

HCR 48 Task Force Meeting #8
Tuesday, December 30, 2014, 9:00 am-12:00 pm
Hawai'i State Capitol, Room 329

Task Force Members Present:

Lance Goto (alternate for Jill Nagamine), Attorney General's Office
Peter Whiticar, Department of Health
Robert Nagamine (alternate for Ted Sakai), Director Department of Public Safety
Jonathan White, Department of Taxation
Lee Ann Teshima, Department of Commerce and Consumer Affairs
Susan Chandler, University of Hawai'i Public Policy Center
Representative Della Au Belatti, House Committee on Health
Senator Rosalyn Baker
Representative Gregg Takayama
Jensen Uyeda, University of Hawai'i Tropical Agriculture and Human Resources
Pam Lichty (alternate for Rafael Kennedy), Drug Policy Forum
Dr. Clif Otto, Physician participating in Hawai'i's Medical Marijuana Program
Karl Malivuk, Patient over the age of 18 and a participant in Hawai'i's Medical Marijuana Program
Jari S. K. Sugano, Guardian of patient under the age of 10 who is a participant in Hawai'i's Medical Marijuana Program
Dana Ciccone, Caregiver participating in Hawai'i's Medical Marijuana Program
Dan Gluck, American Civil Liberties Union of Hawai'i
Alan Shinn, Coalition for a Drug Free Hawai'i

Task Force Members Absent:

Senator Josh Green
Jon Riki Karamatsu, Department of the Prosecuting Attorney
Harry Kubojiri, Law Enforcement Coalition
Dr. Christopher Flanders, Hawai'i Medical Association

Other Legislators in Attendance: Senator Will Espero

Introductions: Roundtable introduction of participants

Review of Ground Rules:

Timeline – Report Draft to Legislature (first week of January)

Approval of Minutes:

Approval of minutes for November 18, 2014, and December 16, 2014, deferred due to time constraints. Minutes will be distributed and approved via email.

Public Input

Federal Law Enforcement no longer raid state medical marijuana dispensaries (memo released December 22). Federal agencies are more receptive to industry and medical marijuana initiatives.

Voting Procedures for Task Force Proposals

YES = I'm OK with putting this recommendation into the Task Force Report.

NO = I do not want this recommendation in the Task Force Report.

DEFER = This proposal needs more work and should be put into an appendix for further discussion.

PROPOSED RECOMMENDATIONS, DISCUSSION & VOTE TALLIES BY TASK FORCE:

Revised recommendations distributed by Representative Belatti. These revised recommendations were a compilation of those recommendations carried over from the December 16, 2014, meeting, recommendations developed by the Policy Subcommittee on December 22, 2014, and revisions based upon Department of Health calculations for resources and staffing needed to establish medical marijuana dispensary system program.

(2) PRODUCERS:

RECOMMENDATION 2.5: The Legislature shall preserve the right of qualifying patients to continue to cultivate their own medication if they wish to do so.

- This recommendation recognizes concern that patients be allowed to continue to grow as they have for last 14 years of existence of program, way to maintain the status quo and allow those growing now to continue to do so.
- Question asked whether this recommendation allows patients to grow together?
- Current statute remains silent on coop growing; this proposal needs to be addressed at a later time.

VOTE TALLY: YES=15; NO=0; DEFER=1

(5) RANGE OF PRODUCTS:

RECOMMENDATION 5.1: All products distributed by a dispensary must be distributed in opaque, child-resistant packaging. These products must be labeled clearly with the phrase "FOR MEDICAL USE ONLY." The label must include information about the potency and contents of the product.

- Question asked about whether chocolate/baked goods would be okay, provided packaging follows the rest of the recommendations (single dosage)?
- This would allow for certain edibles because patients might not like smoking; find smoking uncomfortable. Might prefer product like that made in Colorado – low dose cookie called a “rookie cookie.”
- Question asked about whether this recommendation would apply to concentrated oil in capsule? See Recommendation 5.3 related to “(excluding pills, extracts, and oils).”

