have never done business with a state agency before does that disqualify you?

DHSS Response: "Must” means it is a mandatory requirement needing an answer from you. Your answer is going to be “no” to that question, but you must respond. A No answer does not disqualify you.

Question 10: It goes on and says that if no similar project has been conducted others requiring compatible skills can be used. But that is not a must it is just a can. So you can just say you have never done business with any state agency.

DHSS Response: Remember you are submitting a proposal, and the strength of your proposal, we are giving you an option to demonstrate your strength, to support your proposal. We give you an outlet but the “must “means address this question.

Question 11: The other question is a hypothetical question, if there was an investor another state, I know to be an employee you must be a resident of DE, hypothetically someone from out of state wants to invest or lend a million dollars, is that acceptable if they are not a state resident?

DHSS Response: This hypothetical question potentially involves the laws of several states, as well as federal laws and regulations. Applicants are advised to seek their own legal and financial advice with respect to these matters.
**Question 12:** Secondly if a corporation wanted to invest would you need the stock holders of that corporation?

**DHSS Response:** Applicants are required to list all persons or business entities having 5% or more ownership in the compassion center, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity which owns all of part of the land or building.

**Question 13:** Is a residency requirement going to be placed on board members or subcontractors who may work with the compassion center?

**DHSS Response:** The subcontractors if you were having the plumbing worked on or the hydroponics that person can come from New Jersey; the Department would not have an issue with that. The board members, I believe it clearly says that they have to be residents of the state.

**Question 14:** This gentleman was talking about corporations; the state of DE has thousands of corporations that don’t live in DE. We have thousands of corporations that could invest but they don’t live here in DE.

**DHSS Response:** Applicants are advised to seek their own legal and financial advice with respect to all matters related to financial structure of a corporation or non-profit.

**Question 15:** I have a couple of questions. You talk about contractors bringing in HVAC guys and Hydroponic guys, are they going to be researched to make sure they are reputable people and companies:

**DHSS Response:** That will be the compassion center’s responsibility. To hire people that are reputable or bonded.

**Question 16:** Another question I have is considering this is a variable, it’s a plant there are variables, the amount of patients is variable. What happens if the product runs out and the patients can’t be supplied? Do you have a contingency plan?

**DHSS Response:** Unfortunately, no, with the cap of 150 plants, if you are asking if we are going to ask for the import from New Jersey, that just is not an option. Until the program grows to the point where there are several compassion centers open in the state and they can sell to each other, that’s the only way to address that.
Question 17: So if something runs out it just runs out

DHSS Response: Yes ma’am.

Statement from Program Participant (Patient) 18: Hopefully the compassion center will use a staggered process. Move plants in every two weeks. It shouldn’t lead to a shortage.

Question 19: That kind of leads to my question. For the 150 plants, is that like a year or season, where you can harvest and grow again? Once you harvest you are back to your number again.

DHSS Response: That is 150 plants growing at any one time.

Question 20: The other question I had in regards to organic. When it comes to picking a location, usually certified organic produce, the land that you are picking has to be nontreated with chemicals for at least 3 years. Is that going to be your same protocol, and if you are already a certified organic farm, I assume those are two different inspectors.

DHSS Response: DHSS is not going to hold you to that certified organic standard as far as 3 years and no spraying on the property. Just saying when you plant marijuana there will be no applications of pesticides to it.

Question 21: From that point on?

DHSS Response: Right. It is a lower standard then what you operate under as an organic farm.

Question 22: As far as location, is it specifically looking for agricultural or is this considered something like commercial location.

DHSS Response: The Department is under the impression people are probably going to grow it indoors instead of in the fields, pursuant to applicable laws and regulations.

Question 23: That is what I am asking, so it is not restricted.

DHSS Response: Correct, as long as the growing of marijuana cannot be seen from the street.
Question 24: Regarding do you have in mind a certain location where this one compassion center may be able to reach all the demographics between Sussex, Kent, and New Castle? Coming up from Sussex to New Castle that is going to be quite a haul for caregivers and or patient. Hopefully that is going to weigh heavily in favor of certain spots. Lower New Castle, upper Kent county kind of thing.

