

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

Department of Health Report
November 21, 2017

1. Patient Registry and Operations Update:

See DOH Website at:

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

- a. Patient Count: 19,444 registered patients as of November 20, 2017; maintaining an approximately 3% increase each month during 2017;
- b. Monthly Applications: Approve an average of 1,734 applications per month from January 2017 to current, or about 11 applications an hour; this includes new applications and renewals; Registry received 1,147 applications from 11/1 – 11/19; approved 741 as of 11/17;
- c. Application Turn-around: Ten (10) business days up from seven (7) last month;
- d. Staffing: Six (6) positions; 3 vacant. One (1) new Office Assistant position being established for 1/1/2018 effective date;
- e. Patient Priorities: Continue to expedite processing for minors, patients with cancer diagnoses, and patients in hospice care; turnaround applications same day for hospice or by next business day for other (2-days max); approved 45 patients in these categories from 11/1 – 11/17, with 20 pending from 11/17 to 11/20;
- f. IT System Enhancements: Developing a system through HIC for managing registered user change requests. Change requests are currently submitted in hardcopy form and updated manually. Registry receives average of 61 change requests per month and process 45. Approximately 60% of one person's time is on processing and/or returning incomplete change requests;
- g. Petition on New Medical Conditions: Expect to submit recommendation on ALS and General Anxiety Disorder (GAD) to Director of Health; decision by 12/20, ninety days following public hearing, to approve, deny, or defer for more information. All information provided at the public hearing and through the submission of the written testimony has been reviewed/searched. Bibliography research included PubMed/Medline for reviews on human preclinical and clinical trials on patients/individuals diagnosed with GAD or ALS. Randomized clinical trials which were not included in the published reviews were identified and reviewed. Excluded were non-intervention trials, surveys, and opinion editorials.

2. Dispensary Licensees Update:

a. Hawaii Island:

- i. Lau Ola: Received permits for rebar and footings for cement pad foundation;
- ii. Hawaiian Ethos:

1. Awaiting name of new CEO; CEO unexpectedly passed away; does not impact license;
2. Pad foundation, framing, plumbing, and electrical complete; construction continuing;
- b. Kauai: Plans for retail store submitted to County for approval;
- c. Inspections Conducted: Over 100 inspections since June 2016; 329 staff days.

3. Industry Operations Update: Monthly, non-cumulative

Summary of Operations	September 2017	October 2017	November 1-19, 2017
Total Customer Encounters	4,213	8,037	4,951
Unduplicated Patient Count	1,119	1,214	496
Total Gross Sales Revenue	\$287,699	\$573,283	\$348,711
Total Items Purchased	4,803	15,231	8,958
Total Weight of Sales	14,061.36 g (31 lbs.)	28,526.32 g (63 lbs.)	20,411.66 g (45 lbs.)

4. Laboratory Certification Status:

- a. Onsite audit scheduled on 12/13/17 for chemistry and microbiology for the 3rd private lab; validation studies accepted by SLD for plants and concentrates (oils);
- b. Refer to attached Status Summary provided by DOH State Labs Division.

**Medical Cannabis Lab Certification Status
as of 11/20/17**

	Lab A	Lab B	Lab C
Current Status and Validation Studies	DOH conducted on-site audit on 10/13 Microbiology & 10/12 Chemistry. Provisional Certification granted 10/16/17 for plant matrix.	DOH conducted on-site audit on 7/26 Microbiology & 7/28 Chemistry: Provisional Certification granted 7/31/17. Provisional certification granted for additional Pesticides Matrices (Concentrates and Tinctures) on 9/19/17.	Lab indicated maybe submitting pesticides validation study on Dec 2017. On-site audit scheduled for Dec 2017 for Chemistry and Microbiology.
Chemistry Validation Studies			
THC, cannabinoid profile			
Plant:	Lab submitted, DOH accepted	Lab submitted, DOH accepted	Lab submitted, DOH accepted
Concentrates:	<i>Not submitted</i>	Lab submitted, DOH accepted	Lab submitted Oils, DOH accepted
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	Lab submitted Oils, DOH accepted
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 accepted	Lab submitted, DOH accepted	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	Lab submitted 9/15, DOH accepted.	<i>Not submitted</i>
Tinctures:	<i>Not submitted</i>	Lab submitted 9/13, DOH accepted.	<i>Not submitted</i>
Topicals:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Solvents			
Plant:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Concentrates:	<i>Not submitted</i>	Lab submitted, DOH accepted	<i>Not submitted</i>
Moisture Content			
Plant:	Lab submitted, DOH accepted	Lab submitted, DOH accepted	Lab submitted, DOH accepted
Microbiology Validation Studies			
Total viable aerobic bacteria			
Plant:	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Total yeast and mold			
Plant:	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges:	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Total coliforms			

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Plant	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Bile-tolerant Gram-negative bacteria			
Plant	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
E. coli			
Plant	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Salmonella spp.			
Plant	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
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>
lozenges	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Aspergillus fumigatus, A. Flavus, A. niger			
Plant	Lab submitted, DOH accepted	Lab submitted, DOH accepted	DOH accepted, Lab requested on-site audit for 12/13.
concentrates	<i>Not submitted</i>	Lab submitted, DOH accepted	<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 accepted	Lab submitted, DOH accepted	<i>Not submitted</i>
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>
lozenges	<i>Not submitted</i>	<i>Not submitted</i>	<i>Not submitted</i>
Proficiency Testing (PT) Results	To analyze Emerald PT study for Fall 2017.	To analyze Emerald PT study for Fall 2017.	Emerald PT Spring 2017 completed for micro, potency and heavy metals.
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 on-site audit with different inspector from the one auditing another local lab.	ISO certification visit pending.
DOH On-site Audit	DOH conducted on-site audit on 10/13 Microbiology & 10/12 Chemistry.	DOH on-site audit conducted 7/26 Micro & 7/28 Chemistry	DOH on-site scheduled for Dec 2017.
Additional Comments	Staffing: Sufficient	Staffing: Sufficient	Staffing: Sufficient
Notes:			
Concentrates Include Oils and Oil Extracts Topicals include Ointments and Skin Lotions			