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 5.2: No dispensary or producer shall produce or distribute any candy with medical marijuana; provided that lozenges shall be permitted. “Lozenge” is defined as a small tablet intended to be dissolved slowly in the mouth.

- These recommendations regarding the range of products are broad. Task Force needs more discussion.
- Concern expressed that prescription medicines typically do not come in these various forms. We should not be allowing commercial products that taste good or are pleasurable. Because the intent is to provide accessibility to medication, we should consider limiting range of products to capsules or drops, similar to other current pharmaceutical type products. Note that this is not about food regulation as product is a Schedule I drug with psychoactive ingredients.
- Recognition that there are benefits to methods of delivery that patients can take more easily (i.e. baked goods have a longer lasting effect and are easier to take; capsules may cause nausea).
- Comment made that other medications such as children’s medications are sweetened.
- Comment made that Task Force should act judiciously at the outset as this is a medical product. Colorado is not a good example to use as that state is implementing recreational use not medical use of marijuana. As a starting point, product should be kept more like traditional medicine (pills, capsules, concentrated oils, etc. are okay). Concerns are with products like candies, chocolates, cookies, sodas, etc.
- People can place the medicine in/on various items on their own. Product doesn’t need to be sold at the dispensary in particular form. For example, patients can place oils on cookies themselves.
- We don’t want dispensaries be the purveyors of edibles. Are there are other ways to accommodate those patients who are nauseated?
- There are different forms of delivery being developed all the time. Flexibility in the law needed or else it gets ossified and becomes irrelevant. Process needs to remain dynamic.
- Suggestion made to create a list of permissible items rather than excluded items.
- Report can reflect discussion of the idea of “edible items” and that there should be flexibility to allow for changes to be made later.

VOTE TALLY: YES=10; NO=3; DEFER=1.

RECOMMENDATION 5.3: Lozenges, capsules, and pills containing medical marijuana shall be packaged in such a way so that one dose/serving – a single wrapped item – contains no more than 10mg of active THC.

- Recommendation amended to remove “and edible items (excluding pills, extracts, and oils)” and replace with “capsules, and pills”.
- Question raised about how will gelatin capsules containing oils be singly wrapped? Can these be individually wrapped and put into bottles? What about requiring blister pack containers for pills?
- Include language that would allow the items/range of products to be reviewed and evolve with the program/industry.
- Legislature will need to consider whether to add explanatory language to explain what “single wrapped item” might look like.

- Products identified in this recommendation are still subject to requirements in Recommendation 5.1 above (opaque, child-resistant packaging; labeling).

VOTE TALLY: YES=13; NO=1; DEFER=0

RECOMMENDATION 5.4: Oils and extracts are permitted, provided that they are clearly labeled with the potency and contents of the product.

- Products identified in this recommendation are still subject to requirements in Recommendation 5.1 above (opaque, child-resistant packaging; labeling).

VOTE TALLY: YES= 13; DEFER=2.

(5A) MANUFACTURER REGULATIONS:

RECOMMENDATION 5A.1: “Manufacture” means the production, preparation, propagation, compounding, conversion, or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction or chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by an individual for the individual’s own use.”

- Recommendation from Policy Subcommittee initially state that “process” be defined as including “any procedure by which marijuana buds are converted into another form for consumption by patients.”
- Recommendation made that Task Force adopt definition of “manufacture” in HRS §329-1 in Hawaii’s Uniform Controlled Substances Act such that “process” would be replaced with “manufacturer” and “processor” would be replaced with “manufacturer” in Recommendations 5A.1 through 5A.3.
- Per HRS §329.1: ““Manufacture’ means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for the individual's own use.” Need to make this definition specific to marijuana.

VOTE TALLY TO AMEND RECOMMENDATION 5A.1: YES=14; NO=1; DEFER=0.

VOTE TO ADOPT HRS §329-1 DEFINITION FOR MANUFACTURE: YES=15; NO=0; DEFER=0.

