Sunrise Analysis: Regulation of Medical Marijuana Dispensaries

A Report to the Governor and the Legislature of the State of Hawai‘i

Report No. 14-12
December 2014

THE AUDITOR
STATE OF HAWAI‘I

Office of the Auditor

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Report No. 14-12, December 2014

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Flaw in existing medical marijuana law justifies regulation of dispensaries

Regulation of medical marijuana dispensaries is warranted

Because the sale of marijuana is illegal under state law, there is no place within Hawai‘i to legally obtain medical marijuana, which forces qualifying patients to either grow their own medical marijuana or seek out black market products. We therefore found that regulation of medical marijuana dispensaries is necessary to protect the health, safety, and welfare of qualifying patients in Hawai‘i. Without regulated dispensaries, patients' health is jeopardized because a product's strength, strain, and lack of contaminants cannot be verified. Regulation could also mitigate fears that dispensaries would introduce a criminal element into surrounding neighborhoods by stipulating where and how many dispensaries may operate. Regulation would also satisfy most other criteria in Hawai‘i's "sunrise" law, Chapter 26H, Hawai‘i Revised Statutes: it would not unreasonably restrict potential operators' ability to join the field, fees would likely cover administrative costs of the program, and viable alternatives to protect the public have not been identified. In addition, most other states with medical marijuana programs regulate dispensaries.

Currently, Hawai‘i patients must either grow their own medical marijuana or obtain it from the black market, where there are no assurances of consistent strength or purity.

House Bill No. 1587 is flawed

The proposed regulatory vehicle, HB No. 1587 (2014), has several flaws. First, licensure would be more appropriate than registration for dispensaries. Second, the bill does not specify a funding mechanism for the new regulatory program. No seed moneys are provided, and the existing Medical Marijuana Registry Special Fund statute does not contemplate use of the fund for overseeing a dispensary regulatory program. In addition, various duties in the bill are unclear or inappropriately assigned to the entity to be regulated (dispensaries) rather than the regulating authority (the Department of Health). Finally, the bill needs several technical changes in order to be effectively implemented.

Agencies' responses

The Department of Health offered clarifying technical comments and pointed out that its agreement on a reasonable number of statewide dispensaries was hypothetical. The Department of Public Safety did not comment on the report.

Recommendations

Responses

Prior Studies

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Submitted by

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STATE OF HAWAI‘I

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Foreword

This analysis of the need to regulate a system of medical marijuana dispensaries was prepared in response to House Concurrent Resolution No. 74 of the 2014 regular session, which asked us to examine the proposal for their regulation in House Bill No. 1587 of the 2014 legislative session. The report presents our findings and recommendations on whether the proposed regulation is consistent with policies in Hawai‘i’s “sunrise” law (Chapter 26H, Hawai‘i Revised Statutes) and the probable effects of the proposed regulation.

We wish to express our appreciation for the cooperation and assistance extended by staff of the Department of Health, the Department of Public Safety, and other organizations and individuals whom we contacted during the course of our evaluation.

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Acting State Auditor

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Chapter 1
Introduction

This report on the proposed regulation of a system of medical marijuana dispensaries responds to the "sunrise" provision of the *Hawai'i Regulatory Licensing Reform Act*, Chapter 26H, Hawai'i Revised Statutes (HRS). Section 26H-6, HRS, requires bills seeking to regulate a previously unregulated profession or vocation to be referred to the Auditor for analysis. The Auditor must assess whether the proposed regulation is necessary to protect the health, safety, and welfare of consumers and is consistent with the State's regulatory policies in Section 26H-2, HRS. In addition, the Auditor must examine the probable effects of the proposed regulation and assess alternative forms of regulation.

In House Concurrent Resolution (HCR) No. 74, the 2014 Legislature asked the Auditor to conduct a sunrise review of the establishment of a system of registered dispensaries within the Department of Health (DOH) to dispense medical marijuana as proposed in House Bill (HB) No. 1587, Regular Session of 2014. The resolution also asks the Auditor to include in the review the:

1. Qualifications, duties, and responsibilities for dispensaries of medical marijuana;

2. Registration requirements for dispensaries of medical marijuana to possess and cultivate medical marijuana for dispensing medical marijuana to a qualifying patient or primary caregiver as well as manufacturing, purchasing, possessing, distributing, and using drug paraphernalia in accordance with Hawai'i's *Medical Use of Marijuana* Law;

3. Registration requirements for qualifying patients and primary caregivers to use and obtain services from dispensaries of medical marijuana, including the payment of a cultivation fee to the Department of Health and the cultivation of marijuana in secured facilities that may or may not be part of the dispensary;

4. Registration [sic][1], to include criminal record checks, of dispensary agents who must be registered with the Department of Health prior to working at a dispensary; and

5. Protections afforded to qualifying patients, primary caregivers, dispensaries, and dispensary agents with respect to the regulation of

[1] We assume the word "requirements" is missing here.

a system of registered dispensaries within the Department of Health to dispense medical marijuana.

Background on Medical Marijuana Dispensaries

Medical marijuana dispensaries, which do not currently exist in Hawai‘i, would be locations where qualifying medical marijuana patients or their designated caregivers could legally obtain medical marijuana, arguably without hassle or the fear of being stopped by law enforcement. The goal of a medical marijuana dispensary system is to offer qualified patients safe and legal access to medical marijuana.

Legislative history of medical marijuana in Hawai‘i

In 2000, the Legislature enacted the *Medical Use of Marijuana* law, which has been codified as Part IX of Chapter 329, HRS, the *Uniform Controlled Substances Act*. The law allows for the medical use of marijuana by qualifying individuals under certain conditions and includes registration requirements for medical marijuana patients and their caregivers, administered by the Department of Public Safety (PSD). However, the law does not provide a legal method of obtaining marijuana. Patients or their caregivers may grow their own plants but otherwise have no legal way of obtaining marijuana.

In 2010, the State’s Medical Cannabis Working Group recommended that administration of the medical use of marijuana program be transferred from the medical use of marijuana program from PSD to Department of Health (DOH). In 2013, the Legislature implemented the working group’s recommendation via Act 177, Session Laws of Hawai‘i (SLH) 2013. The act transferred the medical use of marijuana program from PSD to DOH effective January 1, 2015. It also established a new fund, the Medical Marijuana Registry Special Fund (codified in Section 321-30.1, HRS). Also in 2013, the Legislature enacted Act 178, SLH 2013, which changed all references in Sections 329-121 through -123, HRS, from PSD to DOH.

