



MEDICAL MARIJUANA LEGISLATIVE OVERSIGHT WORKING GROUP

ACT 230, HB 2707, SESSION LAWS OF HAWAII 2016

Meeting Minutes

DATE: Wednesday, January 25, 2017
TIME: 1:00 PM – 3:00 PM
PLACE: Conference Room 329
State Capitol
415 South Beretania Street

Working Group Members & Presenters in Attendance:

Senator Rosalyn Baker, Co-Chair
Representative Della Au Belatti, Co-Chair
Representative Joy San Buenaventura
Professor Susan Chandler, Facilitator, UH-Mānoa Public Policy Center
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
Richard Ha, Lau Ola, Dispensary Industry Representative (Hawai'i County)
Karen Kahikina, Department of Transportation, Highway Safety (alt.)
Stacy Kracher, APRN/RX
Ally Park, Laboratory Representative
Keith Ridley, Hawai'i DOH, Office of Healthcare Assurance
Scottina Ruis, Hawai'i DOH, Medical Marijuana Registry Program Coordinator (presenter)
Jari Sugano, Parent of Qualifying Patient under the age of 10
Michael Takano, Pono Life Sciences, Dispensary Industry Representative (Maui County)
Thomas Wills, University of Hawai'i Cancer Center
Greg Yim, MD

Working Group Members Present by Phone:

Patricia Wilson, Honolulu Police Department (alt.)
Bill Jarvis, Qualifying Patient over the age of 18

I. Review of 12/14/2016 meeting minutes

Welcoming remarks made by Representative Belatti followed by brief introductions of Working Group members present in person and by phone.

Susan Chandler presented an overview of the agenda and reviewed the December minutes for approval. Working group approved the January 25, 2017, agenda.

Working group approved the December 24, 2016 minutes with the following changes:

- Mr. Michael Takano attended
- Page 4 – AEOS Labs
- Page 5 – Hawaii Medical Board presentation by Dr. Peter Holt; also corrected another name
- Page 6 – The board requires physicians to obtain CMEs in their specialty.

II. Dispensary Presentation: Lau Ola, LLC (Hawaii)

Richard Ha (CEO of Lau Ola, LLC), Tracy Ryan (CannaKids), Autumn Karcey, and Jaclyn Moore provided a presentation on the status of Lau Ola, timeline, milestones, community engagement, and industry challenges. Lau Ola's presentation is available at: <http://www.publicpolicycenter.hawaii.edu/projects-programs/act230.html>

Following Lau Ola's presentation, Working Group members engaged in the following question and answer session with Lau Ola's representatives:

Q: When you talked about pesticide residue, you talked about concerns related to smoking marijuana. What are you learning that could better inform people about the best strain for certain illness and the best dosage?

A: Agree, smoking is not encouraged and pesticides are not healthy for immune-compromised patients. It depends on what type of extraction method is used. But all of those processes require a heating procedure to go from THCA to THC. Lau Ola will use an ethanol extraction method.

Q: Will Lau Ola be using pesticides?

A: The current plan is not to use pesticides. It will depend on SOPs, but aiming to not use pesticides. There are pesticides derived from essential oils that are safe; rarely if ever have they had to use pesticides in seven years.

Q: Have you looked into whether there is a more precise way to administer a specific dose?

A: Yes, we have worked with vaping and are hoping to work with oils because oils last a lot longer. For certain patients like those with PTSD or anxiety, vaping may be better for immediate relief. Combination processes can also be used, i.e. layer vaping with other methods, use of oil, etc.

Q: Do you see any occasions for vaping with pediatric patients?

A: Only if there is severe nausea. What we have found works better is filling a bathroom with vape smoke. When you do a tiny dose it really coats the mouth and hits sublingually.

Q: How soon will Lau Ola be ready to dispense? Has Lau Ola been approved to begin cultivation?

A: It is going to be a while—maybe October 2017.

Q: What is your timeline? Have you broken ground for your production facility yet? Is your timeline implementation plan impacted by your cultivation method or by DOH?

A: We have taken the time up front to plan agricultural aspects of Lau Ola's operations. The construction process is also taking time. We are building our production facility from ground up. Each step can take months. We have not broken ground and will likely do so next month.

Q: What size space do you have available for the projected 3,000 plants that will be grown?

A: We have about 10,000 square feet of cultivation canopy planned.

Q: Is the idea that there will be a pharmacist on-call at all times? Will you train other staff?

A: Patient safety and drug diversion prevention are the most important objectives with having the pharmacist involved. A pharmacist will be available for comprehensive counseling if desired by patients. We will have 23 training videos on CannaKids website available for patients. We are also planning to create CME accredited courses for medical personnel.

To prevent drug diversion, we will have diligent record keeping. We will be handling the distribution as if the product were a schedule 2 drug.

Q: Is the industry and government moving towards canopy cover versus plant count as a means to regulate production?

