

# Medical Marijuana UPDATE

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

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## Seed-to-Sale Tracking System: Another Major Step Forward to Improve Patient Access

**G**ood news for registered medical marijuana patients and caregivers! The Hawaii State Department of Health reached a new milestone to advance the dispensary system for registered patients by implementing its seed-to-sale tracking system and two dispensaries have already begun to use the system.

Earlier, the state had reviewed a number of proposals for a comprehensive seed-to-sale tracking system that meets the state's statutory requirements.

In November 2016, the Department of Health executed a contract with BioTrackTHC to develop, deploy, and maintain the state's software tracking system to monitor Hawaii's eight licensed dispensaries as they grow, manufacture and sell medical marijuana products to qualified patients registered with the state.

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**Our priorities are patient safety, product safety, and public safety.**

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"A software tracking system is a vitally important component in the medical marijuana dispensary system, so it was important to take the time to find the right partner who could support our priorities of patient safety, product safety, and public safety,"



*Prior to the seed-to-sale tracking system going live on Feb. 1, representatives from all eight licensed medical marijuana dispensaries attended a training session led by BioTrackTHC's Executive Vice President of Government Solutions Daniel McMahon. Live streaming allowed more representatives to participate online.*

said **Keith Ridley**, Chief of the Office of Health Care Assurance with the Hawaii State Department of Health. "We're confident BioTrackTHC will help us move the dispensary system forward to meet the needs of Hawaii's qualified registered patients."

In addition to Hawaii, BioTrackTHC's government software tracking system, also called tracking and traceability software system or seed-to-sale tracking system, is currently being used or in the process of

being implemented in Washington, Illinois, New Mexico, New York, Puerto Rico and California. BioTrackTHC was named Software/Tech Company of the Year for the 2016 Marijuana Industry Awards.

In late January, BioTrackTHC conducted a refresher training session on the software for Department of Health inspectors. The Department of Health also arranged for representatives of BioTrackTHC to lead a sep-

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# Seed-to-Sale Tracking System Improves Patient Access

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arate training session for the eight dispensary licensees to prepare for the Phase I rollout of the system, which went live on Feb. 1, 2017.

## Accounting for Every Seed, Stem, Leaf and Flower

BioTrackTHC's seed-to-sale tracking and traceability system accounts for every leaf, stem and seed that is grown and then either destroyed or harvested, processed, and sold by the licensee.

**Each plant is tagged with a unique identifier number.**

Each plant in the production centers of the licensees is tagged with a unique identifier number that is recorded in the system. No assigned number is repeated or duplicated within the tracking system, both for the individual dispensary and the entire system for all dispensaries, so that no plant can be confused with another.

The code stays with a plant for its entire life. Each plant is tracked at different stages of cultivation, from seed to flowering, and then to either harvest or destruction. Licensees have the option of starting their operations with mature plants.

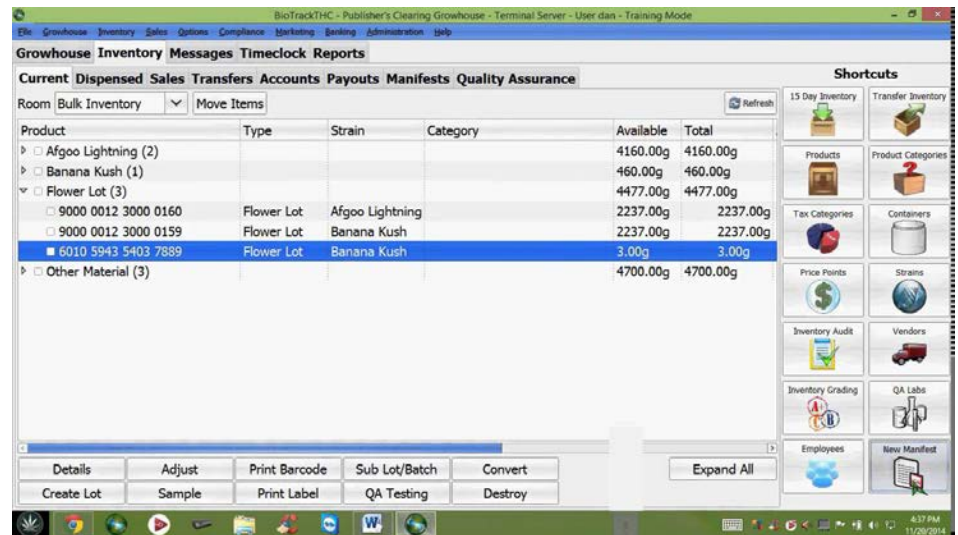
## Preventing Drug Diversion

A search can be conducted by the plant's code or strain. It is a robust system designed to prevent and detect if marijuana or manufactured medical marijuana products are diverted away from their original, legitimate purpose of use by patients.



