Medical Cannabis Insurance Reimbursement (MCIR) Working Group
Act 161 (SB2488 SD2 HD1 CD1) Session Laws of Hawai'i 2018

Meeting Minutes

DATE:	October 23, 2018
TIME:	2:00 PM
LOCATION:	Hawai'i State Capitol, CR229

Working Group Members in Attendance:
Sen. Rosalyn Baker, Co-chair
Rep. John Mizuno
Gordon Ito, Insurance Commissioner
Judy Mohr Peterson, Med-QUEST Administrator
Jennifer Diesman, HMSA (representing a mutual benefit society)
Garret Sugai, Kaiser Permanente (representing a health maintenance organization)
Laura Esslinger, AlohaCare (representing a Medicaid managed care plan via teleconference)
Mike Takano, Pono Life Sciences (representing a licensed medical cannabis dispensary)

Excused:
Rep. Roy Takumi, Co-chair
Sen. Stanley Chang
Monique Chantal, parent of a minor qualifying patient
Randy Gonce, qualifying patient

At the invitation of the chairs, Peter Whiticar and Michele Nakata from the Department of Health (DOH) joined the working group discussion, as well as Jill Nagamine and Daniel Jacob, Deputies from the Office of the Attorney General who advise DOH. Rep. Joy San Buenaventura also attended as did staff from Co-chair Rep. Roy Takumi and working group member Sen. Stanley Chang.

I. Introduction, Sen. Roz Baker

II. Review and Approval of Minutes
There were no corrections or additions to the minutes presented.

III. Department of Health: The Medical Cannabis Program in Hawai'i

- Peter Whiticar (Chief, DOH Harm Reduction Services Branch) and Michele Nakata (Dispensary Program) provided the working group with an extensive review of the medical cannabis programs within the Department of Health. Key points included the following:
    - The two distinct medical cannabis programs within the DOH (the Registry and the Dispensary Programs) will be integrated and renamed the Office of Medical Cannabis Control and Regulation in approximately six months.
    - In 2015, the Department of Health (DOH) took over the medical cannabis program from the Department of Public Safety (PSD). At that time there were less than 12,000 qualified medical cannabis patients. Currently there are approximately 24,000 qualified medical cannabis patients in Hawai'i, increasing at a rate of 2-3% per month.

- To become a qualified patient an individual must have a qualifying debilitating medical condition. The initial list of qualifying conditions was established by the legislature and can be expanded via a DOH petition process from patients or providers, or by legislative action. Proposed additions to the list of qualifying conditions submitted to the Department of Health via petition are reviewed annually and the process includes a public hearing.
- In order to register as a qualified medical cannabis patient, a individual must present certification to the Department of Health that the patient has been diagnosed with one of the qualifying debilitating conditions from a physician (DO, MD) or advanced practice registered nurse (APRN) licensed in Hawai‘i. Less than 150 physicians statewide are making certifications. This is a relatively small number of providers making certifications for a large number of patients. DOH hopes more primary care providers will consider integrating medical cannabis as an option into their regular treatment regimes, rather than referring patients to another provider for certification.
- A bona fide provider-patient relationship is required for an individual to receive certification. The initial office visit consists of an in-person physical exam and a review of the patient's medical records. The provider must discuss with the patient the potential risks and benefits associated with treatment via medical cannabis. DOH does not intervene in the certification process.
- The patient and caregiver (if applicable) submit the provider certification, identification documents and related information to the Department of Health to be added to the registry. The Department then issues a 329 card to the patient and caregiver (if applicable), which designates qualified patient status, confers the patient protections present in HRS Ch329, and allows the patient cultivate or purchase medical cannabis at a licensed dispensary. DOH noted that an accurate registry is particularly important for law enforcement verification purposes. DOH does not provide personal identifying information to law enforcement, rather simply informs law enforcement whether a persons' registration is valid or not. Mr. Whiticar briefly addressed the previous backlog in the registry. He outlined some of the reasons for the backlog, steps the Department has taken to reduce that backlog, and reported that wait-times for registration are down to around a week, with priority cases identified by physicians or DOH processed on the same day they are received.
- DOH is finalizing rules for the registration of qualified medical cannabis patients from other states with the help of the Office of the Attorney General (AG). The rules are planned to be published in December and become effective in 2019. DOH is working with its information technology contractor to develop an online application for out-of-state patients to register as a qualified medical cannabis patient prior to travelling to Hawai‘i. With the adoption of the new rules, DOH will begin issuing electronic 329 cards for both out-of-state and resident patients to further reduce wait-times and mitigate issues created by lost cards.
- There are 8 licensed dispensaries. Six provide retail sales. Currently the two dispensaries in Hawai‘i County do not provide retail sales. Both have received the initial notice to proceed and should be growing cannabis before the end of 2018. Each licensee is responsible for the following operations: growing cannabis, manufacturing any products and conducting retail sales.
- DOH uses a secured seed-to-sale electronic tracking system used by dispensaries. Each plant is barcoded and tracked from the time it is planted, through any