Statement from Program Participant (Patient): I thought they said it was by population zone, wherever the most amount of people are that is where they wanted to put it.

DHSS Response: A location should be accessible, and is otherwise in compliance with applicable laws and regulations – not near a school and things like that. As far as where you actually place the building, this is a business decision to be determined by the applicant.

Question 25: As far as the sample testing for contamines and potency. If that part of the process is subcontracted that would be at a different location. Are there going to be rules around that subcontractor security, anything like that, and how do we move the marijuana from where it is grown to where it is tested and back? How much will we be able to move it back and forth?

DHSS Response: This question presents two issues. Number one is testing. In the pilot compassion center model, we are expecting that is going to be done by the compassion center. It will take several years for the program to have grown enough where the independent testing center that the law talked about is viable. So we are going to be relying on the compassion center to do its own testing. PART TWO: There is a whole section in the regulations on transportation of Marijuana. You will need to have to have a Bill of Lading from where you initiating from, where you are going to, phone numbers that the police will be able to contact. There is a whole section in the regulations on that.

Question 26: Is there a way to setup a harassment line. I have been harassed.

DHSS Response: I am sorry that is outside the scope of this particular contract process.

Question 27: Quick question, cause you mentioned the strains would be chosen by you guys or whoever.

DHSS Response: The contractors.
Question 28: So I am assuming they will be providing the seeds. Or is that up to us to go out and get the seeds?

DHSS Response: Correct, you will be providing your own seeds.

Question 29: I did not see anything about the disposal of products that are no longer usable. It could be dead plants, molded plants, something of this nature. Are there any regulations concerning the disposal of the unusable?

DHSS Response: The Division of Public Health will amplify the regulations in reference to certification of destruction and inventory adjustment.

Question 30: As far as inventory, if you have a crop of 150 plants and 10 of them die, is that still considered 150 plants even though 10 of them are dead.

DHSS Response: When program agents are onsite if you clearly demonstrate that you lost 10 plants and now down from 150 to 140 plants, the program will validate the loss. Program staff will coordinate the destruction of the material and sign the certification of destruction.

Question 31: How involved will DHSS be in collecting research and keeping it published? I know the program doesn’t have a lot of momentum, but I would like to see DE get as much knowledge and gain as much research to be able to share with other people. To be able to get all our citizens involved whose ailments so they could benefit as well. Does DHSS have any sort of criteria for how much research on how well this works and how it affects people and just getting that word out there medically sort of?

DHSS Response: One of the functions and intent of the independent testing facility is for those services. DHSS is not going to become the warehouse of knowledge as far as what studies or articles physicians should read; it would be very difficult for us to judge the legitimacy of them. The Department should not be responsible for telling a doctor to pay attention to this study and not another study. When the program grows a little more the independent testing facility and information center will be do that.

Question 32: I guess my question is: How much weight is going on the research/ medical value vs the business aspect of it?

DHSS Response: We have positions on staff that are reviewing the applications to make sure that valid patients are getting it. Dr. Ming is located in the same suite as the Medical Marijuana
program, he is the expert in those areas also. Yes, there is quite a bit of emphasis on the patient side of this, not just the business side.

**Question 33:** Does it give what date the state will pick the person?

**DHSS Response:** Initially the Selection process was to begin March 24, 2014, and selection was tentatively April 28, 2014. Below is the amended timeline to allow bidders additional time to review the answer to the questions presented at the pre-bid meeting:

- **4/8/14**  Bid Opening
- **4/9/14**  Selection starts
- **4/30/14**  Vendor Selection
- **5/26/14**  Contract negotiations completed
- **6/30/14**  Contract starts

**Question 34:** For the pilot center you are expecting everything to happen at one location?

**DHSS Response:** Yes, correct.

**Question 35:** If you grow it in one location and dispense it in another, that is not permitted under this RFP?

**DHSS Response:** If they choose to have a separate grow area from customer service, they would have to have the same level of security and surveillance. Yes, that is feasible.