In 2014, the Legislature passed two concurrent resolutions related to medical marijuana. HCR No. 74 asked us to conduct this sunrise review. HCR No. 48, House Draft (HD) 2, Senate Draft (SD) 1 established a Medical Marijuana Dispensary System Task Force and asked the Legislative Reference Bureau (LRB) to update its 2009 report (discussed in “Prior Studies” in this chapter) on the policies and procedures for access, distribution, security, and other relevant issues related to the medical use of cannabis in all states that have a medical cannabis program. The task force was directed to report to the Legislature 20 days before the 2015 session convenes; LRB’s report was issued in August 2014.

Current medical use of marijuana program

Hawai‘i’s existing medical use of marijuana program is administered by the Department of Public Safety’s Narcotics Enforcement Division. The program covers only patients and their caregivers; the law does not mention dispensaries.

Under current law, patients who have been diagnosed by a physician as having a debilitating medical condition and whose physician has certified in writing that the potential benefits of the medical use of marijuana would likely outweigh the health risks for the particular patient, may apply for a medical marijuana card. This card gives a patient or specified caregiver the legal right to grow and possess an adequate supply (as defined in Section 329-121, HRS) of usable marijuana for medical use. Patients are allowed only one primary caregiver. To register for the program:

- Physicians who recommend medical marijuana must specify identifying information of the qualifying patient, including the location where the marijuana is to be grown (known as *a grow location*). Beginning January 2, 2015, the recommending physician must be the patient’s primary care physician;

- Qualifying patients must provide sufficient information to identify themselves and their specified caregiver and pay a registration fee of $25 annually, although effective January 2, 2015, the fee will be $35; and

- Primary caregivers must also register with the department. Each primary caregiver can only be responsible for the care of one qualifying patient at a time.

The department issues a registration certificate to the qualifying patient. Patient and caregiver identities as well as grow locations are kept in a database, which law enforcement entities may query 24 hours a day, seven days a week, to confirm if a person is enrolled in the medical marijuana program.

On January 2, 2015, responsibility for the medical marijuana program will transfer to the DOH—specifically, its STD/AIDS Prevention Branch. Transfer of the medical marijuana program from PSD to DOH will include a special fund—the Medical Marijuana Registry Special Fund—with an expenditure ceiling of $150,000 per biennium; one vacant position; and all rights, powers, functions, and duties regarding administering the medical marijuana program. In addition to these resources, DOH will receive three temporary positions and additional funds for the program.

As of October 2014, PSD and DOH are in the process of transferring the existing medical marijuana program, a project which has been taking place over an 18-month period and is scheduled for completion on January 1, 2015. In accordance with Section 5 of Act 177, SLH 2013, DOH has established a temporary transition project coordinator to oversee the transfer of the program and delineate the responsibilities of each department in the transfer process. The temporary position also allows for the transition project to continue beyond January 1, 2015, to allow DOH time to develop administrative rules, policies, and guidelines for the program with technical assistance provided by PSD.

Controlled Substance Registration Revolving Fund

From 2002 to 2013, the medical use of marijuana program was operated out of the Controlled Substance Registration Revolving Fund. The revolving fund is administered by PSD and used to offset costs associated with the registration and control of the manufacture, distribution, prescription, and dispensation of controlled substances under Chapter 329, HRS. The fund consists of all moneys derived from fees collected and legislative appropriations. On August 28, 2013, $253,527 related to the medical use of marijuana program was transferred from this revolving fund to the newly established Medical Marijuana Registry Special Fund. Exhibit 1.1 shows the beginning balance, revenues, interest, expenditures, transfers, ending balance, and encumbrances of the revolving fund for FY2011 through FY2013.

Medical Marijuana Registry Special Fund

Act 177, SLH 2013, codified as Section 321-30.1, HRS, established the Medical Marijuana Registry Special Fund. The fund is to be expended by DOH to offset the cost of processing and issuing patient registry identification certificates and primary caregiver registration certificates; pay for positions authorized by the Legislature; establish and manage a secure and confidential medical marijuana database; and for any other expenditure necessary, as authorized by the Legislature, to implement a medical marijuana registry program. The fund consists of moneys collected from the medical marijuana registration fee, which is capped at $35. The fund's balance at the close of FY2014 was $328,036.

Proposed regulatory measure, House Bill No. 1587

The proposed measure to regulate medical marijuana dispensaries in Hawai‘i, HB No. 1587 (2013), would:

1. Establish a system of registered dispensaries and dispensary agents within DOH to dispense medical marijuana to qualified patients and primary caregivers; and

2. Transfer administrative responsibilities for medical marijuana from PSD to DOH.

The bill would add three new sections to Part IX of Chapter 329, HRS, which would create dispensaries to possess and cultivate medical marijuana; articulate qualifications, duties, and responsibilities of those dispensaries; and establish standards of registration for dispensary agents.

Regulation of dispensaries in other states

As of October 2014, 22 states and the District of Columbia had approved medical marijuana and cannabis programs. Seventeen of these states plus the district have provided for medical marijuana dispensaries. Exhibit 1.1 lists the states with medical marijuana laws and describes how dispensaries are selected and how many are permitted in each state.

Exhibit 1.1
States With Medical Marijuana/Cannabis Program Laws (as of August 2014)

State	Allows Dispensaries	How Dispensaries Are Selected	Number of Dispensaries Allowed
1. Alaska	No	N/A	N/A
2. Arizona	Yes	By lottery	Up to 126 (one for every 10 pharmacies)
3. California	Yes	No state regulation; city and county oversight varies	Unknown; in hundreds, possibly over 1,000
4. Colorado	Yes	Qualified applicants are granted state registration.	470 medical marijuana centers
5. Connecticut	Yes	Department of Consumer Protection decides which applicants to approve.	Number determined by Department of Consumer Protection.
6. Delaware	Yes	Health department decides based on merit-based application process.	Law calls for three compassion centers, but governor may only allow one initially.
7. District of Columbia	Yes	Health department selects applicants.	Up to eight allowed, three as of fall 2013.
8. Hawai‘i	No	N/A	N/A