manufacturing or testing processes, until the time it is sold to a qualified medical cannabis patient, both to ensure product safety and prevent diversion.

- Before medical cannabis products can be offered for sale in a dispensary, they must pass laboratory testing standards for:
  - Potency
  - Heavy metals
  - Pesticides
  - Solvents
  - Visible, foreign or extraneous materials
  - Moisture content (plant materials only)
  - Total viable aerobic bacteria
  - Total yeast and mold
  - Total coliforms
  - Bile-tolerant Gram-negative bacteria
  - E. coli and Salmonella species
  - Aspergillus species
  - Mycotoxins

- Current DOH priorities include updating administrative rules, effectuating the program re-organization mandated by Act 159 SLH 2018 and filling remaining vacancies within the medical cannabis programs. Updated administrative rules are slated to be released in January 2019.
- Currently, there are 3 testing laboratories certified by the Department of Health to conduct testing of medical cannabis: Steep Hill, Aeos Labs Inc. and Pharmlabs Hawai‘i, LLC. Only Steep Hill is certified to complete all the required tests. The remaining laboratories are working towards gaining full certification.

- QUESTIONS TO DOH:
  - Q: Of the approximately 150 physicians who engage in the patient certification process, how many are in palliative care? A: *DOH does not keep track of the certifying provider's specialty. DOH will look into this further and report back to the Working Group.*

  - Q: For qualified patients from out-of-state, is there a process or program to dispose of excess medicine before a patient gets on an airplane? A: *Patients should not have more medical cannabis than they are entitled to have; if they do, that's a problem with the dispensaries' operation. It is illegal to have medical cannabis at an airport due to federal law, though the Transportation Security Administration (TSA) has indicated that enforcement will be limited to overt cases, i.e. where cannabis scent can be detected or flower is clearly visible. There is no current process for out-of-state patients to dispose of their excess medical cannabis. Hawai‘i is the first state to recognize out-of-state patients, so there is no framework from other jurisdictions. Disposal of unused medical cannabis warrants further examination. The Department of the Attorney General (AG), Department of Health (DOH), Department of Public Safety (PSD), the Drug Enforcement Administration (DEA), and the Hawai‘i, Maui, Honolulu, and Kauai Police Departments jointly operate the Hawai‘i Medication Drop Box Program, which could serve as a potential model.*

- Q: Do the dispensaries have the option to re-test medical cannabis that has not met laboratory standards?

  A: *Retesting is allowed, but limited under the statute. The retesting process was intended to act as way to check the labs' work, as most labs are still setting up and standardizing their testing procedures. Dispensaries can go to another lab to test a sample if they feel that one labs results are not accurate, as a way to back-check the labs' work. DOH is considering employing the State laboratory as a reference laboratory to conduct quality assurance checks. Re-testing to date has only been to ascertain potency. If the legislature chooses to authorize dispensing of edible medical cannabis products, additional/alternate laboratory standards may be required, as some edible matrices are not suited to the currently required testing battery.*

- Q: Are there any dosing standards, perhaps from other States with a longer history of medical cannabis, which denote optimum usage for the various strains and strengths of medical cannabis?

