

# 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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## ***A Delicate Balance:*** **Upholding Patient Safety While Supporting Hawaii's Medical Marijuana Dispensaries**

***An Interview with Laboratory Administrator Dr. A. Christian Whelen***

The Hawaii Department of Health's State Laboratories Division plays a critical role in patient safety by ensuring medical marijuana products sold by licensed dispensaries do not compromise the health of registered patients.

The State Laboratories Division, led by **A. Christian Whelen, PhD, D(ABMM)**, ensures that private laboratories that test the products from the licensed dispensaries have appropriate capabilities, resources, protocols and processes in place to provide quality assurance for marijuana to be used for medicinal purposes. The following is a Q&A with Dr. Whelen:

**Q. As part of the Hawaii Department of Health, the State Laboratories Division has a duty to protect and promote the health of Hawaii residents, including patients registered to use medical marijuana. We also see the desire of dispensaries to accelerate the process to certify laboratories so they can meet the market demand for medical marijuana. How do you balance these needs?**

**Dr. Whelen:** This has gotten other states in trouble, so we need to re-



*Dr. Chris Whelen leads more than 100 staff members at the four locations that comprise the Hawaii State Department of Health's State Laboratories Division, which is responsible for diverse testing and ongoing programs.*

sist the temptation of setting the bar too low, and then hoping it will get better. The laboratories are doing a good job with a very challenging set of tasks – we are lucky to have three applicants that all have the goal of providing a complete menu of testing capabilities.

One of our important roles is to verify they are ready to perform these services. The State Laboratories has hosted a session for dispensaries and a session for laboratories to dis-

cuss the requirements and manage expectations, and those were both quite effective according to the feedback I've received.

**Q. What are some steps the State Laboratories Division is taking to expedite the ability of dispensaries to sell medical marijuana to eligible patients?**

**Dr. Whelen:** Private laboratory applicants are at different stages in

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# Insights from the State Laboratories Division

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their preparations to conduct product safety and potency testing. We hope that some of the labs will soon be provisionally certified to conduct certain tests.

To prepare for product testing, we have clarified that incremental certification (e.g., a few tests at a time) is acceptable. So perhaps not all labs can do all required tests to start, but this approach facilitates a framework which expedites the availability of all required tests. Although not necessarily “one-stop shopping,” it also shouldn’t be too inconvenient since dispensaries have already indicated to us that they intend to contract with multiple laboratories. So hopefully all of the tests a dispensary needs to start selling their medical marijuana products to Hawaii’s patients will be available in the network of labs.

**Q. As president of the Association of Public Health Laboratories (APHL), you have the opportunity to network with your professional counterparts in other laboratories across the country to learn best practices. What are some of the product testing implementation challenges that other states that have medical marijuana dispensaries facing?**

**Dr. Whelen:** Other states face the same issues we have in Hawaii. Not only is there an absence of federal guidance to laboratories, but none will be forthcoming because cannabis is illegal under federal law. So APHL gathered information from states, including Hawaii, to formulate a guidance document. It was a good start, but I noticed two prob-



*Dr. Chris Whelen with Chemist Robert Pineda, center, and Wanda Chang, Chief of the Environmental Health Analytical Services Branch of the State Laboratories Division, right, review the use of instrumentation used in analytical chemistry.*

lems immediately. It did not contain Hawaii content and it did not take a systematic approach to gathering information. At times it just described what was happening in one state.

I’m happy to say APHL has fielded a sophisticated survey instrument developed in their Institutional Research Program (<https://www.aphl.org/programs/research/IRP/Pages/default.aspx>) to gather information from all states for an electronic interim update. That update will be an invaluable resource for laboratories involved with cannabis testing and I have already uploaded Hawaii data.

**Q. What can Hawaii learn from other states?**

**Dr. Whelen:** We have learned from their mistakes. It was important to balance state mandated testing for contaminants and potency with cost

and strategies for regulatory oversight. Sure, there are some things we can do better (and the APHL update will help us with that), but I was pleased with our work when a third-party laboratory accreditation assessor recently told me, “I hope California follows Hawaii’s lead.”