RECOMMENDATION 5A.2: Any individual or entity with a license to dispense and/or produce medical marijuana shall be permitted to manufacture medical marijuana; provided that any dispensary and/or producer must also obtain necessary licenses from the appropriate regulatory agency if engaged in the manufacturing of medical marijuana or any other activity that, independent of the medical marijuana program, would require a license.

- Existing Department of Health regulations for commercial kitchens would apply here. The only state regulatory structure/mechanism we have now are kitchen/cooking/food regulations with its own licensing and regulatory system. This is closest to regulatory structure we have at this time.

VOTE TALLY: YES=15; NO=0; DEFER=0

RECOMMENDATION 5A.3: The Department of Health shall conduct inspections and audits of facilities where medical marijuana is manufactured. The Department of Health shall enforce all applicable regulations.

- Would food safety regulation cover oils? Yes
- AG suggested that PSD enforcement division be involved in inspections similar to pharmacy checks because law enforcement should be involved where Schedule I drug is being manufactured.
- DOH disagreed with joint inspections as inspections and audits are about the safety of the products. DOH would conduct the audit and refer to the appropriate department (i.e. PSD) as needed. PSD also joined DOH in disagreeing with joint inspections.

VOTE TALLY: YES=14; NO=0; DEFER=1

(6) INSPECTIONS:

RECOMMENDATION 6.1: Licensed medical marijuana dispensaries and production centers shall be subject to announced and unannounced inspections and audits of its operations by the Department of Health at least annually.

VOTE TALLY: YES=10; NO=0; DEFER=0

RECOMMENDATION 6.2: Requirements for annual reports and audits shall be determined by the Department of Health.

- Task Force should be more specific as to what is required in reporting (i.e. active licenses, volume dispensed, etc.).
- This recommendation deals with inspections of dispensaries and production centers not DOH reports to legislature.

VOTE TALLY: YES=10; NO=0; DEFER=0

(8) FEES AND DESIGN OF A TAX STRUCTURE:

RECOMMENDATION 8.1: The fee for an application for a license to operate a dispensary shall be \$20,000, with \$18,000 refunded to unsuccessful applicants.

- General comment made that two application processes being created by Recommendations 8.1 and 8.2: one process for operating dispensaries, another process for production centers.
- Recommendation made to require 26 vertically integrated dispensaries-production centers as this would simplify application process.
- Consider adding explanatory section in report as to reasons for vertical integration (i.e. simplifying application process).

VOTE TALLY: YES=15; NO=0; DEFER=0

RECOMMENDATION 8.2: The fee for an application for a license to produce medical marijuana up to 500 plants shall be \$2,000, with \$1,000 refunded to unsuccessful applicants. The fee for an application for a license to produce medical marijuana between 501 and up to 1000 plants shall be \$4,000, with \$2,000 refunded to unsuccessful applicants.

- Task Force considered and amended this recommendation to apply tiered application fee depending on number of plants produced (ie. higher fee for higher number of plants).

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 8.3: The existing DOH Medical Marijuana Registry Special Fund shall be amended and renamed the Medical Marijuana Registry and Regulation Special Fund with subaccounts for the medical marijuana registry program and the medical marijuana dispensary program. Fees from qualified patients and caregivers shall be deposited into the medical marijuana registry program subaccount. Fees from applicants and licensees of medical marijuana production centers and medical marijuana dispensaries shall be placed into the dispensary program subaccount.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 8.4: Annual renewal licensing fees for dispensaries shall be \$30,000 subject to review and revision by the department. Annual renewal licensing fees for medical marijuana production centers are to be determined by the Department of Health. These fees shall be sufficient to cover the costs to administer the medical marijuana dispensary program.

- Task Force members discussed necessity that fees from applications and renewed licenses cover the costs to administer the medical marijuana dispensary program.
- No objections raised to setting annual renewal licensing fees at \$30,000 as this is in line with fees in other jurisdictions. There should be some language that allows review and revision of fees by the Department.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 8.5: Sales of medical marijuana shall be subject to the Hawaii General Excise Tax.