  A: *There is no real schedule for medical cannabis dosing. Bioavailability of any substance will vary between individuals. Whether the substance is a standard pharmaceutical or medical cannabis, individuals respond to different doses. However, the dosage range for medical cannabis may be broader than with a standard pharmaceutical drug. Medical cannabis is a botanical product. In addition to the major two components of cannabis, THC and CBD, there can be over 100 different "entourage" compounds present within a plant. These entourage compounds vary greatly between strains of cannabis, and can modify the effect of the two major components. Cannabis scientists refer to this as the "entourage effect". Additionally, people experience symptoms differently and have different behavioral responses based on their subjective experiences. Two patients with a similar painful injury may take different doses of pain medication due to different levels of pain tolerance. Thus, there is a behavioral component to dosing.*

- Q: Is personally identifiable information on the medical cannabis patient registry protected under the Health Insurance Portability and Accountability Act (HIPAA)?

  A: *DOH does not provide personally identifiable information to law enforcement. However, DOH is not a covered entity under HIPAA. Nevertheless, DOH follows the strictest privacy and confidentiality protocols with regard to the medical cannabis program, as the registry does contain patients' personal information. Release of personal information from the Medical Cannabis Registry requires a subpoena.*

- Q: Before the dispensary system was operational, and qualified patients had to either grow their own medical cannabis or have a caregiver do so, what was the patient tracking system like?

A: *The patient tracking system was very similar to what it is like now, because there has always been a critical need for law enforcement to distinguish qualified patients from the non-patients accurately and quickly.*

- Q: Does DOH track the number of qualified patients who grow their own cannabis?

- A: *DOH tracks whether a patient has a caregiver, but cannot tell whether a patient gets their medical cannabis from their own grow site or a dispensary. Patients cannot grow their own cannabis without registering a grow site, but can register a grow site and not actually grow. DOH does not track this, but it does come up with law enforcement. Dispensaries are able to track the number of patients who purchase medical cannabis in the dispensaries.*

- Peter Whiticar expressed concern regarding the price patients are paying for visits to a MD, DO or APRN for the purpose of becoming certified as a medical cannabis patient. In some cases, people are paying $300 or more for the visit, and this is a significant cost for people on disability or a fixed income. Specifically, it is not clear why providers are not charging the office visit to insurance. Mr. Whiticar discussed the potential of a campaign to educate providers that these office visits are allowed to be billed under insurance. Sen. Baker asked HMSA to comment further on this issue. HMSA explained that they have a capitated payment arrangement with most of their primary care providers, but billing codes for services and diagnoses associated with office visits must be tracked for a variety of purposes. If a person visits a provider for pain, a physical exam, etc., those services could be coded and billed. If a provider then chose to make a certification of a debilitating condition pursuant to HRS §329-122, nothing would prevent the visit itself from being billed to insurance. However, if a provider wanted to submit a claim for compensation above and beyond what is required during a regular office visit for making a certification pursuant to HRS §329-122, there is no mechanism for doing so. Mr. Whiticar offered that this might be an area where provider education and reassurance is needed. Providers need to know that this option is available and that there is no risk associated with making the certification to their license. Sen. Baker suggested that the Board of Medicine could be instrumental in disseminating training and education materials. Rep. San Buenaventura noted that there is no billing code for the physical required to obtain a commercial driver's license (CDL) or other work-related issue, the visit is not typically covered by regular health insurance. She then suggested that if the certification process is not employment-related, then there should be a billing code for that service. Jill Nagamine noted that most patient-provider interactions are initially symptom-based with the doctor then recommending methods of treatment with which they are familiar, and there may be a series of failed therapeutic modalities tried before the patient suggests a trial of medical cannabis. The problem may be that a patient does not want to have to go through this process if they already have an idea of what will help their pain. Rep. San Buenaventura advised that a provider, upon hearing a complaint of back pain will first ascertain the cause of the pain, because they must find out where to bill – it could be workers' compensation, auto insurance or regular health insurance. Sen. Baker counseled that the scope of the Working Group's discussion was intended to be limited to health insurance. Jill Nagamine commented that, regardless of what type of insurance is billed, the initial visit should be covered. Ms. Nagamine further opined that providers may be concerned with liability associated with making certifications pursuant to HRS §329-122. Sen. Baker noted that there is no criminal or other risk associated with making a certification that a patient has a debilitating medical condition. Ms. Nagamine replied that the providers must then go one