**Q. Can you describe the certification process for private labs?**

**Dr. Whelen:** Sure. Prospective laboratories obtain the application from our website. They decide on the scope of services they intend to provide, and check the appropriate boxes. They select an accrediting organization that will inspect them to the International Organization for Standardization (ISO) 17025 standard, and begin that process.

They prepare and submit electronic versions of their documents relating

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# Insights from the State Laboratories Division

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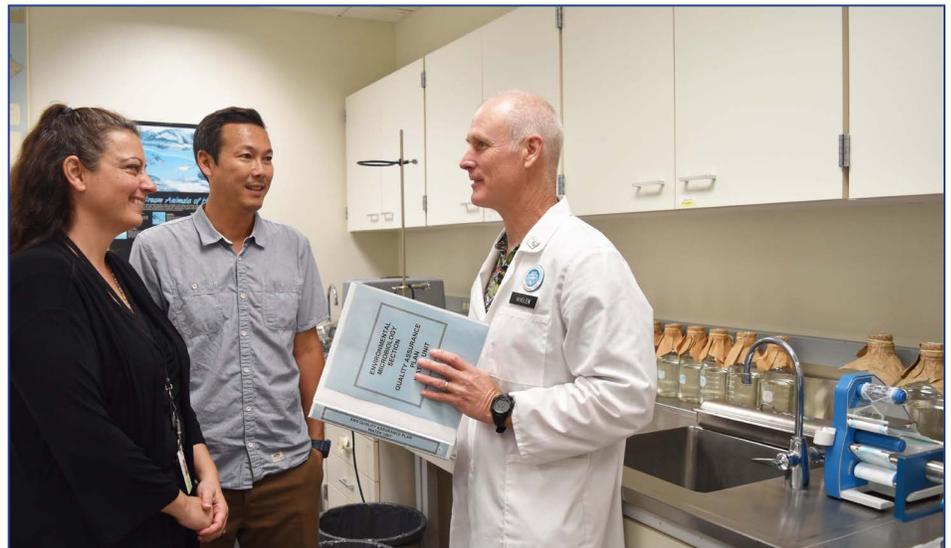
to management systems, security, facilities, personnel, procedures (including references and validation data), and quality systems to us. They provide ISO accreditation inspection findings and responses to us when available.

State Laboratories scientists review and request additional information if and when necessary, and schedule an on-site inspection. This is an iterative process between the applicant and the certification authority until there is sufficient evidence that the laboratory is ready to perform the services. Normally laboratories will be provisionally certified initially, and remain in that status for one to three years to generate more robust data to support full certification. Laboratories renew on an annual basis.

## Q. When can we expect the laboratories to be ready for testing?

**Dr. Whelen:** The laboratories are very aware of the interest to have testing available this summer. The documentation for some testing processes are more complete than others, and we hope to perform on-site evaluations for provisional certification for some of the regulated test processes this month. The soonest we could see certification of all analytes by the same lab would probably be around July, 2017.

## Q. We understand from updates presented by the Department of Health during recent legislative oversight committee meetings that private laboratories are pro-



*Dr. Amy Woron, Deputy Chief of State Laboratories for Antimicrobial Resistance, left, and Dr. Darin Hayakawa, center, discuss microbiology quality assurance measures with Dr. Chris Whelen.*

## gressing at different paces Can you explain why this might be?

**Dr. Whelen:** It would be inappropriate to discuss details in this forum, but suffice it to say this is completely normal. Some labs may choose to focus on chemical analyses first while others develop their methods for detecting microbial contaminants. Every lab is different: different staffing levels, infrastructure, document resources. This is a process – it takes time to do it right.

## Q. What have been the most challenging areas for the private laboratories to achieve certification?

**Dr. Whelen:** I don't want to speak for them, but battling the perception, internally and externally, that laboratories are "black boxes" that can be turned on and off like a light switch doesn't make things any easier. Protecting the testing system to

consistently produce reliable results is hard science, not plug and play.