- This recommendation was amended to remove “currently 5% on wholesale transactions, 4.5% for retail transactions on O’ahu, and 4.0% for retail transactions on all other islands.”
- Basic concept is that the current GET scheme would apply to sale of medical marijuana products.

VOTE TALLY: YES=16; NO=0; DEFER=0

(12) EDUCATION AND TRAINING:

RECOMMENDATION 12.1: The Department of Health shall employ a staff person to provide medical marijuana health education. The Department of Health shall also establish a training or certification program for dispensary employees.

- “Health educator” changed to “staff person to provide medical marijuana health education” because of possible conflict with “health educator” description.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 12.2: The Department of Health shall develop an annual medical marijuana program report to the Legislature.

- Department of Health representative to provide list of factual items that would at minimum be included in report to legislature. This list will be provided in guidance section of report.

VOTE TALLY: YES=16; NO=0; DEFER=0

(13) RESOURCES AND DOH STAFFING:

RECOMMENDATION 13.1: The Legislature should provide sufficient resources each year FY16 (July 1, 2015, through June 30, 2016) and FY17 (July 1, 2016, through June 30, 2017) to establish the Medical Marijuana Dispensary Program. Based on Department of Health projections, the Legislature should allocate \$510,000 in general funds for FY16 and \$510,000 in general funds for FY17 to the Medical Marijuana Registry and Regulation Special Fund in order to set up the Medical Marijuana Dispensary Program. The General Fund shall be reimbursed for the monies allocated in FY16 & FY17 with dispensary and production center application and licensing fees. After these fiscal years, the Dispensary Program will be self-sufficient and funded with dispensary and production center application and licensing fees.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 13.2: The Legislature should direct the Department of Health to establish 5 FTE exempt positions to facilitate implementation of the Medical Marijuana Dispensary Program.

- Discussion about whether creation of an “exempt Medical Marijuana Dispensary Project” is necessary. This language deleted from recommendation.

VOTE TALLY: YES=16; NO=0; DEFER=0

(14) FEDERAL INTERFACE AND PROTECTIONS:

RECOMMENDATION 14.1: The Department of Health shall initiate on-going dialog among relevant state and federal agencies to identify processes and policies that ensure privacy of patients and compliance of patients, caregivers, producers, and dispensaries with state laws and regulations related to medical marijuana.

- Discussed need for stronger wording requiring dialog and delineating specific federal agencies (i.e. DOJ, Homeland Security, Coast Guard).
- Suggestion made to establish MOUs. This may not happen because TSA employees won't violate federal laws.
- Recommendation amended to make Department of Health responsible for initiating dialog.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 14.2: DOH shall petition the DEA to initiate rescheduling proceedings for marijuana.

- Suggestion made to consider and vote on this recommendation.
- Concern expressed that this recommendation is outside the scope of the Task Force.
- Question raised whether petition to DEA is the prerogative of the Department of Health or the Legislature?

VOTE TALLY: YES=4; NO=10; DEFER=1

(15) RESTRICTIONS ON ADVERTISING:

RECOMMENDATION 15.1: The Department of Health shall promulgate rules limiting the size and format of any sign(s) outside the dispensary itself.

- This recommendation split into two: one for signage outside of dispensary, one for prohibiting advertising to children.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 15.2: Dispensaries and producers are prohibited from using cartoon characters or other designs intended to appeal to children.

