May 16, 2021
To the Committee on Veterans and Legal Affairs,

Please find attached a summary of the position of the five groups representing medical caregivers and patients in the state of Maine—the Maine Craft Cannabis Association, the Maine Cannabis Coalition (United Cannabis Patients and Caregivers of Maine), the Maine Growers Alliance, Maine Children for Cannabis Therapy and Medical Marijuana Caregivers of Maine. This consensus position was developed collaboratively with the support of patients, physicians, and industry experts right here in Maine with long experience in this program, and with the helpful support of the volunteer members of the Seed2Health Learning Health Alliance and its manager, Seed2Health, LLC.

Given a compressed timeline this session, we utilized an exacting standard to identify which components of the many bills and Proposed Rule should move forward, namely: what is needed? Ultimately, the answer is 'very little'. **The Maine Medical Use of Marijuana Program is, overall, working exceptionally well**. The MMMP's successful record is borne out in the patient counts, sales tax payments, and lack of material public health or public safety issues within the Program. We anticipate a robust continued discussion within the industry where we believe most 'issues' should be resolved. Ultimately, let most decisions resolve with the consumer and give the consumer the tools necessary to make the best decisions for their health. The consumer deserves the right to make informed decisions, hence labels will be required to indicate what components a product has not been tested for, and the retailer will have to provide access to lab reports to confirm claims. We propose an education-based compliance enforcement model with an escalating enforcement and fine structure.

We suggest the Committee call for the formation of a Medical Marijuana Advisory Committee such as this one to provide continuous feedback and program enhancement working with the Office of Marijuana Policy and the VLA Committee, perhaps offering comprehensive analysis of program management in two years' time. As this group was comprised, a Committee could be comprised of one or two healthcare professionals who participate in the program and one to three representatives from each of the major marijuana advocacy groups in Maine. Given limited time to fully analyze other options, the group is suggesting a spreadsheet-based monthly submission to track transfers amongst registrants in the program much like is done with beer and wine in Maine. Coupled with our enclosed proposal for labeling and batch numbers, this submission through an electronic portal or US Mail will enhance product traceability and patient safety.

We look forward to supporting the Committee in its deliberations and will make ourselves available to work with members and the Committee analyst to help finalize this session's good works. We are deeply grateful to the many bill sponsors and Committee members who have taken up this work and believe that the MMUMP will have a bright future if we can work collaboratively putting the people of this State first. Details are included with this document.

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Contents

Definitions to be added to statute Title 22, Chapter 558-C

Rationale:

These are new terms utilized in several of the following documents. They need to be clearly defined by statute.

Batch Number: Example: 210511MOB-CGR12345 or 210511MOB-CGR12345 where the date is May 11, 2021, the strain is Mob Boss and registrant's number is CGR12345. The Batch Number is a unique identifier for a marijuana product harvested or processed on the same date that indicates the date, optionally the strain with 2 to 6 letters, and the Caregiver or Dispensary from which it originates. The Batch number identifies a specific quantity of medical marijuana produced during a specific period of time by a specific caregiver or dispensary or manufacturing facility.

Marijuana Tincture: A solution prepared from harvested marijuana or marijuana product blended into a menstruum using edible oils, alcohol, glycerin, vinegar, witch hazel, or other edible medium. Manufacture of tinctures does not require a Beverage Plant License.

Digital Certification: An electronic copy of the patient certification in possession of the patient that must be checked against other forms of ID such as a state ID for verification.

Packing Slip: A paper to accompany a wholesale transaction that contains the details that would be required on individual items if the contents were labeled for retail sale.