State	Allows Dispensaries	How Dispensaries Are Selected	Number of Dispensaries Allowed
9. Illinois	Yes	State decides on merit-based application process.	60 allowed
10. Maine	Yes	Health department selects applicants based on merit-based application process.	At least eight allowed; eight operating as of fall 2013.
11. Maryland	Yes	No data available.	No data available.
12. Massachusetts	Yes	Health department selects applicants based on merit-based application process.	Up to 35 licensed by January 2014; more may be approved after that.
13. Michigan	No	N/A	N/A
14. Montana	No	N/A	N/A
15. Nevada	Yes	Health division selects applicants on a merit-based application process.	Up to 66 will be approved in 2014.
16. New Hampshire	Yes	Health department selects applicants based on merit-based application process.	Four alternative treatment centers will be approved.
17. New Jersey	Yes	Health department selects applicants.	At least six alternate treatment centers are allowed, but only two open as of fall 2013.
18. New Mexico	Yes	Health department selects applicants.	Health department determines number; 23 open as of fall 2013.
19. New York	Yes	Health department selects applicants.	Not more than five organizations operating, with no more than four dispensaries each.
20. Oregon	Yes	Oregon Health Authority selects applicants.	No data available.
21. Rhode Island	Yes	Health department selects applicants based on merit-based application process.	Three compassion centers are allowed and approved; two open as of fall 2013.
22. Vermont	Yes	Health department selects applicants based on merit-based application process.	Four non-profit dispensaries approved; two open as of fall 2013.
23. Washington	No	N/A	N/A

Source: National Conference of State Legislatures, Legislative Reference Bureau, and the Marijuana Policy Project

Prior Studies

Our office has not conducted any studies regarding the regulation of medical marijuana dispensaries. However, in 2009, the Legislative Reference Bureau published a report entitled *Access, Distribution, and Security Components of State Medical Marijuana Programs*. The study examined the policies and procedures of medical marijuana programs of 12 other states regarding access, distribution, and security.

LRB's study noted that while Hawai'i's medical use of marijuana program allows qualifying patients to use medical marijuana, there is no way for patients to legally obtain marijuana; the law is silent on this issue. The study also analyzed how other states' medical marijuana programs dealt with removing state-level criminal penalties, establishing patient registries and issuing identification cards, maximum amounts of marijuana allowed, and methods of access and distribution.

In September 2014, LRB published a follow-up report to its 2009 study, which found that 18 of the 23, not including the District of Columbia, states with medical marijuana programs provided for a system of distribution that allows qualifying patients to safely and legally obtain medical marijuana. The study concluded that there is no one model for implementing and regulating dispensaries in Hawai'i.

Objectives of the Analysis

1. Determine whether enactment of the proposed bill to regulate medical marijuana dispensaries is consistent with the policies set forth in Hawai'i's regulatory licensing law.

2. Assess the probable effects of enacting House Bill No. 1587 (2013), specifically the effects on users of the medical marijuana program, and the appropriateness of alternative forms of regulation.

3. Make recommendations as appropriate.

Scope and Methodology

To determine whether the proposal to regulate medical marijuana dispensaries as proposed in HB No. 1587 is consistent with state law, we applied the criteria for regulation set forth in Section 26H-2, HRS, of the *Hawai'i Regulatory Licensing Reform Act*.

The Legislature established policies in Section 26H-2 to ensure that regulation of an occupation takes place only for the right reason: to protect consumers. Regulation is an exercise of the State's police power and should not be imposed lightly. Consumers rarely initiate regulation; more often, practitioners themselves request regulation for benefits that

go beyond consumer protection. Practitioners often equate licensure with professional status in seeking respect for the occupation.

The policies set forth in Section 26H-2 reinforce that consumer protection is the primary purpose of regulation by stipulating:

- The State should regulate professions and vocations only where reasonably necessary to protect consumers;
- Regulation should protect the health, safety, and welfare of consumers and not the profession;
- Evidence of abuses should be given great weight in determining whether a reasonable need for regulation exists;
- Regulation should be avoided if it artificially increases the costs of goods and services to the consumer, unless the cost is exceeded by potential dangers to the consumer;
- Regulation should be eliminated when it has no further benefit to consumers;
- Regulation should not unreasonably restrict qualified persons from entering the profession; and
- Aggregate fees for regulation and licensure must not be less than the full costs of administering the program.

We were also guided by the publication, *Questions a Legislator Should Ask*, published by the Council on Licensure, Enforcement, and Regulation (CLEAR), a national organization. According to CLEAR, the primary guiding principle for legislators should be whether an unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If it does, regulation may be necessary; if not, regulation is unnecessary and wastes taxpayers' money.

We also used additional criteria for this analysis, including whether:

- The incidence or severity of harm based on documented evidence is sufficiently real or serious to warrant regulation;
- No alternatives provide sufficient protection to consumers (such as federal programs, other state laws, marketplace constraints, private action, or supervision); and
- Most other states regulate dispensaries for the same reasons.

In assessing the need for regulation and the specific regulatory proposal, we placed the burden of proof on proponents to justify the need for regulation. We evaluated their arguments and data against the criteria stated above. We examined the regulatory proposal and determined whether proponents have made a strong enough case for regulation. It is not enough that regulation *may* have *some* benefits. We recommend regulation only if it is *demonstrably* necessary to protect the public.

Types of regulation

We also scrutinized the language of the regulatory proposal, HB No. 1587, for appropriateness. We determined whether the proposed legislation appropriately fits one of the three approaches to occupational regulation. These approaches, from most restrictive to least restrictive, are:

- *Licensing*. A licensing law generally gives persons who meet certain qualifications the legal right to deliver services—that is, to practice a profession (for example, social work). Penalties may be imposed on those who practice without a license. To institute and monitor minimum standards of practice, licensing laws usually authorize a board that includes members of the profession to establish and implement rules and standards of practice.

- *Certification*. A certification law usually restricts the use of certain titles (for example, social worker) to persons who meet certain qualifications, but does not bar others who do not use the title from offering such services. This restriction is sometimes called *title protection*. Government certification should not be confused with professional certification, or credentialing, by private organizations. For example, social workers may receive certification from the National Association of Social Workers.

- *Registration*. A registration law simply requires practitioners—or in this case, a dispensary business entity—to enroll with the State so that a roster or registry is created and to enable the State to keep track of practitioners (or business entities). Registration may be mandatory or voluntary.

