

Medical Cannabis Legislative Oversight Working Group
Act 230, HB 2707, Session Laws of Hawaii 2016

Department of Health Report
August 23, 2017

1. Registry Update:

See DOH Website at:

<http://health.hawaii.gov/medicalcannabisregistry/submenu/program-statistics/>

- a. 18,004 registered patients as of July 31, 2017.
- b. 413 patient increase from June 30 (average 3% increase).
- c. The Registry receives an average of 1,700 applications per month.
- d. The turnaround time for issuing 329 cards is 4 business days.
- e. There has been no perceptible spike in applications since the 2 dispensaries opened; however, it is too soon to tell whether there will be an increase as more retail locations open.

2. Dispensary Status:

- a. Maui Grown Therapies and Aloha Green opened their retail dispensary locations on August 8 and August 9, respectively. Maui Grown Therapies chose to use a soft opening approach by opening for limited hours and seeing patients on an appointment basis only. Aloha Green opened for business on August 9 for all patients on a first come, first served basis.
- b. As of 9:30 a.m. today, 3,632 patients or caregivers purchased 4,087 items of cannabis flower products. A total of 12,105 grams were purchased which is roughly equivalent to 26 pounds and 11 ounces.
- c. Cure Oahu was provided a Notice to Proceed to Acquire and Cultivate on July 28, 2017. A second inspection of their initial retail location is anticipated to be scheduled in September upon their request.
- d. Manoa Botanicals' first retail location is scheduled for a pre-retail inspection in September, 2017. Assuming everything is in compliance and the products are approved by a lab, a pre-opening retail inspection will be scheduled upon their request.
- e. Production center and retail center inspections continue upon request of the dispensary, as well as on an unannounced basis.
- f. Summary description of inspection phases are attached (inspections 1, 2, and 3).
- g. Ongoing meetings with the dispensaries continues. Next meeting is Friday, August 25th to discuss the interim Administrative Rules and operational issues.

3. Laboratory Certification Status - Please refer to Summary provided by DOH State Labs Division.

- a. Steep Hill Labs received provisional certification on July 31, 2017 to test flower products.
- b. Certification to test derivative products is pending.
- c. Submission and review of validation studies for the remaining labs continue.
- d. At the end of July, a Colorado dispensary recalled products due to pesticides being found in the products. *Please see attached article.*

4. Computer Software Tracking System

a. Registry integration:

- i. Integration of the computer software tracking system provided by BioTrackTHC integrated successfully with the Registry System and the application interface provided by Hawaii Information Consortium.
- ii. Any glitches or programming issues were addressed via coordination and monitoring by the Dispensary Program. Telephone contact took place with Maui Grown Therapies and Aloha Green personnel throughout the go-live and retail opening process.
- iii. Post opening inspections and consultations have occurred on a formal and informal basis to resolve the following issues:
 1. Entry into retail locations by patients/caregivers under the age of 21 years old.
 2. Registry cards renewal: Overlap of current and newly issued card when the card was renewed within the last 60 days.

b. Laboratories

- i. Steep Hill credentialed and entering results. Batches that are tested and pass are released for transport to the retail dispensing location.
- ii. Other labs are set-up in software tracking system in test environment.

5. Protocol for Inter-Island Transport for Lab Testing

- a. Protocol developed. Currently reviewing based upon feedback from licensees, labs, and stakeholders prior to publication and general distribution.

6. Medical Cannabis Update Newsletter: published August 23, 2017.

**Medical Cannabis Dispensary Status
as of August 22, 2017**

County	Licensees	Inspections	Production Centers		Retail Locations		Notes
			1	2	1	2	
Hawaii County	Hawaiian Ethos	Inspection 1: Inspection 2: Inspection 3:	8/8/2016	No plans	8/8/2016	8/8/2016	Proposed inspection #2 of production and retail centers in Spring 2018
	Lau Ola	Inspection 1: Inspection 2: Inspection 3:	6/30/2016	No plans	12/19/2016	3/23/2017	Proposed inspection #2 of production and retail centers in Spring 2018
Honolulu County	Aloha Green	Inspection 1: Inspection 2: Inspection 3:	6/21/2016 1/20/2017	6/21/2016 5/2/2017	8/26/2016 5/26/2017 8/7/2017	No Plans	On-Going regulatory inspections of PC #1 and PC #2. Retail 1 open.
	Cure Oahu	Inspection 1: Inspection 2: Inspection 3:	8/29/2016 5/25/2017	No Plans	8/26/2016 9/17	No Plans	PC #1 issued Notice to Proceed to Cultivate on July 28, 2017.
	Manoa Botanicals	Inspection 1: Inspection 2: Inspection 3:	6/14/2016 2/8/2017 NA	6/14/2016 6/20/2017	6/9/2016 9/17	No Plans	On-Going regulatory inspection of PC #1.
Kauai County	Green Aloha	Inspection 1: Inspection 2: Inspection 3:	7/27/2016 5/15/2017	No Plans	7/27/2016	No Site Yet	PC #1 - received copy of Certificate of Occupancy 6/20/17. NTP to cultivate issued 6/20/17.
Maui County	Maui Wellness	Inspection 1: Inspection 2: Inspection 3:	6/7/2016 3/30/2017 5/23/2017	6/7/2016 5/23/2017 5/23/2017	7/13/2016 5/19/2017 8/4/2017	5/24/2017	On-Going regulatory inspections of PC #1 and PC #2. Retail 1 open.
	Pono Life Sciences	Inspection 1: Inspection 2: Inspection 3:	7/13/2016 2/10/2017	No Plans	8/4/2017	No Plans	On-Going regulatory inspections of PC #1