A: Lau Ola would like to move away from plant count. Kauai has the same plant count and Big Island. We do not know how those numbers were decided. When plant count is used, licensees lose versatility. Canopy cover is also a better measurement to use to calculate how much medicine is needed.

Q: What is the working relationship between Lau Ola, CannaKids, and Technion? Is there a partnership planned with researchers here in Hawaii including UH Hilo's Pharmacy School?

A: Lau Ola wants to collaborate with as many people as possible in terms of research. We want to do as many clinical trials as possible to find out what will be helpful to kids. We began doing trials in California, but we are also conducting trials in Canada. The door is open for partnership. First and foremost we want to get in with our formulations. We know we have some formulas to help specific conditions such as autism, epilepsy, etc.

Lau Ola is actively exploring a partnership with UH Hilo's Pharmacy School. CannaKids is willing to collaborate with the Pharmacy School. We have to see how it develops.

Q: How is Lau Ola bringing blends in?

A: We are not shipping in cannabis. We have 350 different strains, experimenting with different cancer treatment and different formulations using terpenes. We are shipping terpene blends developed in Canada.

III. DOH Monthly Update:

DOH representatives (Keith Ridley and Scotti Ruis) presented an update of the two parts of the DOH Medical Marijuana Program: (1) the Medical Marijuana Patient Registry Program; and (2) the Dispensary Program.

DOH Dispensary Update:

- February 1, 2017: DOH anticipates going live with State's BioTrack tracking system. Licensees will be able to link into the system. Continued training with DOH staff and licensees are scheduled for January 26, 2017, and January 27, 2017, respectively. A working computer tracking system is one of the criteria that must be met to allow for notice to proceed with cultivations to be issued.

- Short window to test and check connectivity between state and licensee's system (prior to Feb 1).
 - Live system will allow DOH to issue cultivation permits.
 - Four licensees have requested final inspections with one inspection to occur on January 30, 2017, and others to be inspected after February 1, 2017.
 - If inspections go well and tracking system is operational, licensees can receive their notices to proceed and cultivation may begin.
- Phases are not sequential. Other processes that are going forward:
 - Finalizing interface between tracking system and patient registry;
 - Ensuring sale limitations are working within seed-to-sale tracking system; &
 - Certification of labs (3 labs have expressed interest; DOH has received applications from two entities; labs will need to obtain NED certificates; State lab Division is taking leadership role in certification of labs).
 - Throughout phases of work, DOH will be conducting inspections of dispensaries

DOH Patient Registry Update:

- As of December 31, 2016, there were 15,334 registered patients.
- 102 physicians and 7 APRNs are providing certifications to registry patients
- DOH has a 5 business day application turn-around for certifying patients.
- DOH has been able to work through their backlog with approved overtime.

Q: There are concerns about concentrations and consistency of products. Is there any discussion with DOH about the lab testing standards and where the standards are coming from?

A: Great question. We will ask the state's lab director to attend next meeting.

Q: Can DOH lab representatives and subcommittee members meet and not wait until next month?

A: Yes.

Q: Will individual patients be allowed to test their medicine at certified labs?

A: This request has come up. The concern is that the statute does not provide for patients to test their medicine at the certified labs. Authorizing language would need to be added to the statute.

Q: Lau Ola is trying not to use any pesticides. The lab is looking at thousands of pesticides. Can the scope of pesticides being tested be narrowed down?

A: We are continuing to ask licensees about their process to understand what pesticides will be used. We will begin to catalog what is being used. This question is better deferred to lab entities.

Q: Can you find out what's being used in the community and start with that rather than starting with thousands of pesticides and then narrowing down?

A: Yes, we could.

Q: Have you set internal target dates for interface between the patient registry and the seed-to-sale tracking system and certification of labs?

A: Final Statement of Work was sent out and we are expecting signatures soon on documents related to the registry and tracking system interface. The deadline set for response is eight weeks. Labs are a little more difficult to set a date on.

Q: Can you elaborate on the potential delays with the seed-to-sale tracking system?

A: From a contractual perspective, we do not anticipate delay as both parties have come to an agreement.

Q: Are there any consequences if the eight weeks go by and the vendors are not ready?

A: At this point the interface has to get done. We have not designed a plan B.

Q: Would you let it go back to the dispensary to track?

A: There are two required parts to the statewide seed-to-sale tracking requirement: tracking product and verifying patients on the registry. The interface has to occur for requirements to be met.

Q: When you say you are working with another contractor, is the state bound to a particular contractor?

A: No, but we would have to show a faster provider.

Q: Regarding the patient registry, are you seeing any change in trends related to caregivers or grow sites?

A: Caregivers are decreasing. We have about 8% identifying caregivers now. Earlier in the program we had around 15%. What we are seeing is the stacking cards or multiple patients using the same grow site location. It is unclear to us whether people are in control of those grow sites as they claim to be on their application. All of the other statistics are pretty steady.