Methodology

We reviewed literature on medical marijuana dispensaries and its regulation and practices, including any standards promulgated by relevant national bodies, and regulation in other states. We inquired about enforcement actions filed by the state Office of Consumer Protection and complaints made to the Regulated Industries Complaints Office and the Hawai‘i Better Business Bureau. We also reviewed

regulatory statutes in other states related to medical marijuana dispensaries and analyzed the various forms of regulations and their provisions.

We contacted relevant personnel at DOH and PSD, county law enforcement agencies, non-profit organizations who displayed a vested interest in medical marijuana dispensaries, and other individuals with relevant expertise. We attempted to identify the costs and possible impacts of the proposed regulation.

Our work was performed from June 2014 to October 2014 in accordance with the Office of the Auditor's *Manual of Guides*.

Chapter 2
Flaw in Existing Medical Marijuana Law Justifies Regulation of Dispensaries

This chapter presents our findings and recommendations on the need to regulate a system of medical marijuana dispensaries in Hawai‘i. Because the sale of marijuana is illegal under state law, there is no place within the state to legally obtain marijuana, which forces qualifying medical marijuana patients to either grow their own medical marijuana or seek out black market products. For this overriding reason, we conclude that regulation of dispensaries is needed to protect the public from potential harm; although most of the other criteria for regulation in Chapter 26H, Hawai‘i Revised Statutes (HRS), the *Hawai‘i Regulatory Licensing Reform Act*, are also met. However, we also conclude that regulation as proposed in House Bill (HB) No. 1587 of the 2014 Regular Session needs some amendments prior to enactment.

House Concurrent Resolution (HCR) No. 74 of the 2014 Legislature also asked us to include a number of specifics regarding dispensaries, dispensary agents, qualifying patients and caregivers, and cultivation fees that are outside the scope of a sunrise review. We note that these issues fall under the purview of the Medical Marijuana Dispensary System Task Force, which is due to report to the Legislature 20 days prior to the 2015 legislative session.

Summary of Findings

1. The regulation of medical marijuana dispensaries is warranted, and satisfies most criteria under Hawai‘i’s sunrise law, Chapter 26H, HRS.

2. The proposed regulatory measure, HB No. 1587, should be amended. Specifically, dispensaries should be licensed rather than registered. Some technical amendments are also needed.

Regulation of Medical Marijuana Dispensaries Is Warranted

In determining the need for consumer protection regulation, the burden of proof rests on those promoting regulation to show its necessity. We found that regulation is necessary to protect the health, safety, and welfare of qualifying patients in Hawai‘i. Without regulated dispensaries, patients’ health is jeopardized because a product’s strength, strain, and lack of contaminants cannot be verified. Regulation could also mitigate fears that dispensaries would introduce a criminal element into surrounding neighborhoods by stipulating where and how many dispensaries may operate. Regulation would also satisfy

most other statutory criteria, as it would not unreasonably restrict potential operators' ability to join the field, fees would likely cover the administrative costs of the program, and viable alternatives to protect the public have not been identified. In addition, most other states with medical marijuana programs regulate dispensaries.

Regulation is necessary to protect the health, safety, and welfare of qualifying patients in Hawai'i

In assessing the need for regulation it is not enough that regulation may have some benefits; it must be demonstrably necessary to protect the public. We found that regulating medical marijuana dispensaries is necessary to protect the health, safety, and welfare of both qualifying patients and the general public. Without regulation, patients' health would be jeopardized due to the risk of variations in product strength and unintentional contaminants. Furthermore, regulation is needed to protect patients' welfare by eliminating the need for patients to rely on the black market—and the criminal element that may entail—to source medical marijuana. Finally, regulation of medical marijuana dispensaries is needed to protect the public's safety in general, as state regulation can control the number and location of dispensaries and thereby limit potential access by children (for instance, by keeping them away from schools) as well as reduce overall reliance on the black market and its associated crime.

Without regulated dispensaries, patients' health is jeopardized

Medical marijuana is, by definition, a medicinal (rather than recreational) drug. Under federal law, manufacturers of pharmaceutical drugs must provide the Food and Drug Administration with evidence of safety and efficacy before a drug can be sold. Similarly, medical marijuana should be subject to quality control measures so that patients know how much active ingredient per dose they are purchasing. Patients must be able to obtain their medication from an operator whose quality is controlled to ensure a safe product. Regulation would provide such controls and therefore protect consumers. Exhibit 2.1 shows the interior of a medical marijuana dispensary in California.

Exhibit 2.1
Interior of a Medical Marijuana Dispensary in San Jose, California

Source: Harborside Health Center, San Jose, California

While it is important to control for how much active ingredient is being packaged for sale, it is also important to control for contaminants. For the same reason that food establishments are regulated, imposing quality control requirements on dispensaries would ensure consumers receive their medicine free from pesticides, mold, fungus, or other contaminants that could pose health hazards. Exhibit 2.2 shows a sample medical marijuana-infused product that could be regulated for strength, strain, and quality.

Exhibit 2.2
Sample Medical Marijuana-Infused Edible Product

Source: Harborside Health Center, San Jose, California

In the absence of regulated dispensaries, consumers must either grow their own product or obtain it from the black market, where there are no assurances of consistent strength or purity. If dispensaries are regulated, however, the State can impose quality standards for the medical marijuana sold. Such regulation would protect patients, who would then know the product they are purchasing is safe for medicinal purposes. Different strains of marijuana are used to alleviate different symptoms, and various strengths of medical marijuana are also used to varying effect. Exhibit 2.3 shows various strains of medical marijuana that may be used to address different symptoms along with their cannabidiol, tetrahydrocannabidinol, and tetrahydrocannabidinol acid—the active ingredients in marijuana—concentrations.

Exhibit 2.3
Photo of Different Strains of Medical Marijuana and Corresponding Labels

Source: Harborside Health Center, San Jose, California

According to the Legislative Reference Bureau, forcing patients to either grow their own medical marijuana or seek out black market products—as is the case under current Hawai‘i law—is analogous to requiring patients seeking prescription drugs to not only manufacture, but also regulate the dosage, of their own medications rather than purchasing them from a regulated pharmacy. In addition, the American Civil Liberties Union of Hawai‘i believes it is not feasible to expect every qualifying patient to grow marijuana in his or her home, or to find a primary caregiver with the space, time, and skill to grow medical marijuana for the patient. Given the debilitating medical conditions that afflict qualifying patients, expecting them to not only grow their own medication, but also understand and implement the botanical nuances of cultivating marijuana plants is unreasonable—consider, for example, if medical marijuana were replaced with Vicodin and the same expectations for self-medication were placed on the patient. Exhibit 2.3 shows a medical marijuana cultivation facility, a complicated operation that can be difficult and costly for sick patients or their caretakers to reproduce in their own homes.