Packaging and Labeling

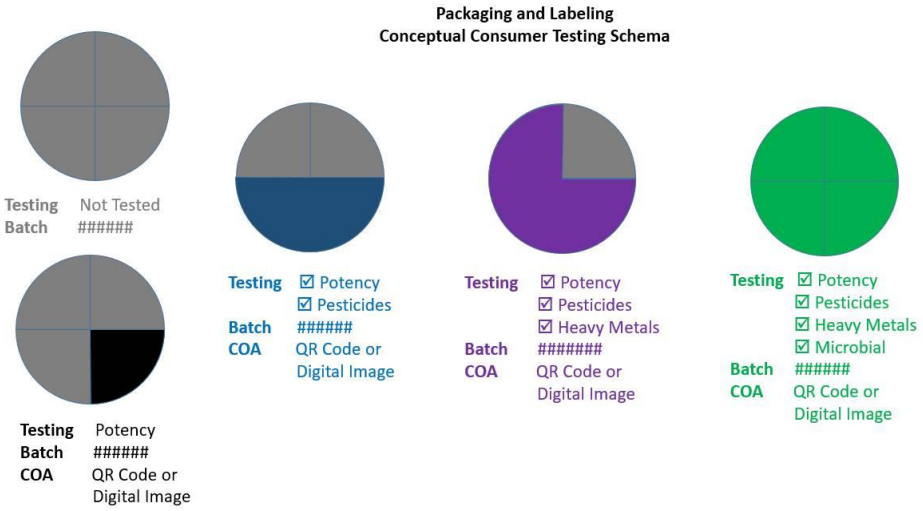
Rationale:

Clear and simple packaging and labeling requirements that indicate what tests/labs have been obtained for the product. The consumer has a right to know if labs have been run, what those labs indicate, and by which laboratory stated tests were processed. The required Batch Number (see definition) will encompass the CGR# (or Dispensary #) and will allow for product tracing in the event of product recall.

Standard

PACKAGING AND LABELING

Testing Indication: Tested/Untested, Cannabinoid Profile, Pesticides, Microbials



- **State Certified Lab License #:** IF a product is Tested, a LAB IDENTIFIER must be included and reports must be made available upon request to the consumer and/or Department. *Note that to verify a lab report, the product should be tested by the same laboratory since processes and results vary.*
- As currently required by statute, any claim such as cannabinoid profile must be verifiable by lab reports. Any claims of lab reports can be requested by purchaser and may be provided electronically via QR code or image of labs.

Packaging Criteria for RETAIL SALE per statute:

- Child-resistant by statute. Definition: A. Specially designed or constructed to be significantly difficult for a typical child under 5 years of age to open and not to be significantly difficult for a typical adult to open and reseal;
- Prepackaged in child-resistant and tamper-evident packaging or placed in child-resistant and tamper-evident packaging with a signifier that the package contains harvested marijuana at the final point of sale to a qualifying patient;

- Prepackaged in opaque packaging or an opaque container or placed in opaque packaging or an opaque container with a signifier that the package contains harvested marijuana at the final point of sale to a qualifying patient;
- Packaged in a container with an integral measurement component and child-resistant cap if the marijuana product is a multi-serving liquid;

Minimum Labeling for Retail Sale

- **Adding 'batch number'** to allow the Caregiver to identify and if necessary, recall a product. This batch number should also indicate to the Caregiver the source of the product (the grow or the lab for example) for public safety issues such as product recall. Note that by proposed definition, the Batch Number encompasses the CGR#.
  - Note that proposed tracking of transfers will allow a retailer or other caregiver to know the origin of a product in the event of product recall via monthly submitted spreadsheets.
  - Only required on 'final retail layer', not on individual pieces of items. Packing slip (and Trip Ticket) to accompany product not labeled for retail sale.
  - IF an item is too small to label with at least a font size 8, or if the item is packaged at the point of retail sale (such as loose flower), then the item may be accompanied by a card containing the information the label would otherwise contain.

Flower

- Description ("Outdoor Blueberry")
- Weight/quantity
- Batch # (see definitions)
- Universal THC symbol
- Test indication via color circle schema

Edibles

- Information as required by Department of Agriculture kitchen licensing processes
- Universal THC (on packaging)
- Batch #(encompasses retailer CGR#)
- Manufacturer's registrant #
- Test indication via color circle schema

Concentrate

- Batch # (encompasses retailer CGR#)
- Processor's/Manufacturer's registrant #
- Universal THC
- Test indication via color circle schema

Tincture, Topicals

- Batch # (encompasses retailer CGR#)
- Processor's registrant #
- Universal THC
- Test indication via color circle schema

Minimum Packaging and Label for Wholesale

- *Opaque packaging such as a bag or box*
- **Trip ticket** if still necessary to satisfy statute.