step further and make a medical judgment with regard to the outcomes of treatment with medical cannabis. Sen. Baker read the statute and commented that the statutory language used in subsection (a)(2) was not intended to be more than a provider offering an opinion on a number of potential outcomes, and wasn't meant to be a liability concern, because the doctor is not prescribing anything. (HRS §329-126 has broad protections for providers engaging in the certification process). Sen. Baker expressed the need for additional provider education, as well as easy access to scientific studies and medical cannabis frameworks developed from other jurisdictions. Mr. Takano noted that there is an incentive for physicians in capitated payment arrangement to take on medical cannabis patients since the provider would probably see additional compensation in the long-term than a $300 initial visit. He further noted that the dispensaries have met with provider groups who have reviewed the certification process and are comfortable with billing visits for certifications, noting that no new processes were required. The dispensaries also spoke with the federation of medical boards, and while they have typically been neutral on cannabis-related issues, the federation of medical boards agree that data collection on medical cannabis is an essential next step.

- Sen. Baker suggested that the working group carry the following topics over into the next meeting:
    - Potential reimbursement models
    - Dosing models
    - Questions that HMSA submitted to the Chairs be transmitted to DOH and the AG's office for review

- Sen. Baker opened the floor to Mike Takano to present a synopsis of their research paper entitled Rising Above the Opioid Crisis: Medical Cannabis Insurance Reimbursement – A New Wave of Medical Cannabis. His summary included the following key points:
    - The paper attempts to cover the major objectives of the working group as laid out in Act 161 SLH 2018, as well as medical cannabis' impact on the opioid epidemic.
    - New York's DOH created rules to allow medical cannabis to play a role in treating opioid addiction. He notes that the Legislature could further de-risk stakeholders to facilitate access to medical cannabis for those persons who might benefit from treatment.
    - Injured workers in Hawai‘i have strong protections for work-related injuries. Medical cannabis might provide an important treatment option for patients within that system.
    - The Legislature could provide an important role for influencing public policy going forward.

- HMSA: Can patient certification be done via telehealth?
  DOH: *Renewal can be done via telehealth but initial certification must be in person.*

- Kaiser: Most medical cannabis patients have pain-related debilitating medical conditions. Is there data that shows reduction in pain-related symptoms for medical cannabis patients in the paper?
  Mike Takano: *There is data from other states, but not from Hawai‘i. There are patient privacy concerns associated with tracking this data. The Department of Health is hoping to get an epidemiologist on board to analyze the medical cannabis program and other*

health-related metrics in Hawai‘i. There is data in the paper that suggest some promising trends. Additionally, when you compare the risks associated with medical cannabis treatment vs. treatment with opioids, medical cannabis poses far less risk for both deaths and addiction.

- Sen. Baker: Has anyone reviewed the scientific literature on medical cannabis in other jurisdictions that could help answer some of the questions raised by the working group?

  Mike Takano: *The existing data is limited. If Hawai‘i were to begin to create data on medical cannabis, it would be superior to that created by other states due to the strength of our regulatory framework and our geographical isolation. Most states with medical cannabis programs have at least one bordering states that does not have a medical cannabis program, and people are able to freely cross those borders. Out-of-state residents traveling into a jurisdiction to access cannabis can affect data sets in a number of ways, as can State's regulatory framework. Hawai‘i's data would be not be affected in so strong a manner as other states and would thus be of higher quality.* Carl Bergquist from the Hawai‘i Drug Policy Forum offered to submit to the working group a study on the effect of medical cannabis programs' effect on opioid overdoses and opioid prescription rates.

III. Next Steps and Announcements

- The next working group meeting will be Friday Nov. 9th at 10AM in CR325. Topics to be covered will include:
  - Costs of medical cannabis,
  - How patients receive information regarding dosing and how those providing that information are trained,
  - Information from other jurisdictions that provide insurance reimbursement for medical cannabis, and
  - Questions that HMSA submitted to the Chairs be transmitted to DOH and the AG's office for review
- Sen. Baker suggested that members:
  - Review the paper from Pono Life Sciences, Rising Above the Opioid Crisis: Medical Cannabis Insurance Reimbursement
  - Visit the DOH website for the medical cannabis program
  - Review the literature that Carl Bergquist will provide to members.

IV. Adjournment