Exhibit 2.4
Interior of a Medical Marijuana Cultivation Facility

Source: Harborside Health Center, San Jose, California

Regulation is needed to protect patient welfare and public safety

Opponents suggest that the presence of medical marijuana dispensaries will draw the criminal element to surrounding neighborhoods. They believe there will be increases in theft (because dispensaries are likely to have large amounts of cash on hand) and assume that other crime will follow. However, we found that HB No. 1587, the proposed regulatory vehicle in Hawai‘i, would mitigate this possibility by requiring dispensaries to have security systems to prevent theft and other criminal activity. Most other states that regulate dispensaries likewise require security systems. Of the 17 states that regulate dispensaries, only one (Maryland) does not have security requirements for dispensaries. Exhibit 2.5 describes various security requirements that cultivation centers and dispensaries are subject to.

Exhibit 2.5
Security Requirements for Cultivation Centers and Dispensaries

State	Security Requirements
1. Arizona	Alarm, video surveillance, exterior lighting, single entrance
2. Colorado	Lighting, physical security, video, alarm, internal control procedures
3. Connecticut	Alarm, video surveillance, storage vaults, backup power, failure notification system
4. Delaware	Alarm, exterior lighting, video surveillance, inventory controls
5. Hawai‘i	**Proposed in HB No. 1587:** Medical marijuana must be maintained in a secured facility equipped with locks, security cameras, alarms, or other security devices
6. Illinois	Alarm, security plan reviewed by state police including but not limited to: facility access controls, perimeter intrusion detection systems, personnel identification systems, 24-hour interior and exterior surveillance
7. Maine	Fence, exterior lighting, intrusion detection, video surveillance
8. Maryland	None
9. Massachusetts	Alarm, storage vaults, exterior lighting, video surveillance, backup systems, failure notification system
10. Minnesota	Alarm, facility access controls, perimeter intrusion detection systems, personnel identification system
11. Nevada	Alarm, single entrance, intrusion detection, exterior lighting, video surveillance, battery backup, failure notification system
12. New Hampshire	Lighting, physical security, video security, alarm requirements, measures to prevent loitering, on-site parking
13. New Jersey	Alarm, exterior lighting, video surveillance, power backup, automatic notification system
14. New Mexico	Alarm system
15. New York	Surveillance system
16. Oregon	Alarm, video surveillance, safe
17. Rhode Island	Alarm, emergency notification system, exterior lighting
18. Vermont	Alarm, exterior lighting, intrusion detection, video surveillance

Source: Legislative Reference Bureau and Office of the Auditor

Opponents are also concerned about dispensaries being located near schools and other family-oriented community venues. Regulation, as proposed in HB No. 1587, can control this likelihood by either stipulating the distance that dispensaries must be from certain entities (which would require an amendment to the current bill), or limiting the number of dispensaries per geographic area (as contemplated in the current bill).

Other stakeholders worry that dispensaries may try to target sales to minors by producing candy-like, marijuana-infused products, or to individuals who are not permitted to possess or use medical marijuana. Exhibit 2.6 shows a marijuana-infused candy that could arguably appeal to children.

Exhibit 2.6
Example of Marijuana-Infused Product That May Appeal to Children

Source: Denver Police Department

However, we found that regulation can provide controls to mitigate these concerns. For example, either the Legislature, through statute, or the Department of Health, through administrative rules, could mandate that dispensaries cannot be located near schools and edible products must comply with specific labeling requirements, to avoid looking like candy. The law already requires qualifying patients to register with the State, which requires dispensaries to verify “blue card” status at the time of purchase.

Regulation would satisfy most other statutory criteria, too

In addition to being warranted to protect consumers' health, safety, and welfare as required under Section 26H-2, HRS, regulating medical marijuana dispensaries would also meet most of the other statutory criteria for regulation. Specifically, regulation is not likely to unreasonably restrict dispensary operators' ability to open a dispensary in Hawai'i, and fees for regulating dispensaries are likely to cover administrative costs of the program. Additionally, we did not find any suitable alternatives to state regulation that would adequately protect consumers from the threats to their health, safety, and welfare posed by unregulated dispensaries.

Although we found no evidence of abuses by existing dispensaries (outside Hawai'i, since none are in operation in the state yet) and were unable to determine whether regulation would adversely affect the price of medical marijuana for qualifying patients, we determined that these findings do not outweigh the arguments for regulation.

Regulation is not likely to unreasonably restrict potential dispensary operators' ability to join the field in Hawai'i

Federal law prohibits transportation of Schedule I controlled substances through any federal security checkpoint. Marijuana, medical or otherwise, is classified as a Schedule I substance and would be confiscated at federal security checkpoints at any airport. As a result, patients are restricted to obtaining and consuming their medical marijuana on their home island.

To address this issue, HB No. 1587 calls for at least one dispensary per county, and allows DOH to raise the number of allowable dispensaries based on patient needs by adopting rules pursuant to Chapter 91, HRS, *Administrative Procedure*. Since DOH will have a registry of all qualified patients and their geographic locations, it is best suited to determine the appropriate number of dispensaries per county (effectively, per island), along with where they should be located. Provided DOH allows for enough dispensaries to serve each island's patient population, we do not anticipate that regulation would unreasonably restrict entry into the field for potential dispensary operators.

Fees for regulating dispensaries will likely cover administrative costs of the program

Under Section 26H-2, HRS, regulatory programs must be self-sustaining via fees. We were unable to conclusively determine whether DOH's regulatory program would be self-sustaining, although it appears likely that both fees and the number of allowable dispensaries in the state will be balanced so that the program pays for itself.

DOH estimated that in the first year, it would require funds for information technology (IT) development; two professional staff to oversee development of rules, standards, requests for proposals, evaluation criteria, monitoring, and violation system travel; office equipment and rent. DOH estimated its annual recurring costs would include two professional staff to administer, regulate, and monitor the program; one health educator; one accounts clerk/office assistant; travel to visit neighbor-island dispensaries; and annual IT services. Exhibit 2.7 outlines DOH's estimate of the cost to regulate dispensaries.