- **Packing Slip** with the details that would be required on the individual items at Retail Sale including indication of testing status via color circle schema.
- **Lab Reports** for any test results

STATUTORY CHANGES

4. Educational materials. A person that provides harvested marijuana to a qualifying patient must make educational materials about the use of harvested marijuana available to the qualifying patient at the time of the transaction. The department shall develop the minimum content of the educational materials provided under this subsection and make that content available publicly. Educational materials may include digital resources.

For reference only:

Current Title 22 Chapter 558C Statute on this matter:

2. Packaging prohibitions. Harvested marijuana sold in a retail transaction under this chapter may not be:
A. Labeled or packaged in violation of a federal trademark law or regulation or in a manner that would cause a reasonable consumer confusion as to whether the harvested marijuana was a trademarked product; [PL 2017, c. 452, §18 (NEW).]
B. Labeled or packaged in a manner that is specifically designed to appeal particularly to a person under 21 years of age; [PL 2017, c. 452, §18 (NEW).]
C. Labeled or packaged in a manner that obscures identifying information on the label or uses a false or deceptive label; [PL 2017, c. 452, §18 (NEW).]
D. Sold or offered for sale using a label or packaging that depicts a human, animal or fruit; or [PL 2017, c. 452, §18 (NEW).]
E. Labeled or packaged in violation of any other labeling or packaging requirement or restriction imposed by rule by the department. [PL 2017, c. 452, §18 (NEW).]

§2429-A. Packaging and labeling requirements
1. Packaging requirements. As applicable based on the form of the item sold, harvested marijuana sold in a retail transaction under this chapter must be:

1. Prepackaged in child-resistant and tamper-evident packaging or placed in child-resistant and tamper-evident packaging with a signifier that the package contains harvested marijuana at the final point of sale to a qualifying patient; [PL 2017, c. 452, §18 (NEW).]
2. Prepackaged in opaque packaging or an opaque container or placed in opaque packaging or an opaque container with a signifier that the package contains harvested marijuana at the final point of sale to a qualifying patient; [PL 2017, c. 452, §18 (NEW).]
3. Packaged in a container with an integral measurement component and child-resistant cap if the marijuana product is a multi-serving liquid; and [PL 2017, c. 452, §18 (NEW).]
4. In conformity with all other applicable requirements and restrictions imposed by rule by the department. [PL 2017, c. 452, §18 (NEW).]

Any package required under this subsection that contains edible marijuana products must include a signifier that the package contains harvested marijuana.
Labeled or packaged in a manner that obscures identifying information on the label or uses a false or deceptive label; [PL 2017, c. 452, §18 (NEW).]

1. Sold or offered for sale using a label or packaging that depicts a human, animal or fruit; or [PL 2017, c. 452, §18 (NEW).]
2. Labeled or packaged in violation of any other labeling or packaging requirement or restriction imposed by rule by the department. [PL 2017, c. 452, §18 (NEW).] [PL 2017, c. 452, §18 (NEW).]

3. Labels. If a registered caregiver, dispensary or manufacturing facility affixes a label on the packaging of any harvested marijuana provided to a qualifying patient and that label includes information about contaminants, the cannabinoid profile or potency of the harvested marijuana, the label must be verified by a marijuana testing facility. This subsection does not apply if there is no marijuana testing facility operating in accordance with section 2423-A, subsection 10.
[PL 2017, c. 452, §18 (NEW).]

4. Educational materials. A person that provides harvested marijuana to a qualifying patient must make educational materials about the use of harvested marijuana available to the qualifying patient at the time of the transaction. The department shall develop the minimum content of the educational materials provided under this subsection and make that content available publicly. [PL 2019, c. 331, §28 (AMD).]

