COLLEGE OF SOCIAL SCIENCES
public policy center
UNIVERSITY OF HAWAI'I AT MĀNOA

MEDICAL CANNABIS LEGISLATIVE OVERSIGHT WORKING GROUP
ACT 230, HB 2707, SESSION LAWS OF HAWAII 2016

Meeting Minutes

DATE: Wednesday, August 23, 2017
TIME: 2:00 – 4:00 pm
PLACE: Conference Room 309
State Capitol
415 South Beretania Street

Working Group Members & Presenters in Attendance:
Jose Barzola, Facilitator, UH-Manoa Public Policy Center
Representative Della Au Belatti, Co-Chair
Senator Rosalyn Baker, Co-Chair
Senator Will Espero
Representative Joy San Buenaventura
Carl Bergquist, Drug Policy Forum of Hawai'i
John-Paul Bingham, University of Hawai'i, College of Tropical Agriculture
Christopher Garth, Executive Director, Hawai'i Dispensary Alliance
Wendy Gibson, Drug Policy Forum of Hawai'i/Medical Cannabis Coalition of Hawai'i (alt.)
Brian Goldstein, Manoa Botanicals
Richard Ha, Lau Ola, Dispensary Industry Representative (Hawai'i County)
Karen Kahikina, Department of Transportation, Highway Safety (alt.)
Alyssa "Ally" Park, President, Clinical Labs of Hawai'i
Michael Takano, Pono Life Sciences, Dispensary Industry Representative (Maui County)
Danette Tomiyasu, Deputy Director, Department of Health
Thomas Wills, University of Hawai'i Cancer Center
Greg Yim, MD

Working Group Members & Presenters Participating via Teleconference:
None

I. Introduction of Members

Welcoming remarks made by Jose Barzola followed by brief introductions of Working Group members.

II. Review of Past Meeting Minutes

April 12, 2017 meeting minutes approved with correction identifying Patricia Wilson from Honolulu Police Department. July 19, 2017 meeting minutes approved with correction removing Alyssa Park from attendance.

II. Dispensary Presentation: Cure Oahu

Keith Kamita of Cure Oahu provided brief presentation and answered questions from Working Group members. The presentation slides are available at http://www.publicpolicycenter.hawaii.edu/projects-programs/act230.html

Following Cure Oahu's presentation, Working Group members engaged in the following question and answer session with Mr. Kamita:

Q: When do you expect to start selling?
A: We started growing in September, so we are shooting for December this year.

Q: Are you looking to market things other than dried flower?
A: Yes.

Q: Can you talk a little about the community outreach and education, specifically law enforcement?
A: We have been talking to law enforcement and the medical community about the opioid epidemic, and the question always comes up, what they have to do. I go through with them about how they have to register. I tell them with medical marijuana it's not a prescription.

Law enforcement groups typically want to know what's the law and who do they contact if they need to verify the number of plants.

Q: Will the software systems you're using be able to help with verification of out of state patients?
A: It would be able to do it. Our software would work with BioTrak. I was talking with others about this, on the reciprocity side we need to figure out a way that patients can pre-register, perhaps prior to coming.

Q: I am thinking if we can create a solution where dispensaries are in partnership with DOH that might streamline the process. But I don't know what the software capabilities are.
A: If you make the dispensaries do it you may run into an issue.

Q: Is there a solution to the banking issue that you know of?
A: We're exploring a local solution here in Hawaii but we aren't ready to say yet. Eventually you want to get to where dispensaries can take credit card or cash.

Q: What is your thought on schedule 1 and whether than is going to change?
A: The problem is that schedules 2-5 go through the FDA. Going through the FDA process can go on for many years.

Q: How is hemp being dealt with? Because it is being imported.
A: Hemp products have to be made from the seed or the stalk. Not from the flower, not from the leaves. Sale of hemp is still an issue locally.

Q: In the original law, we did include that if there is a change in scheduling, the law that prevails is our state laws. So, it's an open legal question, and we should move forward as it is an open question. If the State can maintain and assert our regulatory standards we can make the argument that we are marketing and ensuring state products.
A: Many other states have told us we are really strict, but that's good.

Q: We are proponents of getting it out of the controlled substance act rather than rescheduling. What do you think of that?
A: The federal side is the important side right now.

Q: There is a pathway to banking. A credit union guy did tell me he has approached credit union representatives here in Hawaii. But talking to the Washington guy, the credit unions had steep surcharges at $8,000 a month.
A: Canada has some solutions too.

Q: What do you think of what Colorado is doing, re-classifying all of the recreational to medical?
A: I think it is interesting. It is difficult, but I think it is good they are looking at it.

Q: What do you think about the potential location of a dispensary in Waikiki?
A: We are looking around at where the public is and where we can best service them.