Exhibit 2.7
DOH Estimated Annual Costs to Operate a Medical Marijuana Dispensary Program

	Start-up	Recurring
Staff	$160,000	$270,000
Information technology	100,000	50,000
Equipment	100,000	-
Consultant	35,000	-
Rent	20,000	20,000
Travel	-	70,000
Total	**$415,000**	**$410,000**

Source: Office of the Auditor based on DOH information

HB No. 1587 contemplates charging fees for dispensary applications, annual dispensary registrations, and annual cultivation center registrations. Other states also charge fees for dispensary applications, dispensary registration or licensure, and cultivation center registration or licensure. Among the 18 states that regulate medical marijuana dispensaries, the highest regulatory fee is $75,000 annually for producers (separate from dispensaries) in Connecticut. The lowest registration fee is $1,000 for dispensaries, also in Connecticut. Numerous states impose regulatory fees between $10,000 and $50,000 annually. As shown in Exhibit 2.8, regulatory fees, not including application fees, charged to dispensaries by other states range from $1,000 to $75,000 annually.

Exhibit 2.8
Regulatory Fees Charged to Medical Marijuana Dispensaries

State	Fees Charged to Dispensaries
1. Arizona	$5,000 application fee $1,000 renewal fee
2. Colorado	Medical marijuana centers: $6,000 to $14,000 application fee $3,000 to $11,000 license fee $3,300 to $11,300 renewal fee Optional premises cultivation operations: $1,000 application fee $2,200 license fee $2,500 renewal fee
3. California	Unknown. Dispensaries are regulated at the city and county level, so fees vary widely.
4. Connecticut	Dispensaries: $1,000 application fee $1,000 per year license and renewal fees Producers: $25,000 application fee $75,000 annual license and renewal fee
5. Delaware	$5,000 application fee $40,000 annual certification and renewal fees
6. Illinois	Fees will be determined by administrative rule.
7. Maine	$15,000 application fee $15,000 renewal fee
8. Maryland	Fees to be determined by administrative rule.
9. Massachusetts	$31,500 in fees for a 2-step application process $50,000 annual registration fee
10. Minnesota	$20,000 application fee Annual fee to be established by Commissioner of Health
11. Nevada	Medical marijuana dispensaries: $5,000 application fee $30,000 registration fee $5,000 renewal fee Cultivation facilities: $5,000 application fee $3,000 registration fee $1,000 renewal fee
12. New Hampshire	Fees will be established by Department of Health and Human Services

State	Fees Charged to Dispensaries
13. New Jersey	$20,000 application fee ($18,000 refunded to unsuccessful applicants) $20,000 renewal fee
14. New Mexico	$1,000 application fee $5,000 to $30,000 renewal fee
15. New York	Fees to be determined by the Commissioner of Health
16. Oregon	$4,000 application fee $4,000 renewal fee
17. Rhode Island	$250 application fee $5,000 registration fee $5,000 renewal fee
18. Vermont	$2,500 application fee $20,000 registration fee $30,000 renewal fee

Source: Legislative Reference Bureau

The DOH anticipates charging graduated fees of $10,000, $35,000, or $50,000 per dispensary based on the number of patients served. Whether DOH's regulatory program is self-sustaining based on its anticipated fees also depends on how many dispensaries are allowed to operate in the state. We have no data to suggest how many dispensaries, or their size, are contemplated, although DOH agreed that 20 dispensaries statewide would be a reasonable number. At an average of over $30,000 per dispensary, this would amount to more than $600,000 in revenue and fully cover DOH's estimated program costs.

No alternatives to regulation have been identified to protect consumers

In determining the need for regulation, we also considered whether any alternatives, such as federal programs, other state laws, marketplace constraints, private action, or supervision, would provide sufficient protection to medical marijuana consumers. We researched various state dispensary models and contacted stakeholders and dispensary program administrators alike, and found no viable alternatives to state regulation of dispensaries that would adequately protect consumers. Neither the American Civil Liberties Union of Hawai‘i, the Coalition for a Drug-Free Hawai‘i, nor the administrator for the Rhode Island medical marijuana dispensary program were able to offer any alternatives to regulation that would protect consumers. We also received responses from the Honolulu Police Department, Community Alliance on Prisons, Maui Police Department, and the Honolulu Prosecuting Attorney, none of whom provided any other viable alternatives to regulating medical marijuana dispensaries.

No evidence of abuses by dispensaries

Section 26H-2, HRS, stipulates that evidence of abuses by providers is to be accorded great weight in determining whether regulation is desirable. Since there are currently no medical marijuana dispensaries operating within Hawai‘i, we contacted medical marijuana program administrators in other states. We did not receive any indication that abuses by dispensaries have occurred. The Rhode Island Department of Health told us it was unaware of any instances of abuse by dispensaries in its state. New Mexico medical marijuana dispensary administrators reported that to counteract potential abuses by dispensaries of illicit sales to individuals who are not qualified medical marijuana patients, the program uses a rigorous screening process for dispensary applicants so that only legitimate business operators may distribute medical marijuana. The program also uses a seed-to-sale tracking system for marijuana plants grown and sold by dispensaries.

Despite it currently being illegal to operate a medical marijuana dispensary in Hawai‘i, we also contacted the state’s Better Business Bureau, Ombudsman, and the Department of Commerce and Consumer Affairs’ Regulated Industries Complaints Office and Office of Consumer Protection regarding any complaints related to medical marijuana dispensaries. None of the four entities were able to locate any relevant complaints within the last three years.

Nevertheless, although we did not find any instances of abuses perpetrated by dispensaries, either within or outside Hawai‘i, we believe that the threat to consumers’ health, safety, and welfare is sufficiently strong to warrant their regulation.

Effect of regulation on the price of medical marijuana is unknown

State law also specifies that regulation should be avoided if it artificially increases the costs of goods and services to consumers, unless the increase in cost is exceeded by potential dangers to the consumer. We found that it is unclear whether the price of medical marijuana would change following regulation of a dispensary system in Hawai‘i. However, we believe a potential cost increase is outweighed by the risks to consumers’ health, safety, and welfare in the absence of regulation.