# BioTrackTHC™

The Only Seed to Sale Solution



**Illustrative Sample BioTrackTHC Screen Shot:** The tracking system's dashboard provides a digital representation of the actual physical dispensary. The system also tracks when a plant is sick or is destroyed. (Licensees must give a minimum of 72 hours notice before destroying a plant that has been moved to that designated room.)

The medical marijuana dispensaries will be responsible for populating their own tracking system with data. Most will be using BioTrackTHC's commercial software to monitor their operations and to help make business decisions.

Using an Application Program Interface (API), the licensees will only have to enter their data once, but their system will interface directly with the Department of Health's software tracking system, which will allow state inspectors to view what is growing at each of the facilities in real-time to ensure transparency at all times.

Inspectors will conduct onsite in-

spections of the dispensaries as well as monitor the dispensaries through the state's tracking system.

Phase I focuses on cultivation and the software's "dashboard," or interface on the computer screen, shows different "rooms" or folders of medical marijuana plants at different stages of growth.

These folders can be named and organized in different ways at the discretion of the licensees. Folders may contain specific strains of marijuana, and separated by age or plant height. Others may contain "mother plants," so that genealogy can aid in identifying plants with specific qualities to be used for future cloning. 🌱

# State Laboratories Division Facilitating Lab Certifications to Avoid Putting Patients at Risk

A major ongoing step in creating a medical marijuana dispensary system for Hawaii is the certification of private laboratories that will objectively test for the safety of medical marijuana and medical marijuana products prior to being sold to patients or caregivers by licensed dispensaries.

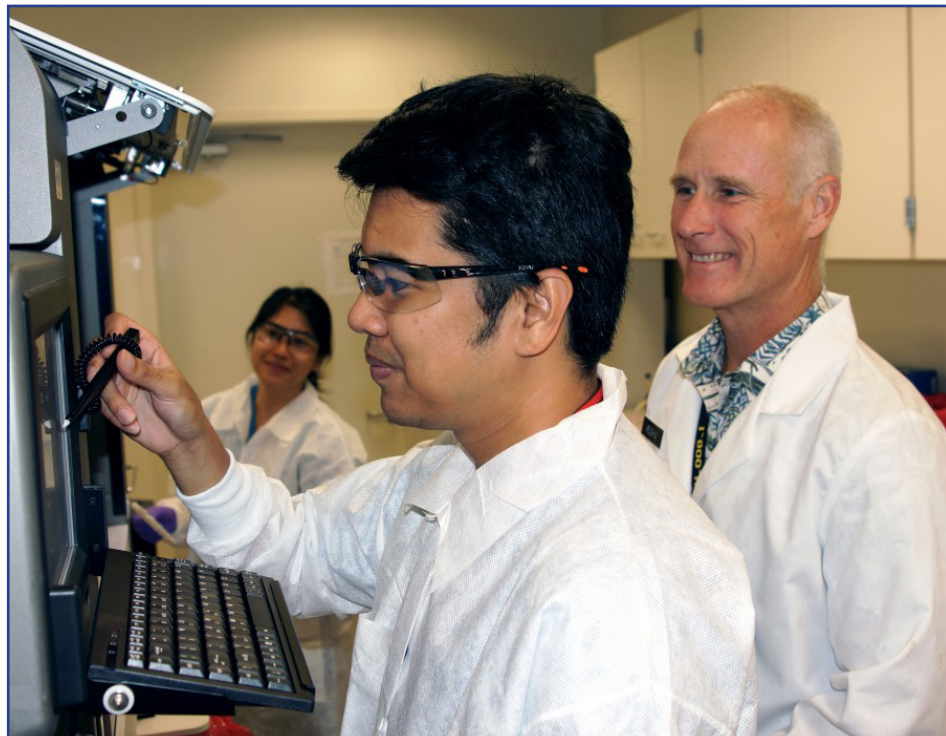
The Hawaii State Department of Health's State Laboratories Division is playing a key role in helping prospective laboratories become certified and meet internationally-recognized standards for good laboratory practice (GLP).

"Hawaii is fortunate to have several laboratory organizations interested in this testing, which is challenging because there is no federal guidance for medical marijuana testing," said **Dr. A. Chris Whelen**, Laboratory Director of the State Laboratories Division. "We have learned from other states with dispensary systems, and adopted the standards set by the International Organization for Standardization, or ISO 17025. We did not want to create an entirely new lab certification; otherwise, the process would become bogged down with excessive and unnecessary bureaucratic requirements."