See page 2 for summary description of each inspection.

Dispensary recalls medical marijuana concentrates because of pesticide residues

POSTED 12:27 PM, JULY 24, 2017, BY SARAH SCHUELER, UPDATED AT 12:28PM, JULY 24, 2017



DENVER — A dispensary is voluntarily recalling all of its medical marijuana concentrate products because they could contain unsafe pesticide residues.

The City and County of Denver Environmental Health issued the alert about the products made by Buddies Wellness and sold at La Bodega dispensary.

The recall applies to medical marijuana concentrates with the OPC code of 403-00364, sold by La Bodega at 1270 W. Cedar Ave. before Friday.

During a Denver Department of Environmental Health investigation, residual levels of myclobutanil were found in samples of marijuana concentrate products.

Myclobutanil is a pesticide the Colorado Department of Agriculture has determined cannot be used on marijuana in the state.

There are no reports of illness and the possible health impacts are unknown. However, short- and long-term health impacts might exist.

Anyone with products that fall under the recall should dispose or return them to the store.

Anyone who has consumed one of the products and has concerns about health should contact a doctor, the DEH recommends.

La Bodega can also be reached at reactionhomes@gmail.com for more information about the recall.

Anyone with questions about recalled products or pesticide residues in marijuana products can contact the DEH Public Health Inspections division at pcomments@denvergov.org or 720-913-1311.

**Medical Cannabis Lab Certification Status
as of 8/22/17**

	Lab A	Lab B	Lab C
Current Status and Validation Studies		DOH conducted on-site audit on 7/26 Microbiology & 7/28 Chemistry: Provisional Certification granted 7/31/17.	Lab indicated maybe submitting pesticides valid. study on Sept 2017.
Chemistry Validation Studies			
THC, cannabinoid profile			
Plant:	Lab submitted, DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Lab submitted, DOH accepted
Concentrates:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Topicals:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Heavy Metals			
Plant:	Lab submitted, DOH accepted	Lab submitted, DOH accepted	Lab submitted, DOH accepted
Concentrates:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Topicals:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Pesticides			
Plant:	Lab submitted, DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Topicals:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Solvents			
Plant:	Lab submitted, DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	<i>Not submitted</i>	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Moisture Content			
Plant:	<i>Not submitted</i>	Lab submitted, DOH accepted	Lab submitted, DOH accepted
Microbiology Validation Studies			
Total viable aerobic bacteria			
Plant:	Lab submitted, DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Total yeast and mold			
Plant:	Lab submitted, DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>

**Medical Cannabis Lab Certification Status
as of 8/22/17**

	Lab A	Lab B	Lab C
Total coliforms			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Bile-tolerant Gram-negative bacteria			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
E. coli			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Salmonella spp.			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Aspergillus fumigatus, A. Flavus, A. niger			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Mycotoxins			
Plant:	Lab submitted. DOH reviewed. DOH requested additional lab info. DOH awaiting lab response.	Lab submitted, DOH accepted	Not submitted
Concentrates:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Proficiency Testing (PT) Results	None received	Performed for micro, but not official participant. Will officially participate next round	None received
ISO Certification	Perry Johnson conducted multiple ISO audits. Auditor conducting audit with amended checklist which will encompass compliance with HAR 11-850. Audit conducted July for Heavy Metals and Micro.	Perry Johnson completed 7/31 onsite audit with different inspector from the one auditing another local lab.	ISO certification visit pending

**Medical Cannabis Lab Certification Status
as of 8/22/17**

	Lab A	Lab B	Lab C
DOH On-site Audit	Prelim visit done; awaiting validation studies to determine need for follow-up onsite visit	DOH onsite audit conducted 7/26 Micro & 7/28 Chemistry	Requested after move is complete
Additional Comments	Staffing: Possible issues with 1 Chemist, 1 QA, 1 part-time Microbiologist	Staffing: Sufficient	Staffing: Sufficient