**Question 36:** I wonder about the cost of the product to the consumer, is that something that the state is going to set? Are you going to have some sort of high/low that they can use?

**DHSS Response:** Unfortunately, that is going to be a business decision, based off the compassion center’s capacity to stay in business. If DHSS directed the Compassion Center on how much they could charge, then if they failed it could be attributed to the Department.

**Statement from Program Participant (Patient):** Of the amendments that I got Markell to put though is where it is based on salary and not the price of cannabis, so the compassion center will have to work within that.
**Question 37:** If you have a residential property that has acreage will they be allowed to be considered?

**DHSS Response:** All questions about zoning are outside my expertise. You will need to work with your local community as far as that.

**Question 38:** I will have to clear it with my zoning board and community?

**DHSS Response:** Correct.

**Question 39:** Page 32 says there should be a potential for delivery services for patients that are not able to get to the center. I thought I might provide a delivery service, is that still allowed?

**DHSS Response:** Delivery services for patients would have to be very well structured. Applicants should have a well-developed plan as it relates to delivery services, if contemplated by the applicant.

**Question 40:** The delivery person would have a red card?

**DHSS Response:** There would have to be a Bill of Lading with locations and stops.

**Question 41:** It is just like a patient being stopped, right?

**DHSS Response:** A patient would have 3 oz. he is authorized to have. The delivery person is not considered a caregiver, so he would not be afforded the legal protections that a caregiver has.

**Question 42:** So you wouldn’t want to offer delivery service?

**DHSS Response:** If a Compassion Center wants to provide a delivery service, a clear and concise plan would be required. DPH doesn’t object to the premise, but it would need to be well structured to prevent theft or diversion.

**Question 43:** Since there are already courier services available, is there a way that the courier business could get into the delivery of the product?
DHSS Response: That would be a subcontract situation that DHSS probably wouldn’t support. DHSS does not see itself approving that level of a subcontract job.

Question 44: DHSS is controlling this project; are there any plans in the future for Food and Drug Administration or Tobacco and Fire Arms getting involved in it? Where we will have more people than just you guys knocking on our door?

DHSS Response: This is a two part response. Part one: As it relates to the State of Delaware, the Agency will conduct inspections and oversight. The State of Delaware makes no representations with respect to whether dispensaries will not be prosecuted under federal law or whether inspections will be conducted from the Federal Government. Applicants are advised to seek their own legal advice with respect to this issue. Applicants are further directed to the memorandums issued by the U.S. Department of Justice.

Question 45: In regards to the biannual fee, in situations that we have been in we have lost thousands of dollars whether to weather or stink bugs, or whatever. Are there any protocols in place to look at that?

DHSS Response: No, you would still be responsible for the permit fee if you planned to renew your permit.

Question 46: Does it matter where we grow the plants, indoors or outdoors?

DHSS Response: No, as long as you can get it through the local zoning authority. It needs to be out of the public eye. Someone walking by should not be able to see the production of marijuana. That is in the RFP. How you do that is your choice.

Question 47: Everything that you went through, all that will be posted on the website?

DHSS Response: February 24, this was subsequently revised to be March 11, 2014.

Question 48: Will this panel be making those decisions?

DHSS Response: No
Question 49: Is there some way we can let doctors in DE know that by them filling out this paperwork, that doesn’t mean they have to provide the patients with the medical marijuana? That they are just verifying that what is wrong with you?

DHSS Response: Again that is a little outside the scope of this RFP. I will say that I have prepared a question and answer document for the physicians so they can understand that better. It is not yet on the website.

Question 50: When will that be on the website?

DHSS Response: After I meet with the medical society

Question 51: If someone already has a successful compassion care center in another state and wants to give some money. Is that allowed?

