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TESTIMONY ON HOUSE BILL 2097 HD2 SD1
RELATING TO MEDICAL CANNABIS
By
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Senate Committee on Judiciary
Senator Karl Rhoads, Chair
Senator Jarrett Keohokalole, Vice Chair

Tuesday, June 30, 2020; 9:46 AM
State Capitol, Conference Room 016

Thank you for the opportunity to provide testimony on this measure. I have an interest in this bill because of the impact it will have upon our Medical Cannabis patients.

You all know how much time and energy I have put into advocating for our patients and trying to eliminate the discrimination that they face every day because of the current misconception that our medical cannabis program violates federal law.

But let's put patient concerns aside for a moment and focus on a subject that you can more easily relate to: MONEY.

UNBEARABLE TAX BURDEN:

This bill should really be called "Relating to Rescuing Dispensaries". Remediation, edibles, and medical/scientific education are all activities that are directly connected to increasing dispensary revenue.

Instead of throwing the dispensaries a few more bones to help them make it through the long federal winter, you should be looking at one area that could provide the dispensaries with massive economic relief: FEDERAL TAX DEDUCTIONS.

This article from the August 11, 2019 online edition of The Gazette out of Iowa is perhaps the first time that a dispensary has admitted to the extent of the tax burden that they must bear due to not being able to deduct standard business expenses on their federal tax returns because of being classified as a Continuing Criminal Enterprise by the IRS.

"Marijuana companies - including Iowa's licensed medical cannabidiol producers and dispensaries - do not qualify for certain federal tax deductions and credits because their business is not recognized by the federal government.

By some estimates, that effectively equates to a 70 percent tax penalty. Inevitably, those costs are passed on to people who purchase medicine through the state-authorized businesses.

"That's an absurdly high amount. … That directly impacts patients," Lucas Nelson, general manager of MedPharm Iowa, told me recently."

I can't think of any other legitimate business that could survive with a 70% tax burden. Why in the world would you allow such discrimination to continue against our dispensaries, while at the same time applying band aids to the wounds that continue to fester under the current solvable conflict with the federal regulation of the non-medical use of marijuana ?

In order to stop the federal regulation of the non-medial use of marijuana from being unconstitutionally applied to the state-authorized medical use of cannabis in Hawaii, the follow provision, taken from SB2462, which has already been heard this session, needs to be included in this bill:

"329D-25 Coordination among state and federal agencies. The department shall initiate ongoing dialogue among relevant state and federal agencies to identify processes and policies that ensure the privacy of qualifying patients and qualifying out-of-state patients and the compliance of qualifying patients, primary caregivers, qualifying out-of-state patients, and caregivers of qualifying out-of-state patients and medical cannabis dispensaries with state laws and regulations related to medical cannabis. The department shall submit a written request, in accordance with title 21 C.F.R. section 1307.03, to the Office of Diversion Control, Drug Enforcement Administration by September 1, 2020, stating that part IX of chapter 329 and this chapter do not create any positive conflict with state or federal drug laws and regulations and are consistent with title

21 U.S.C. section 903, and requesting formal written acknowledgement that the listing of marijuana as a controlled substance in federal schedule I does not apply to the nonprescription use of cannabis under the medical cannabis registry and dispensary programs established pursuant to chapters 329 and 329D."

Please don't let the current power structure of the Legislature prevent this committee from adopting a solution that can resolve this conflict once and for all by removing the misconception that our medical cannabis program violates federal law and allowing our dispensaries to function like any other legal enterprise.

PROGRAM MISMANAGEMENT:

Before authorizing any additional activities for dispensaries, this committee needs to first address the gross mismanagement of our Dispensary Program by the Department of Health (DOH), which is being caused in part by the overall poor construction of our Medical Use of Cannabis Act.

For example, this process of "remediation" is a way for dispensaries to sell material to patients that has failed first round testing, which applies primarily to flowers that are too moldy to pass the required mold and fungi tests. The fact that remediation is being addressed in this bill tells us that this is a process that deserves statutory authorization and formal regulation.

And yet, DOH has been allowing this process to go on for at least the past year without any standardized protocol or regulatory oversight aside from requiring that failed material test within limits before it is sold to patients. DOH has been justifying this potentially unsafe practice with the unethical policy that any activity that is not specifically prohibited by state law is good enough for our patients.

But, we know that such unregulated remediation by dispensaries has resulted in elevated levels of ethanol in vape cartridges that have reached ten times the allowable level in California, which is also due in part to the fact that DOH does not require dispensaries to test for ethanol in their products.

DOH knew about the potential for elevated levels of certain untested solvents in dispensary products nearly two years ago and did nothing about it.

Any formal authorization for remediation by dispensaries should include creation of standardized remediation processes that all dispensaries must follow, and product labeling that notifies patients about which products have been remediated, by which process, and for what kind of failure.

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The department shall adopt rules that allow for remediation of
failed material and require that all dispensaries follow
standardized remediation protocols that are subject to
inspection and validation.  The department shall also require
dispensaries to disclose on product labeling whether a product
has been remediated, by which process, and for which failure.
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DOH also knew about the possible contamination of dispensary cartridges with lead back in February of this year, and instead of issuing a temporary ban on dispensary cartridge sales and performing independent third-party testing on oils that have been heated in these cartridges to look for possible lead content, they again did nothing.

We are not talking about finger painting here. We are talking about the state-authorized production of a medicine that patients are putting into their bodies with the faith that their health and welfare, and not the bottom line, are DOH's top priorities.

I believe that the hands-off approach that DOH has maintained towards our Medical Cannabis Program from the time that it inherited administration of the program is due to the department's discomfort with regulating an activity that it still believes is in violation of federal law. This is another reason why the federal exemption provision above needs to be included in this bill.