## Q. The State Laboratories Division recently issued a list of pesticides the certified labs will be testing for in medical marijuana. Why is this an important step?

**Dr. Whelen:** We published the list recently, but we have had many discussions with various stakeholders on this subject. We started with a list of pesticides that were known historically to be used and abused in Hawaii, but it contained compounds that were no longer available and termiticides.

Together with the Department of Agriculture we published a list derived from one developed in Oregon, but excludes one compound for technical and rarity reasons, and two others because they are not allowed to be imported into Hawaii.

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# Insights from the State Laboratories Division



Perched high above Pearl City in a secured area at the top of Waimano Home Road, State Laboratories Division of the Hawaii State Department of Health conducts testing for environmental quality, Zika, Ebola, rat lungworm, and other diseases of public health importance.

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**Q. Some dispensaries have asked the Department of Health about batch sizes for product testing. What do you recommend for the dispensaries?**

The Hawaii Administrative Rules require “statistically significant” sampling, which is conducted by the laboratories. Large batches require less testing, but more product is at risk if it doesn’t meet standards. Smaller batches will require more testing because each batch must be tested.

Quality control testing can be conducted prior to regulatory testing,

which can reduce risk, but also at a cost. Ultimately these are business questions that are best left to the discretion of the dispensaries.

**Q. What other community laboratory activities is the State Labs involved with?**

**Dr. Whelen:** The State Laboratories Division is constantly involved with the lab science community here in Hawaii. We routinely participate in local professional lab activities, collaborate with private labs and academia to conduct applied public health research, serve as adjunct faculty, provide undergraduate internships, support the U.S. Affiliated Pacific Islands, and host training for local and visiting lab scientists.

Some recent activities of note include organizing the lab presence at the recent “March for Science” at UH, “twining” with the Vietnam public health lab network, working with UH and clinical labs to develop a clinical track for microbiology majors, and outbreak support testing for Zika and dengue in American Samoa, dengue on Big Island, rat lungworm on Maui and Big Island, and mumps and *Salmonella* on Oahu. 🌿



Please kōkua!

# Be a Good Neighbor

## Eight Tips For Medical Marijuana Use in Hawai'i

### 1 Use with Caution

Until you know how you react to marijuana, use less. Research on adverse risks or reactions may not be readily available for your specific condition. Don't use medical marijuana when nursing or pregnant unless advised to do so by your health care provider.

### 2 Don't Drive

Although medical marijuana is legal, driving under the influence of marijuana is illegal. You might get arrested or hurt yourself or someone else. So, ask a friend for a ride, call a cab, or take the bus.

### 3 Be Aware of Addiction

Although marijuana can be used as medicine, marijuana has the potential to be addicting. Be sure to discuss all risks and benefits with the doctor that is treating you.

### 4 No Public Use

All use of medical marijuana must be on private property. Do not use marijuana in your car while on the road, at work, at school or on school grounds, at the beach, at a park, on hiking trails, on a bus, or in any other public space. It is illegal to use or possess marijuana on any federally owned property such as military installations and national parks.

### 5 Prevent Accidental Misuse

Marijuana is medicine in Hawaii. Keep your medicine secured and away from children at all times. If someone you know ingests too much marijuana, call the Poison Help line at 1-800-222-1222.

### 6 Secure Your Plants

If you have a personal grow site, be sure to keep your plants secure, not visible by neighbors, and not accessible by children.

### 7 Safe Travels

When you leave home, your medical marijuana must be in a sealed container and not visible to the public. Remember, you are not protected when you travel with medical marijuana interisland, between states, or in other countries.

### 8 Obey All of Hawai'i's No Smoking Laws

Laws that do not allow smoking or vaping in certain areas apply to the use of medical marijuana. Be mindful of others and never use medical marijuana in a manner that may endanger the health or well-being of another. Secondhand smoke is harmful. Never smoke near infants, children, or pregnant women.