Tracking Transfers & Record Keeping in Maine Medical Marijuana Program

- Transfers of Plants & Harvested Material (as required by Title 22, Ch 558-C State of Maine Statute – see below).
- Submission to the Department by 15th of each month for monthly sale's tax filers and quarterly filing for quarterly sale's tax filers.
- In addition to the forms, each entity would keep their own sales records (*whether it be electronically or on paper*) which they use to pay their sale's tax as already required.
- Each caregiver or dispensary would not only have wholesaling forms/spreadsheets that are submitted via the internet *(or mail)* "portal" to the department (similar to monthly alcohol spreadsheet sales reports), they will also have a running sales record of products sold that is used to report sales to the State Revenue Department quarterly or monthly.
- To enhance patient safety, and to make recall of a product easier, we need to account for what goes where. This may be easier facilitated by labels. Incorporating Batch Numbers and knowing where those batch numbers items were sold will allow a caregiver the ability to recall a batch when necessary for patient safety.
- Product recalls could also be facilitated by media outlets as other recalls are handled for pet food for example. Having a batch number (as proposed for labeling) will facilitate this process.

Spreadsheet Example:

The Department could provide an electronic version that a Caregiver could update as often as they opted (daily?) as long as the Caregiver updated by the 15th of the month (or quarterly for quarterly sale's tax reporters) following the transfers.

Registrant # CGR12345	Registrant Name		Date of form Submission:	
Date of Transfer in format 2021/05/15	Recipient's Registrant #	Product Description	Batch # of product transferred	Product Weight in grams

Title 22, Chapter 558C applicable Statute:

§2430-G. Record keeping; inspections; reporting requirements

1. Tracking; record keeping. This subsection governs the tracking, record-keeping and disclosure requirements of registered caregivers, registered dispensaries, marijuana testing facilities and manufacturing facilities.

A. A registered caregiver, a registered dispensary, a marijuana testing facility and a manufacturing facility shall:

(1) Keep a record of all transfers of marijuana plants and harvested marijuana;

(2) Keep the books and records maintained by the registered caregiver, registered dispensary, marijuana testing facility or manufacturing facility for a period of 7 years;

(3) Complete an annual audit of business transactions of the registered caregiver, registered dispensary, marijuana testing facility or manufacturing facility by an independent 3rd party; and

(4) Make the books and records maintained under this subsection available to inspection by the department upon the department's demand.

Records kept under this paragraph must avoid identifying qualifying patients. [PL 2017, c. 452, §24 (NEW).]

B. The department shall develop and implement a statewide electronic portal through which registered caregivers, registered dispensaries, marijuana testing facilities and manufacturing facilities may submit to the department the records required under paragraph A and in accordance with rules adopted by the department. A registered caregiver, registered dispensary, marijuana testing facility and manufacturing facility shall pay all costs and fees associated with the use of this electronic portal and all other fees associated with the keeping of records required in this section in accordance with rules adopted by the department. The department shall adopt rules regarding the process and content of records to be submitted, the frequency with which the records must be submitted, the costs and fees associated with using the electronic portal and any other requirements necessary to implement this paragraph. [PL 2019, c. 331, §32 (AMD).]

Improving Patient Access

Rationale: Maine residents deserve unimpeded access to the Program of their choice, particularly as guided by a medical professional. The more we study the therapeutic potential of cannabis, the more we affirm it.

Digital Certification: Participants are already allowed to accept out-of-state digital certifications, such as New York. Why can't Mainer's also have this? There would be no mandated storage of this info for market participants. It would be exactly like having a digital car insurance card, or a digital version of your driver's license when your physical copy has expired. Both of these are accepted by LEOs as proof of compliance with driving laws. This should be the same as medical certifications.

Patient Certifications: Leave certification between doctor and patients. We have dozens of minor patients being successfully treated for symptoms and behaviors who are on the Autism Spectrum. Pediatric patients' parents require far more post-certification assistance with constant dose changes due to their ever changing bodies and often nervous parents. Statute would mandate a plan by which the parent can reach the doctor. Additionally, many Maine patients are successfully treated with marijuana to TREAT a drug addiction. Statute rightfully calls for a treatment plan in this case. Primary doctors are often hard to obtain in rural Maine – many doctors do not have the capacity to accept new patients, and many people do not have health insurance. Patients should not be required to have a primary care provider. Additionally, as noted by group member Dr. John Woytowicz, the term "medical provider" has been clarified in proposed statutory language.