No stakeholder or dispensary system administrator was able to provide evidence that regulation would cause a price change, either up or down, from current black market prices. The Coalition for a Drug-Free Hawai‘i said that regulation would “definitely” increase prices, since dispensaries would pass on the cost of doing business to consumers. The Coalition further asserted that such a cost increase could encourage consumers to continue to rely on the black market—where presumably there are no overhead costs—to obtain their marijuana.

However, we found no evidence that other states' regulation of medical marijuana dispensaries has affected the price of marijuana post-regulation. While the Coalition's argument fits basic economic principles of a regulated market, we found that because marijuana is both a recreational and medicinal drug—and in the absence of any significant evidence to the contrary—we are not persuaded that such an outcome is a foregone conclusion. According to articles in the *Honolulu Star-Advertiser* and *The Economist*, the street price of marijuana increased in Washington and Colorado following legalization of recreational use in those states. However, this is not particularly indicative of what might happen in Hawai‘i, because recreational use arguably caters to a different market than medicinal use of marijuana.

Furthermore, comparing the street price of marijuana in an environment where recreational use is legal versus one where only medicinal use is legal is inappropriate and inconclusive. Regardless, if the street price of marijuana in Hawai‘i were to rise following the regulation of dispensaries, it would further support the argument that regulation would protect public welfare by reducing demand on the black market and thereby reducing criminal activity.

Most other states with medical marijuana programs regulate dispensaries

In considering whether regulation is appropriate we also looked at whether most other states with medical marijuana programs regulate dispensaries, and for the same reasons. We found that 18 of the 23 states (78 percent) with medical marijuana programs also regulate dispensaries. These entities are, for example, variously called medical marijuana centers, dispensaries, dispensing organizations, medical marijuana dispensaries, and medical marijuana facilities. Thirteen states require dispensaries to be registered; four require them to be licensed, either with the state or county; and one issues permits to qualifying dispensaries. Exhibit 2.9 lists these states and the level of regulation they require of dispensaries.

Exhibit 2.9
Types of Dispensary Regulation in Other States

State	Type of Regulation	Name of Dispensing Entity
1. Arizona	Registration	Nonprofit Medical Marijuana Dispensaries
2. California	Registration	Cooperatives or Collectives
3. Colorado	Licensure	Medical Marijuana Centers
4. Connecticut	Licensure	Dispensaries
5. Delaware	Registration	Registered Compassion Centers
6. Illinois	Registration	Dispensing Organizations
7. Maine	Registration	Dispensaries
8. Maryland	Licensure	Dispensaries
9. Massachusetts	Registration	Medical Marijuana Treatment Centers
10. Minnesota	Registration	Medical Cannabis Manufacturers
11. Nevada	Registration	Medical Marijuana Dispensaries
12. New Hampshire	Registration	Alternative Treatment Centers
13. New Jersey	Permit	Alternative Treatment Centers
14. New Mexico	Licensure	Licensed Producers
15. New York	Registration	Registered Organizations
16. Oregon	Registration	Medical Marijuana Facilities
17. Rhode Island	Registration	Compassion Centers
18. Vermont	Registration	Dispensaries

Source: Legislative Reference Bureau

House Bill No. 1587 Is Flawed

Regulation of a system of medical marijuana dispensaries in Hawai‘i is warranted. However, the proposed regulatory vehicle, HB No. 1587, has several flaws. First, licensure would be more appropriate than registration for dispensaries. Second, the bill does not specify a funding mechanism for the new regulatory program. No seed moneys are provided, and the existing Medical Marijuana Registry Special Fund statute does not contemplate use of the fund for overseeing a dispensary regulatory program. We also found that various duties in the bill are unclear or inappropriately assigned to the entity to be regulated—dispensaries—rather than the regulating authority, the Department of Health. Finally, the bill needs several technical changes in order to be effectively implemented.

Licensure is more appropriate than registration for dispensaries

We found that given the level of harm unregulated dispensaries would pose to both qualifying patients and the general public, *licensure* is a more appropriate form of regulation than *registration*. At present, HB No. 1587 proposes that dispensaries should be registered. Registration merely requires practitioners or entities to enter their names on a state registry; it does not prevent unregistered practitioners or entities from providing the same services. In contrast, a licensing law prevents persons or entities that are not licensed from providing specified services. Licensure is used by governments to protect society from incompetents and charlatans. Licensing benefits the public by assuring consumers of quality goods and services—an important consideration when dealing with marijuana in the form of medicine. In this case, licensure is warranted because it would allow only licensed dispensaries to operate. However, we found that HB No. 1587 already essentially outlines a licensure program, since it requires dispensaries to be registered prior to manufacturing, cultivating, dispensing, possessing, using, or distributing medical marijuana or drug paraphernalia. Therefore, HB No. 1587 should be amended to propose a system of *licensed* rather than *registered* dispensaries.

The bill does not provide seed moneys or specify a funding mechanism

Section 26H-2, HRS, requires regulatory fees to cover the costs of administering a regulatory program. New regulatory programs are commonly provided seed moneys from which to begin their first-year operations before a program is expected to be self-sustaining. However, HB No. 1587 does not provide any seed moneys or specify a funding mechanism for the medical marijuana dispensary program's start-up.

According to DOH's STD/AIDS Prevention Branch, which would oversee the regulation of dispensaries, approximately $415,000 in startup moneys for IT development and professional staff is needed. The branch also requires physical space from which to operate the dispensary regulation program. In the absence of a start-up appropriation for the program, the department would need to find resources for the program within its existing budget.

Furthermore, although a Medical Marijuana Registry Special Fund already exists under Section 321-30.1, HRS, the statute refers only to the medical marijuana registry system (which currently applies to patients and caregivers only); it does not mention *dispensaries*. The statutory purpose of the fund, should medical marijuana dispensaries become regulated, may need to be amended to allow use of the fund for regulating medical marijuana dispensaries.

Various duties are unclear or inappropriately assigned

At present, HB No. 1587 imposes several duties and requirements that are either ambiguously or inappropriately assigned. For example, the bill requires dispensaries to revoke or suspend the registration of any person or entity if DOH determines the person or entity has violated the relevant statute. However, it is inappropriate to assign dispensaries the duty of revoking or suspending registrations; this power should be reserved to DOH as the regulating authority. Similarly inappropriate, the bill requires dispensaries to establish sliding scale registration and annual renewal fees for all persons and entities required to register under the relevant statute. Again, it is inappropriate to assign such a duty to the regulated entity, rather than the regulating authority (i.e., DOH).