DHSS Response: Applicants are required to list all persons or business entities having 5% or more ownership in the compassion center, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity which owns all of part of the land or building.

Question 52: Will a loan count as over a $5000 investment?

DHSS Response: If the bidder receives a loan, we would want to know the terms and conditions. However, applicants are advised to seek their own legal and financial advice with respect to all matters related to financial structure of a nonprofit.

Questions received prior to the Medical Marijuana RFP Pre-Bid Meeting

Question 53: Under Section 5 of Scope of Services (Page 20 of RFP) – Data Verification Systems, the bidder is required to develop and host a secure computer interface to receive patient and caregiver card data from the department. What system is the state utilizing to generate and store caregiver and registered patient card data? How does the state anticipate patient data will be stored and disseminated to the Compassion Center?

DHSS Response: The program is not committed to any specific platform to disseminate cardholder information. The program is committed to working with the contractor to find the
most suitable solution based on cyber security demands. The program anticipates logging into the Compassion Center’s secure site and uploading a file with the applicable information.

**Question 54:** Will the state follow HIPPAA rules for patient record reviews? Will all MMP patient participants be required to sign a medical records release?

**DHSS Response:** Patients sign a “release of medical information form” currently in the application process allowing DHSS to contact the treating physician for information.

**Question 55:** Does the State of Delaware intent to fund any aspects of the MMP?

**DHSS Response:** The Medical Marijuana Program was initially designed to be self-sufficient; however, with the scope of the program changed, the State General Fund is paying salaries for the program management until the fee revenue is sufficient to cover the expenses.

**Question 56:** The State of Delaware requires the Compassion Center to be operated as a not for profit. How does the State anticipate for the proprietors to be compensated and recover the cost of capital required to set up and operate the Compassion Center?

**DHSS Response:** Applicants are advised to seek their own legal and financial advice with respect to all matters related to financial structure of a non-profit.

**Question 57:** Will 24 hour video surveillance of the grow location be satisfactory for audit purposes, or will the State require access to the grow facility. Any access to the grow location by non-agents of the Compassion Center may introduce or increase the risk of contamination of product and may compromise security measures established to control and monitor the grow location.

**DHSS Response:** Agents of the State will regularly visit all areas of the compassion center, including the grow facility/area.

**Question 58:** The Federal Controlled Substances Act calls for a minimum mandatory jail sentence of not less than 5 years and not more than 40 years for the possession of more than 100 cannabis plants or 100 kilograms of cannabis. Will the State of Delaware provide immunity from Federal prosecution given the required 150 plant and 1500 ounce requirement outlined in the RFP?
DHSS Response: The State of Delaware makes no representations with respect to whether dispensaries will be prosecuted under federal law. Applicants are advised to seek their own legal advice with respect to this issue. With respect to federal prosecution priorities, applicants are further directed to the memorandum of James M. Cole, Esquire, U.S. Department of Justice dated August 29, 2013 and the previous U.S. Department of Justice memorandums.

Question 59: Can the Compassion center be incorporated as an LLC with By-Laws supporting how the entity will be operated in the character of a not for profit entity.

DHSS Response: Applicants are advised to seek their own legal and financial advice with respect to all matters related to financial structure of a nonprofit.

Question 60: Does Section C on page 35 of the RFP preclude a registered compassion center from hiring subcontractors to provide consultation services regarding the cultivation, harvest and dispensing of marijuana if the subcontractors will not be physically handling the plant? For example, so long as a subcontractor does not physically touch the plants, may a registered compassion center pay a subcontractor for consultation on the following: 1)treatment of pests, fungi or disease; 2) proper humidity levels in the grow facility; 3) proper ph levels for optimal plant growth; 4) development of hybrid strains and like issues?

DHSS Response: Subcontractors to provide consultation services are fine.

Question 61: May the Compassion Center retain a subcontractor to maintain or repair any hydroponic, filtration, or irrigation system utilized to grow its crop? May it do so, if the system contains marijuana plantings?