III. Department of Health Update

DOH representatives (Danette Tomiyasu, Tami Whitney, Peter Whiticar, Peggy Leong) presented an update on multiple aspects of the DOH Medical Marijuana Program.

Department of Health Report will be posted on the Act 230 website with relevant details on Patient Registry, Dispensary Status, Laboratory Certification, Computer Software Tracking System, and Laboratories.

Patient Registry Program Update

- The efficiency of the program has been greatly improved. Application processing time has gone from 4-6 weeks to 4 days. It has transformed from a paper-based system to a modern, online system.
- See DOH report on Act 230 website for further details.

Questions & Answers from Working Group about Laboratory Certification

Q: What is it going to take to get a lab certified to test manufactured products? The DOH doesn't want people to smoke but no one is certified to test oils, tinctures, etc.
A: The remaining outline contaminant they need to complete is the pesticide analysis. Those studies are ongoing and I believe they are getting close to submitting those to us.

Q: Is there only going to be one lab certified this century?
A: We are verifying the work they are doing but its incumbent upon the laboratories to provide those data to us.

Q: Have you given them a set of requirements? I want to be sure you're giving them appropriate guidance.
A: We communicate with the laboratories frequently.

Q: When do you anticipate another lab is going to be certified?
A: That's a crystal ball question. I can't predict when they will submit those data packages to me. I can assure you that when we get them we turn them around very, very quickly.

Q: Do all of the labs know what needs to be done in terms of testing and manufacturing product?
A: I'm open to any questions they have.

Q: So, if I want to manufacture products today, can you give me a list of what it will be tested for? Is that a handout that you can give them?
A: The requirements are in rules.

Q: But do you have that in a simplified form, versus going through your website and reading pages and pages of rules? Are you making it easier for them to be certified? I'm not hearing they have that process in simplified, easy form.
A: I think I understand your question, but that borders on prescribing what they do. It also assumes I know the manufacturing processes they will employ.

Q: Is it that difficult to transfer the testing from flower product to a lozenge or a tincture.
A: Once they've established their protocol to one matrix, transferring that analytical strategy to a lozenge or tincture.

Q: It doesn't matter to me how the labs do that, it's that they have checklist of what they need to do. It sounds to me like you don't have that checklist.
A: When we do a visit, we go in as lab scientists knowing they are lab scientists as well.

Q: Part of this questioning is that I've heard from patients who aren't smokers, that ask when other products will be online.
A: What they tell me is that they are getting very close. It's the pesticide analysis that is taking the most time.

Q: Seems like we have the cannabinoid profile down, what seems to be a problem are the pesticides.
A: They also need to test for microbiology.

Q: Can you tell us why the microbiology statements have not been tested?
A: They tell us that they will get it to us.

Q: So, it's not your kuleana to help them figure out what they need to test for?
A: I'm not saying that at all. We're not performing the analyses, we're verifying.

Q: There seems to be a disconnect between where the labs may be. From a patient's perspective, we aren't where we need to be. We can't have children smoking. I'm not trying to lay blame, but we know that some of the dispensaries have other products ready to test, and they are waiting on the lab. Is there a collaborative process where you and the labs can come up with a process.
A: We touch base with the labs constantly. We are a regulatory agency. The speed at which it goes. This is not simple stuff. It's not easy. I spend half my day on medical marijuana, and the scope of my responsibilities as state lab director go far beyond that. We can do compliance assistance. Our common goal is to get them where they need to be to provide products.

Q: I'm going to ask it differently. I'll be the nice guy. Have the labs approached you and asked for guidance, or a checklist?
A: Yes.
Q: Have you given it to them?
A: To the best of my knowledge, we have given them what they needed.

Q: Would integrating the Department of Agriculture help with the pesticide aspect?
A: We do all of this type of testing at the state lab, we just don't do medical cannabis.

Q: To be clear, there are not data packages that have been submitted correct? It's not an issue of capacity? They are working on their packages?
A: Yes, we've touched bases with all of the labs this week. The response we get is we're working on it.

Q: Can you let them start and then analyze the product retrospectively?
A: Depends on what level of risk you are ready to accept. As a regulatory agency, usually we don't accept that level of risk. The risk is selling product that has chemical or microbial contaminants that make people sick.

Q: Can we limit that risk if they show that the buds that were previously tested are used to create the concentrate?
A. The operative term is "ingredients" plural. No. No, because you may be introducing unacceptable contaminants with the other materials. Also, things that are not an issue in the buds may be an issue at higher concentrate.

Q: When all of the labs are certified, how many islands will be served?
A: All of them. Because if there's not a lab on the island they can transport.