In addition, some responsibilities in the bill are ambiguous. For example, the bill currently requires dispensaries to notify DOH if a dispensary agent ceases to be associated with that dispensary, in which case the agent's registration card is to be revoked; however, the bill does not specify by whom. We suggest this duty be articulated as belonging to DOH. Likewise, the bill is silent on who is to revoke dispensary agent registrations and suspend dispensary registrations in the event an agent violates the relevant statute. Again, this duty should clearly be assigned to DOH.

These powers should be reserved for DOH as the state agency responsible for administering the regulatory program. It is inappropriate to delegate these powers to the entity being regulated. Delegating suspension or revocation power to dispensaries would create a conflict of interest and circumvent DOH's regulatory oversight function.

Technical changes are needed

Certain technical amendments to the bill are also needed. For example, DOH will need a period of time in which to establish a regulatory program for dispensaries before it can be expected to implement it, so the effective date of the act should be appropriately extended. Likewise, if the Legislature chooses to enact a licensure, rather than registration, scheme for dispensaries, then Section 4 of the bill should be amended to remove dispensaries from the list of entities *registered* with DOH.

Conclusion

Given that marijuana is still classified as a federal Schedule I drug yet is legal as a medicine under Hawai‘i state law, the regulation of a distribution system for medical marijuana is warranted to protect Hawai‘i's qualifying patients and the wider community. According to the Legislative Reference Bureau's September 2014 report, there is no model program for regulating a system of medical marijuana dispensaries. There are, however, numerous examples to draw from that can collectively address the needs of patients in Hawai‘i while also

protecting the safety and welfare of the community at large. Based on the level of potential harm to consumers, we conclude that medical marijuana dispensaries should be licensed rather than merely registered. In addition, in order to effectively implement such a regulatory framework, certain flaws in HB No. 1587 need to be corrected.

Recommendations

1. A system of medical marijuana dispensaries should be regulated in Hawai‘i.

2. The Legislature may wish to consider amending HB No. 1587 to:

    a. Require dispensaries to be licensed;

    b. Grant authority to the Department of Health to determine the number of dispensaries to be allowed in Hawai‘i, and where the dispensaries are to be located;

    c. Assign revocation and suspension powers regarding medical marijuana dispensary licenses and dispensary agent registrations to the Department of Health;

    d. Provide start-up funding to DOH for the medical marijuana dispensaries regulatory program; and

    e. Extend the effective date of the act to allow the Department of Health time to implement the program.

3. The Legislature may wish to consider amending Section 321-30.1, HRS, to specify that the Medical Marijuana Registry Special Fund may be used to administer the regulation of medical marijuana dispensaries.

Response of the Affected Agencies

Comments on Agency Responses

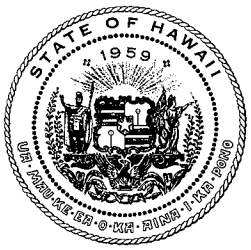
We transmitted a draft of this report to the Department of Health (DOH) and the Department of Public Safety (PSD) on November 14, 2014. A copy of the transmittal letter sent to DOH is included as Attachment 1. DOH's response, dated November 19, 2014 and received on November 21, 2014, is included as Attachment 2. PSD did not submit a response.

DOH expressed its appreciation for our analysis and offered several technical comments, regarding use of the term "primary caregiver" and clarifying the current registration fee for medical marijuana patients and estimated startup costs for the dispensary program. DOH also clarified that its agreement on the reasonable number of dispensaries statewide was hypothetical.

We made minor technical corrections for accuracy, clarity, and style prior to publication.

ATTACHMENT 1

STATE OF HAWAI'I
OFFICE OF THE AUDITOR
465 S. King Street, Room 500
Honolulu, Hawai'i 96813-2917



JAN K. YAMANE
Acting State Auditor

(808) 587-0800
FAX: (808) 587-0830

November 14, 2014

COPY

The Honorable Linda M. Rosen, M.D., M.P.H.
Director
Department of Health
1250 Punchbowl Street
Honolulu, Hawai'i 96813

Dear Dr. Rosen:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Sunrise Analysis: Regulation of Medical Marijuana Dispensaries*. We ask that you telephone us by Wednesday, November 18, 2014, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit your hard copy response to our office no later than 4:30 p.m., Friday, November 21, 2014.

The Department of Public Safety, the Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

for Jan K. Yamane
Acting State Auditor

Enclosures

NEIL ABERCROMBIE
GOVERNOR OF HAWAII

LINDA ROSEN, M.D., M.P.H.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:
14-004509

November 19, 2014

Ms. Jan K. Yamane
Acting State Auditor
Office of the Auditor
465 S. King Street, Room 500
Honolulu, HI 96813-2917

2014 NOV 24 PM 12:40

Dear Ms. Yamane:

Subject: Department of Health Comments on Draft Auditor's Report Entitled, "Sunrise Analysis: Regulation of Medical Marijuana Dispensaries"

The Department of Health (DOH) thanks the Office of the Auditor for the work done developing the report entitled, "Sunrise Analysis: Regulation of Medical Marijuana Dispensaries" and for opportunity to review a draft of this report. Our comments are as follows:

1. There appears to be an incorrect usage of the term primary caregiver in place of the term caregiver on pages 1, 3 and possibly other pages.

2. The current medical marijuana registration fee is $25. The Department of Public Safety is in the final stages or changing its administrative rules to provide for a $35 annual fee - Page 3.

3. There appear to be inconsistencies in reporting of the estimated startup cost for DOH to establish the dispensary system. Exhibit 2.7 on Page 22 details startup costs estimated at $415,000 while on page 28 the estimate startup cost is $100,000. Although the definition and duration of startup can vary the more detailed estimate on page 22 is the more accurate figure.

4. DOH's stated agreement that "20 dispensaries statewide would be a reasonable number" is hypothetical and not based on in depth deliberations or research by DOH - Page 24.

Thank you for the opportunity to provide comments.

Sincerely,

Linda Rosen MD MPH

Linda Rosen, M.D., M.P.H.
Director of Health

c: Communicable Disease and Public Health Nursing Division
STD/AIDS Prevention Branch