ISO is an independent, non-governmental international organization with a membership of 161 national standards bodies.

## Maintaining Quality Assurance

The laboratory application process verifies laboratories meet recognized quality assurance standards, and the requirements are not any more rigorous than what is required



*Dr. A. Chris Whelen, right, leads the team at the State Laboratories Division, which is assisting medical marijuana laboratories with the certification process.*

in other regulated testing covered by Environmental Protection Agency, Food and Drug Administration, Department of Agriculture, or Centers for Medicare and Medicaid Services programs.

"We know registered patients want the dispensaries to open as soon

as possible to address their health needs," added Dr. Whelen, who is president of the Association of Public Health Laboratories (APHL). APHL conducts monthly conference calls on this and many other important public health and environmental

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## Position on Medical Marijuana Legislative Bills

About 45 medical marijuana bills have been introduced in this legislative session, but **Governor David Ige** and the Hawaii State Department of Health believe it is essential for the medical marijuana dispensary program to first be launched and become operational before making modifications to existing laws or introducing new ones.

Changes to the existing law may be premature and will divert attention away from the immediate priorities necessary to ensure a dispensary system is underway to serve Hawaii's eligible patients.

# State Laboratories Division Facilitating Lab Certifications

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laboratory topics. Representatives from other state laboratories that have marijuana programs in their states use this forum to discuss issues and provide mutual assistance.

“We are committed to Hawaii’s patients and have several experienced certification officers participating to move this process along as quickly as possible without sacrificing health and safety that testing was designed to ensure,” Dr. Whelen said.

## Detecting Chemical and Microbial Contaminants

Prospective laboratories can apply to perform testing for any or all of the contaminants and potency compounds required by Hawaii law and rules. Once certified, they would then contract directly with the dispensary to provide these services.

Potency analysis of medical marijuana must assess the concentration (dose) of specific active ingredients: (Delta 9)-Tetrahydrocannabinol (THC), Tetrahydrocannabinol Acid (THCA), Cannabidiol (CBD), Cannabidiolic Acid (CBDA), Cannabigerol (CBG), and Cannabinol (CBN).

Dispensaries are also required to have medical marijuana tested for the presence of toxic metals such as arsenic, lead, cadmium, and mercury known to exist in soil, pesticides that are regulated by the state Department of Agriculture and the EPA, solvents that may be used in processing medical marijuana (e.g., butanes, heptanes, benzene, toluene, hexane, total xylenes [m, o, p-xylene], alcohols such as methanol, ethanol, etc. and ketones like acetone).

Products must also be tested for microbial contaminants that could cause infections in patients, especially if their health is already compromised. This includes coliform bacteria, pathogenic E. coli, Salmonella, certain molds (*Aspergillus fumigatus*, *Aspergillus flavus*, *Aspergillus niger*), and fungal toxins (mycotoxins).

## Preventing Unnecessary Health Risks for Patients

“We know that timeliness is paramount in developing a medical marijuana dispensary system, but these laboratories are building brand new services that have not existed in Hawaii until now. That’s no small task and it takes time to do it right. The laboratory certification process simply verifies they are ready to provide services. If the Department of Health did not require the laboratories to test for the presence of certain contaminants, it would reduce testing demands on the lab-

oratories, but patient safety may be compromised,” Dr. Whelen said.

## A Collaborative Process

Gaining laboratory certification for the medical marijuana dispensary program is a collaborative, iterative process. It requires ongoing dialogue between the State Laboratories Division and the laboratory applicants for it to be productive and progressive.

“We are so grateful there are laboratory organizations working hard to acquire space, purchase materials and equipment, hire staff, establish and validate test methods, and set up quality management systems,” Dr. Whelen said. “Our intent from the start was to help the labs be successful; our emphasis is on compliance assistance and not just compliance enforcement. We try to keep communications open, and are happy to have discussions with all prospective and current applicants to keep the process productive. 🌿

## Next Steps for Retail Dispensaries

Now that the software tracking system is in place, what’s next? The next phase will involve interfacing the Department of Health’s Patient Registry with the tracking system. This will ensure only registered patients and their caregivers are allowed to enter dispensary retail sites to purchase medical marijuana. The Hawaii Information Consortium (HIC), which is used to meet information technology require-

ments for Hawaii State government agencies, is managing the patient registry website and data collection. The Department of Health is contracting with HIC to integrate the two systems. In addition, laboratory test results will be fed into the integrated system, so that dispensaries can confirm product samples have passed certified lab tests for safety before selling them to registered patients.