

Medical Cannabis UPDATE

Ensuring Hawaii's qualified patients have access to safe medical cannabis products through an efficient system of responsible, licensed dispensaries

Vol. I, No. 4

A Publication for Registered Patients and Caregivers

July 2017

Demystifying the Dispensary Approval Processes

Hawaii's licensed medical cannabis dispensaries continue to diligently work on meeting the requirements of Hawaii laws and rules to enable them to sell their products to qualified patients or primary caregivers.


This issue explains the different types of inspections required of licensed dispensaries to operate production centers and retail dispensing locations. It also provides information on the requirements for private laboratories to attain certification to test the cannabis products before they are sold by the dispensaries.


The requirements for the dispensary licenses are based on the Hawaii Revised Statutes and the Hawaii Administrative Rules.


A retail dispensing location shall not be at the same location as a production center. Considerations for determining whether locations are the same include proximity and whether there are separate buildings, entrances, and parking areas, according to Hawaii Administrative Rules, Section 11-850-31.

The requirements for the laboratories are based on Hawaii law, Hawaii Administrative Rules, best practices from other states, and international laboratory standards.

Production Center Inspection Process

1  **Inspection #1: Location of Production Center**
Medical cannabis production centers must comply with all county zoning ordinances, rules, and regulations. In addition, HRS 329-D states that medical cannabis production centers may be located in areas zoned for agricultural production. Production centers cannot be located within 750 feet of playgrounds, schools, or public housing complexes. If a production center meets these requirements, the Hawaii Department of Health will issue a written "Notice to Proceed" with construction.

2  **Inspection #2: Pre-Production**
According to Hawaii Administrative Rules 11-850-32, at least 30 days before producing or manufacturing any marijuana or marijuana products, a licensed production center, dispensary licensee must provide the Hawaii Department of Health with their address, tax map key number, and a copy of the premises title or lease of the proposed production center location. In addition, the Department of Health must inspect the premises to determine the dispensary's ability to comply with the requirements of HRS 329 and HAR 11-850 (requirements include security features and deploying a seed-to-sale tracking system, and connectivity to the state's tracking system). After a licensee meets this requirement, the Department of Health will issue a written "Notice to Proceed" with possessing, planting and harvesting marijuana inventory.

3  **Inspection #3: Pre-Manufacturing**
Hawaii Administrative Rules 11-850-32 also applies to this inspection. When a licensee meets the requirements, the Hawaii Department of Health will issue a written "Notice to Proceed" with processing, or manufacturing marijuana or manufactured marijuana product.

What Goes into Laboratory Certifications?


All medical cannabis products sold at dispensaries to qualified patients must undergo rigorous testing. The Hawaii Department of Health's State Laboratories Division is responsible for ensuring private laboratories are capable of conducting these tests.

Some of the labs can be certified to conduct certain tests; while other laboratories will be certified to conduct other tests. Each laboratory must pass four key areas:

1. Demonstrate ability to test for the presence of a number of items in the medical cannabis.
2. Show their proficiency testing results.
3. Meet International Standards Organization (ISO) certification requirements.
4. Pass an onsite audit by the Hawaii Department of Health.

The laboratories must submit validation studies that document their test for the following:

- Cannabinoid profile (including THC), compound that are considered "active ingredients"
- Heavy metals (arsenic, etc.)
- Pesticides
- Solvents
- Moisture content
- Microbial contaminants
 - Total viable aerobic bacteria
 - Total yeast and mold
 - Intestinal bacteria and pathogens
 - Total coliforms (bacteria found in soil)
 - Bile-tolerant Gram-negative bacteria
 - E. coli (all strains) (bacteria)
 - Salmonella spp.

- Aspergillus fumigatus, A. Flavus, A. niger (dangerous molds that can cause infection and disease); and
- Mycotoxins (toxins produced by molds) 

Readying Retail Sites

Retail Center Inspection Process

1



Inspection #1: Location of Retail Center

Medical cannabis dispensaries must comply with all county zoning ordinances, rules, or regulations. Retail centers cannot be located within 750 feet of playgrounds, schools, or public housing complexes. If a retail center meets these requirements, the Hawaii Department of Health will issue a written "Notice to Proceed" with construction.

2



Inspection #2: Pre-Retail

At least 60 days before opening a licensed retail dispensing location for business, a dispensary licensee must provide the Department of Health with the address, tax map key number, and a copy of the premises title or lease, as applicable, of the proposed location of that retail dispensing location and allow DOH to inspect the premises to determine the dispensary's ability to comply with the requirements of HAR 11-850 and HRS 329D. After meeting the inspection requirements,* the Department of Health will issue a written "Notice to Proceed" for transferring marijuana or manufactured marijuana products to a retail dispensary location.

3



Inspection #3: Retail

The requirements of HAR 11-850-33 and HRS 329D also apply to this inspection. When a licensee meets the inspection requirements, the Department of Health will issue a written "Notice to Proceed" with dispensing/selling marijuana or manufactured marijuana products to qualified patients or primary caregivers.

** Note: The inspection requirements at this point include much more than the address, TMK, title/lease, etc. Inspection includes but is not limited to ensuring employees are trained and knowledgeable in laws and protocol to ensure patient safety and confidentiality, product labeling and security. In addition, the inspection checks if all retail security features and the tracking system are operational and properly used by appropriate personnel.*

New Law Gives More Flexibility for Qualifying Patients and Caregivers

Governor David Ige signed into law a comprehensive bill that gives more latitude to qualifying patients to grow and test medical cannabis and expand its use for other health conditions. The law went into effect on June 29, 2017.

Through the legislative process, Hawaii now added four debilitating health conditions for which medical cannabis can legally be used to alleviate symptoms. The four health conditions are: epilepsy, lupus, multiple sclerosis, and rheumatoid arthritis.

It is important to note that the Hawaii Department of Health's petition process also allows the community to submit evidence-based data for review to determine

if these are qualifying health conditions for medical cannabis use. Two that have been recently submitted are amyotrophic lateral sclerosis or ALS, a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord, and Generalized Anxiety Disorder, which is characterized by persistent and excessive worry about various things.

The new law creates more flexibility for the qualified patients and caregivers:

- Under the new law, patients can also grow as many as 10 plants in any stage of development to ensure an "adequate supply" of medical cannabis. Previously, those who grew their own

medical cannabis could have up to seven plants. (A single location cannot be used to cultivate medical cannabis for no more than five qualifying patients.)

- This new law also allows qualifying patients and caregivers to access private laboratories to test their own medical cannabis.
- The new law also extends the right for designated caregivers to continue to grow medical cannabis for qualified patients from 2018 to 2023. This was originally scheduled to sunset at the end of 2018. In addition, a single location cannot be used to cultivate medical cannabis for more than five qualifying patients after 2023. 