In order to ensure proper management of our Dispensary Program by DOH, this committee first needs to address the following existing administrative deficiencies:

<u>UNQUALIFIED INSPECTORS:</u>
Proper regulation of Hawaii's dispensaries requires rigorous inspections. We are being told that one of DOH's new inspectors has absolutely no experience in this field and is much less thorough than previous inspectors. The fact that DOH cannot even regulate for product labeling that clearly shows concentrations and storage instructions, and DOH's allowance of what dispensaries are calling "soft lozenges" (ie. Gummy bears) that do not meet the definition of a tablet under HRS 329D-10(10)(b), are just some of the examples of DOH's inability to regulate this program.

Instead of relying on DOH's own inspectors, we need to have independent third-party inspectors with certified experience in chemistry and regulatory procedures. There are already several such independent companies in Hawaii that could provide such service, which would be an excellent use for part of that one million dollars that DOH is collecting from patient registration fees every year (30,000 patients x $38.50 = $1,155,000).

The department shall employ third-party inspectors from a qualified local quality assurance company with expertise in chemistry and regulatory protocols for all dispensary inspections.

SILENT ENFORCEMENT POWERS:

DOH has enforcement powers under HAR 11-850-101 to discipline dispensaries for statutory and administrative violations. However, there have been no such enforcement remedies to date that we are aware of, even after it was found that five of our eight dispensaries were in violation of HAR 11-850-72 and HAR 11-850-75 for importing third-party terpenes and adding these to vape cartridges without the knowledge of DOH or patient customers.

One way to help correct this situation is to require that DOH make public on its website all dispensary violations and their remedies, so that the regulatory process is as transparent as possible, and interested parties have a way of learning about issues that need correcting.

The department shall make public on its website all dispensary violations and their remedies that have occurred since inception of the dispensary program.

NONEXISTENT EXPERT MEDICAL ADVICE:

It was about a year ago, while we were inquiring with DOH about which advisory body should be addressed to take up the issue of a federal exemption, that we discovered that DOH has no medical cannabis advisory board. Not only did this vacuum of an advisory board preclude the opportunity to petition for our issue to be added to a medical advisory board's agenda, but it also revealed that there is no formal advisory board that can provide expert medical advice to the Registry and Dispensary programs for their decision making and enforcement workload.

Instead it appears that DOH is relying primarily upon the dispensaries themselves for advice on changes that need to be made to the program. This is demonstrated time and time again with the privileged access that the dispensaries seem to have with DOH behind closed doors, and the complete lack of advance communication with other stakeholders on important bills such as this one. This needs to change immediately.

The department shall create a Medical Cannabis Advisory Board within thirty days of enactment of this bill. The Medical Cannabis Advisory Board shall contain at least one medical doctor who is a Certified Cannabinoid Specialist.

INADEQUATE INTERIM RULES:

Unfortunately, the suspension of Hawaii's Administrative Procedures Act, Chapter 91, under current interim dispensary rules, precludes pursuit of administrative remedies for many of the regulatory issues that we are currently facing. DOH needs to adopt formal dispensary rules immediately to allow for formal public participation and submission of rulemaking petitions.

The department shall adopt formal dispensary rules within thirty days of enactment of this bill to allow for restoration of Chapter 91 administrative procedures.

UNNECESSARY EDIBLES:

I can't remember the last time my patients needed their metformin, or their losartan, or their simvastatin in cookie form to improve effectiveness and compliance.

Allowing dispensaries to sell edibles before restructuring DOH's regulatory capabilities would be a disaster. And allowing dispensaries to do so at this time would only prove that commercial interests, and not health priorities, are driving this train.

In addition, edibles are really the bread and butter of recreational use establishments. This is not the direction our dispensaries should be heading. A better goal would be the production of intra-state pharmaceutical grade medical cannabis products that would not require FDA approval for interstate marketing and could be accepted for coverage by local medical insurance companies.

INAPPROPRIATE EDUCATION:

Keith Ridley started this misconception that “bud-tenders” can give medical advice to dispensary patient customers in an interview that appeared in the August 18, 2017 edition of the Star Advertiser, in which he said “dispensaries will discuss dosing recommendations with the patient or caregiver based on patients' needs and the dispensaries knowledge of their products.”

Last time I checked, a discussion of treatment options and dosing of medications falls under the category of medical advice and requires a medical or similar health professional license in the State of Hawaii.

Unfortunately, Mr. Ridley’s comments gave dispensaries the impression that their staff can elicit confidential medical information from our patients and use this to recommend particular products and dosing regimens for specific medical conditions. Menus are even given out to patients to guide the selection of products based upon medical claims for which there are no FDA-approved clinical studies.

Medical education for patients should be left to the certifying physician or APRN. If there are doubts about the ability of certifying providers to properly educate patients during the certification process, then Hawaii’s Medical and Nursing Boards should adopt guidelines for performing medical cannabis evaluations and create minimum certification requirements for all certifying providers.

In addition, education on the medical use of cannabis is an authority that already rests with DOH under HRS 329D-26:

HRS 329D-26 Public education.
(a) The department shall conduct a continuing education and training program to explain and clarify the purposes and requirements of this chapter or to provide substance abuse prevention and education. The program shall target community partner agencies, physicians and other health care providers, patients and caregivers, law enforcement agencies, law and policy makers, and the general public.
(b) The department shall employ at least one full-time staff member whose qualifications and duties include the provision of medical cannabis health education.

Transferring this function to dispensaries goes against DOH’s mission of protecting the health and welfare of our patients and prevents an impartial distribution of educational information to our patients. Do not allow it.

Aloha.