VOTE TALLY: YES=16; NO=0; DEFER=0

(10) SECURITY:

RECOMMENDATION 10.1: The Department of Health shall promulgate regulations mandating the following security measures to ensure that medical marijuana is provided only to patients and is not diverted for non-medical use:

- (1) For dispensaries:**
- (a) Video surveillance;**
 - (b) Inventory tracking software (“seed to sale”);**
 - (c) Alarm system; and**
 - (d) Exterior lighting.**

- (2) For producer grow sites:**
- (a) Video surveillance;**
 - (b) Inventory tracking software (“seed to sale”);**
 - (c) Alarm system; and**
 - (d) Black-out fencing for open outdoor grow sites.**

- Recommendation amended to add “alarm system” as requirement for grow sites.
- Question raised whether “black-out fencing” would be required of enclosed greenhouses. Recommendation as to “black-out fencing” being required for open outdoor grow sites.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 10.2: The Department of Health may place additional security restrictions on dispensaries and production centers.

VOTE TALLY: YES=16; NO=0; DEFER=0

RECOMMENDATION 10.3: Applicants for licenses to operate and prospective employees of dispensaries and production centers shall submit to criminal background checks. Those with felony convictions shall be prohibited; provided that the department may promulgate regulations to allow individuals with felony convictions related to marijuana more than 10 years ago to own or work at a dispensary or production center.

- Concerns expressed that those with felony convictions, notwithstanding any length of time, should be prohibited from ownership or work at any dispensary or production center.
- EEOC has relaxed rules pertaining to drug related felonies as limitations to employment.
- The LRB should consult EEOC guidelines from 2012 for language to be placed in bill related to this recommendation.

VOTE TALLY: YES=15; NO=0; DEFER=1

RECOMMENDATION 10.4: Patients and caregivers shall be allowed to purchase up to eight ounces of medical marijuana per month from a dispensary, provided that no patient or caregiver may possess more than four ounces of marijuana at any one time.

- Questions raised about physician making recommendation for amount instead of applying an upper limit, what does “equivalent” mean, how would tracking of amounts be done (ie. through a DOH directory)?
- Recommendation is deferred and appendix to be added to report by those on Task Force who did some of the initial work on this recommendation.

RECOMMENDATION 10.5: The patient possession limit for processed medical marijuana shall be based on the equivalent amount of dried bud leaf. Therefore patients may possess no more than four ounces of medical marijuana, or the equivalent of four ounces of medical marijuana in other forms.

- Recommendation is deferred and appendix to be added to report by those on Task Force who did some of the initial work on this recommendation.

(11) QUALITY/LABORATORY SCREENING:

RECOMMENDATION 11.1: The Department of Health shall promulgate rules to provide for screening of medical marijuana for content (e.g. THC, CBD, and/or other cannabinoid concentrations), contamination and consistency.

- The Department will need to bring in experts to help develop screening.

VOTE TALLY: YES=15; NO=0; DEFER=0

Public Input

- Placing limits on how much one can buy is discriminating against people not individually growing, certain strains of medicine, & certain diseases that require different medication dosage.
- Products and edibles - KISS system
- Annual inspections are not enough. Recommend inspections on quarterly basis.
- Recommend smaller production centers with less plants.
- Testing - recommend physician’s discretion.
- Signage - use current regulations.
- Advertising - not required or necessary.
- Potential issue for patient’s privacy created by video surveillance, purchase limits & tracking of purchase.
- Background checks - pharmacies do not require it – dispensaries shouldn’t either.
- Concerned about low dosage limits on products of 10mg/dose. If patient requires 100mg, does not want to have to take 10 pills.
- Task Force geared toward regulatory process. Perspective has been based on law enforcement model, not patient model.
- Concerned that new forms require a lot of information and violates patients' privacy.
- Questioned where there is caregiver experience on the Task Force.
- The use of edibles is important for many patients.
- Growing takes a lot of work to be limited to 4oz

- What is advertisement? Listings in phone book? Email discussions? Word of mouth? Anything on the Internet?

Next Steps

- Review the minutes from Nov 18 and Dec 16
 - Review votes from Dec 16 meeting – AG had 2 votes
 - Distribute to TF via email for approval
- Revised recommendations will be distributed by end of the day Jan 31
 - Distribute to TF via email
 - Distribute to the LRB no later than Jan 5

Final Task Force Meeting adjourned.