Q: Does UH have to be certified as a lab?

A: Yes, they have to be certified.

Comment by Dr. Bingham: UH will be applying for DEA certification/federal license.

Q: The law is silent on whether dispensaries will start with cuttings, clones, or fully mature plants. Are there restrictions in the state law that keep dispensaries from starting with a fully vegetated plant or a flowering plant?

A: No. DOH anticipates dispensaries will have plants at different stages of maturity.

IV. Subcommittee Reports

a. Overall: Representative Belatti is working on the Working Group's draft report for the Legislature that she hopes to be able to circulate.

b. Education Subcommittee: Ms. Kracher reported that the subcommittee has met twice with good participation. Key discussion points were on recommendations to increase funding, identify and establish committee and prioritize needs. Decisions were made on who needs to be educated. Substance abuse prevention and education. Ideas were shared on who can do trainings. Dispensaries have a lot of information to share. There is an upcoming expo with other CE trainings coming up in February. We looked at not trying to re-create information. Like the "Good to Know" information from Colorado. Also, from Berkeley on chemical impairment rating. Discussed potential guest speakers.

i. Please add upcoming trainings to website under new link called "Education"

- c. Patient Issue Subcommittee: Mr. Bergquist reported that the Patient Subcommittee met earlier today. Many of the issues we are hearing about touch on patient concerns. Pesticides for example, relates to keeping cost down. Subcommittee is going to prioritize what we want to pass this session. Some of the issues considered include protecting card holders from discrimination by employers and expanding interisland transport and travel of patients.
- d. Product Subcommittee: Mr. Takano reported that this subcommittee has met twice. The subcommittee has started with a review of existing laws. The first involves manufactured medical marijuana products. Existing definitions are very limiting at this stage. We need to seriously explore and discuss soon. Definitions, such as transdermal patches versus transdermal devices. I believe that transdermal devices is the proper term.

Paraphernalia needs to be addressed, the law is confusing and limiting. I would like to get this committees intent on vaporization. If we force patients to fend for themselves, we are putting patients in a difficult situation.

The final topic is related to advertising. Dispensaries are not allowed to advertise, but ancillary industries are. The pharmaceutical industry can advertise directly to public and present in a “fair and balanced” manner the benefits and contraindications of different products.

- e. Working Group Discussion:

Senator Baker commented that we are really looking at how to better enforce the prohibitions and regulations spelled out in the law and what we allow dispensaries to do needs to better defined. Because dispensaries are closed facilities, marketing within the dispensary may be okay, but that is not the priority right now. As a Working Group, we need to take all of these issues and begin to work through them but lower our expectations about what is going to come out of this session until we get some experience with the setup we currently have.

Mr. Takano concurred that industry needs clearer definitions. We know that logos are not allowed to be sold, but can they be given out?

Representative Belatti commented that Act 230 does not prevent dispensaries from giving out information to a patient and it was not the intent that providing information to a patients would fall into advertising that is prohibited by Act 230.

Mr. Takano asked whether education is only for the patient or prospective patients.

Subcommittee reports will be circulated by co-chairs.

VII. Questions and comments from public

Comment: Representative of Steep Hill lab introduced himself and explained that Steep Hill lab has been DEA certified, will have the capability to test individual patients’ products, are ready ready to work with dispensaries, and would like to be on the Working Group’s laboratory subcommittee.

Comment: Not sure why the Legislature decided not to allow branding. Branding assists patients in knowing which products worked best for them. Patients need name recognition to know they are getting consistent, safe products.

Comment: Testing for patients is essential. Delays are fine for well people but are not good for sick patients.

Comment: PharmLabs Hawaii representative offered their time to be on lab subcommittee. PharmLabs is hoping to submit final review to DOH on Monday for their lab which will be located on Maui. Narcotics inspection will be scheduled in the next two weeks. Agree that testing for patients is vital. Explained that planned lab will provide terpene testing.

Comment: Eight licensees have come together to form Hawaii Educational Association for Licensed Therapeutic Healthcare (HEALTH). HEALTH will streamline communication with government and address issues common to all licensees.

Question: Is autism going to be added to the list of diagnoses for registry? Can patients with mobility issues have someone assist them onto the dispensary property and into the dispensary?

VIII. Next Steps & Announcements

Representative Belatti explained the next working group meeting will be held sometime between February 23rd to March 1st. The April meeting will be held on April 12, 2017, with the possibility that the meeting is held on Maui.

Ms. Sugano clarified that sales could not occur until three things happened at the DOH: (1) BioTrack system is operational; (2) registry interface is established; and (3) laboratories are certified.

Mr. Garth announced the upcoming Hawai'i Cannabis Expo on February 10-12, 2017, at the Neil Blaisdell Exposition Hall. Part of the Expo will include CME opportunities for healthcare professionals.

IX. Adjournment

The next Task Force Meeting is TBD.