Q: Can we take the discussion one step further, there are different ratios of CBD and THC. If a concentrate is already cleared, and you're choosing what ratio is put into a pill will it have to undergo separate testing? Can we have clarity on that?
A: The intent behind the rules was to test products prior to packaging. If the manufacturer is doing quality control testing, the verification testing of the final product will still have to be done but the sample size can be smaller.

Q: Can you test products separately before they are combined?
A: I think that's a decent approach. You have the cannabis tested product, and then you test the other aspects. That defines the matrix. If you go that route, the sampling of the final product would be rather small.

There are two issues: (1) certifying the product is safe; and (2) certifying that the product has a certain potency. Labs shouldn't really be responsible for the second part, but we can do it. But when the products are combined, that changes the nature of it. After combining them, we have to test again.

Q: Is there a way that the process can be simplified or streamlines for labs?
A: I will ask them again if there is anything they need for us.

Q: Are oils a straightforward, simple product that you can test today?
A: Can our state labs? No. Because we don't have validation studies. No one has submitted for microbial or pesticides for anything other than plants.

Comments from the Public to the DOH

Comment (M.Rollins): Our lab has worked with the product many years in California. The policy or procedure of working with an ISO accreditor has been much easier process. Also, we have not had any subcommittee meetings to iron out problems. We're doing it independently. There needs to be a bigger gathering, that could solve a lot of problems. Changing ingredients changes the products. It's really about developing good sample prep. The labs need to be trusted for good product prep.

Comment (B.Goldstein): The fundamental flaw in this system is that you are asking the DOH -- who has never tested cannabis -- to certify labs for testing. This is not how it's done in any other state. Instead, other states use testing agencies that are very competent in testing and test it for multiple states and countries to certify their products.

V. Working Group Discussion about Manufactured Products

Update provided by Senator Baker.

Questions & Discussion from Working Group to the Products Subcommittee

Q: Do you want to speak to why sub-combustion is important?
A: This is probably the best way to administer small quantities. It makes sense medically and based on the cannabinoid system.

Q: So, the canister itself is glass or metal but the device can be plastic?
A: As far as I understand it has to be glass or metal.

Q: So, I've been visiting dispensaries and taking pictures, and it is a glass cartridge that can fit into vape pens, but we're not going to call it that.
A: Vaping oils in quality containers seems to be safer.

Chris Cole, Director of Maui Grown Therapies: Vape pens or e-cigarettes are usually made of plastic, which results in some plastic being combusted. The product we are recommending is glass or stainless steel. This will result in no harmful pyrolytic compounds being released into the lungs.

Q: Concerns about sub combustion include the anti-smoking law.
A: We can do specific metered doses, or metered dosing. The goal is to make them simple.

Q: Does the oil smell like weed?
A: Yes, however, less so.

Q: Is there a way that the smell can be taken out of the oil?
A: I think it can be taken away to a large extent, but I wouldn't commit to it being odorless, because some of the compounds that are responsible for the odor also have important therapeutic effects.

Comment: By us adding the language nebulizer or inhaler that trumps the interim rules. We could do a slight modification of the statute but that would take until next year. We are kind of at a place for a recommendation actually. Perhaps at the next working group meeting we can decide on the rules. Is it ok of members of this working group that we propose this language and the DOH reviews it before next month?

VI. Subcommittee Breakout Discussions & Report Back to Working Group

A. Licensing: (Representative Buenaventura)

- There doesn't seem to be any objections to doing a limited number of production licenses. It's a recommendation of the subcommittee.
- But we intend to support the existing dispensary licenses. We are supporting a vertical licensing system, such as what they have in Colorado. We know we need to support current licensing and those would be grandfathered in if we make any changes, but as far as the production licenses, I think that would decrease the cost to dispensaries. We are not currently able to meet the needs.
- We need to know and understand the black market. What we're hoping is that the legal market will be more diverse and salutary so people make that choice.

B. Products Subcommittee: (Senator Baker) See handout on Act 230 website.

VI. Questions and Comments from Public

Comment: We all said all along we weren't going to reinvent the wheel. Good news is that Hawaii passed a law, the bad news is we are still reinventing the wheel. I'm still hearing some marijuana naïve questions about smell and whatnot. I respectfully suggest you visit some states that have instituted recreational marijuana to learn some of these things. We are so far behind the curve.

Comment: I know today's hot topic was the labs. I don't think we all understand, it's a lot of hard work to get validation studies done. There is a method to their madness. Product certification is right around the corner. The real question is how things will be packaged and distributed.

Comment: We have been anxiously awaiting release of a plan for inter-island transport. I also think the law is flawed in that respect. We need the laws to make it possible to ship between islands.

VII. Next Steps & Announcements

The next meeting will be on September 20, 2017, 2:00 pm, room to be announced.

VIII. Adjournment at 4:01pm.