DHSS Response: Subcontractors to provide repair services are fine.

Question 62: Will the agent registry card application be the same application as the caregiver application found on the DHHS website?

DHSS Response: Very close to the same. The Program will receive the information from the Compassion Center as to who is employed with them, and the employee will be responsible for submitting the application and background check.
Question 63: What date will the Compassion Center be required to have medical marijuana available for sale to clients?

DHSS Response: Whenever the compassion center is ready to sell. Once a contractor is identified and the contract is in place, the State medical marijuana program will issue a certificate to operate which will give the compassion center the legal authority to begin growing marijuana on July 1, 2014. The program expects it will take the compassion center 8 to 12 weeks before the marijuana is matured enough to sell.

Question 64: Will the medical marijuana cards provided to cardholders contain bar codes identifying the patient by a bar code?

DHSS Response: Yes, the second-generation cards will have a bar coding strip on the reverse side.

Question 65: If the answer to #64 is in the negative, what, if any, information other than the patient's name will be contained on the card to enable the compassion center to verify patient identity and track a patient's use.

DHSS Response: The identification card will have the patient/caregiver picture, name, address, physical description and a 10-digit alpha/numeric identifier assigned by the program. In the case of a caregiver, the 10 digit identifier of each patient the care-giver supports will be listed on their card.

Question 66: What will be the verification system available to a Compassion Center to confirm with DHSS the authenticity of a medical marijuana card? e.g. a telephone consult or secure website?

DHSS Response: As stated on page 20, section 5 of the RFP, the compassion center will host a secure site that DHSS MMP will log in and upload a file containing the current card information.

Question 67: What will be the verification system available to a Compassion Center to confirm with DHSS that a medical marijuana card is effective and has not been revoked at the time the patient produces it.
DHSS Response: As stated on page 20, section 5 of the RFP, the compassion center will host a secure site that DHSS MMP will log in and upload a file containing the current card information. This information will be updated weekly, or more often in the case of a revoked card.

Question 68: Does the Delaware law contemplate the sale of edible marijuana products? e.g., cookies, brownies, lollipops.

DHSS Response: The program will encourage the sale of tincture, creams and oils, but not edible products.

Question 69: Will vending be an option and if so, what are the guidelines?

DHSS Response: No, the program does not foresee a situation where machine dispensed marijuana would be suitable.

Question 70: Page 5 – “Contract renewal every two years is contingent on executive and legislative action” – What could this be? AND “center performance.” – What are the performance criteria/benchmarks/covenants that will be used to evaluate the contract and determine if it is renewed? What would cause the contract not to be renewed?

DHSS Response: Page 36 & 37 of the RFP discuss the Expiration, renewal, suspension and termination of a contract.

Question 71: Page 13 – “cultivate up to 150 marijuana plants” - How long will this cap stay in place?

DHSS Response: The 150 plant cap is the current guidance. The program has no indication that the cap will change.

Question 72: Page 41 - “Evidence of not-for-profit status” – Can the company meet this requirement by just including in the Bylaws the Title 16 #4919A clause: “The bylaws of a registered compassion center shall contain such provisions relative to the disposition of revenues to establish and maintain its not-for-profit character. A registered compassion center need not be recognized as tax-exempt by the Internal Revenue Service and is not required to incorporate pursuant to Title 8.”
DHSS Response: Applicants are advised to seek their own legal and financial advice with respect to all matters related to financial structure of a nonprofit.

Question 73: What is the cost associated with verifying customer/patients through the Delaware registry system?

DHSS Response: The costs associated with hosting a secure web site is the contractor’s responsibility. If the compassion center contractor needs to call the medical marijuana office to validate a card, there will not be a cost associated with that service.

Question 74: How many patients are currently registered with the program and are eligible to receive medical marijuana?

DHSS Response: The patient count is a fluid figure, and is considered non-FOIA information. For the purposes of planning, the current number would not be very helpful, as it is relatively low, under 100 active cards at this point.