Certification of Minor Patients (under 18): Current statute has not been reflected in OMP rules as it is simply not how the program works. A process for a second opinion and family reimbursement has not been established by OMP, and never been enforced. We desire to make actual process align with actual Program Statute and Rule. Additionally, we would like post-certification consultation mandated by statute for pediatric patients as again, this is how the program works in practice and it is a sound medical model for a parent and pediatric patient.

Statute level language for fixing patient access issues including patients under the age of 18

§2423-B. Authorized conduct by a medical provider

A medical provider may provide a written certification in accordance with this section for the medical use of marijuana under this chapter and, after having done so, may otherwise state that in the medical provider's professional opinion a qualifying patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's medical diagnosis. A medical provider includes: an MD or Medical Doctor, a DO or Doctor of Osteopathy, an ND or Naturopathic Doctor, an NP or Nurse Practitioner, and a PA or Physician's Assistant who holds a valid medical license in the State of Maine. [PL 2017, c. 452, §5 (AMD).]

1. Adult qualifying patient. Prior to providing written certification for the medical use of marijuana under this section, a medical provider shall inform an adult qualifying patient or the patient's legal guardian or representative of the risks and benefits of the medical use of marijuana and that the patient may benefit from the medical use of marijuana.
[PL 2017, c. 452, §5 (AMD).]

2. Minor qualifying patient.
[PL 2017, c. 452, §5 (RP).]

2-A. Minor qualifying patient. A medical provider who provides a written certification to a patient who has not attained 18 years of age:

A. Prior to providing written certification for the medical use of marijuana for a minor patient under this section, a medical provider shall inform the patient's legal guardian or person having legal custody of the patient of the risks and benefits of the medical use of marijuana and that the patient may benefit from the medical use of marijuana.

B. A doctor certifying a patient who has not attained the age of 18 must be available to the patient's legal guardian or person having custody of the patient to provide advice for dosage and side effect management. A plan as to how to contact the doctor during office hours and during non-office hours must be provided to the patient's legal guardian or person having legal custody of the patient.

~~A. Shall inform the qualifying patient and the parent, legal guardian or person having legal custody of the patient of the risks and benefits of the medical use of marijuana and that the patient may benefit from the medical use of marijuana; [PL 2017, c. 452, §5 (NEW).]~~

~~B. May provide a written certification to a qualifying patient if the patient is eligible for hospice services and has a medical diagnosis that, in the medical provider's professional opinion, may be alleviated by the therapeutic or palliative medical use of marijuana; [PL 2017, c. 452, §5 (NEW).]~~

~~C. May provide a written certification to a qualifying patient if the patient has a medical diagnosis of epilepsy, cancer, a developmental disability or an intellectual disability that, in the medical provider's professional opinion, may be alleviated by the therapeutic or palliative medical use of marijuana; and [PL 2017, c. 452, §5 (NEW).]~~

~~D. If a patient does not satisfy the requirements of paragraphs B and C, may provide a written certification to a qualifying patient after consulting with a physician from a list of physicians who may be willing to consult with a medical provider maintained by the department that is compiled by the department after consultation with the Department of Health and Human Services and statewide associations representing licensed medical professionals. The consultation between the medical provider and the consulting physician may consist of examination of the patient or review of the patient's medical file. The consulting physician shall provide an advisory opinion to the medical provider and the parent, legal guardian or person having legal custody of the qualifying patient concerning whether the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's medical diagnosis. If the department or the consulting physician does not respond to a request by the medical provider within 10 days of receipt of the request, the medical provider may provide a written certification without consultation with a physician.~~

~~The parent, legal guardian or person having legal custody of a qualifying patient who has not attained 18 years of age may submit a request to the department for reimbursement of the costs associated with obtaining a 2nd opinion required by this paragraph. Requests must be submitted on a form developed by the department. The department shall review the family's annual income and expenses in determining whether to reimburse the family from the Medical Use of Marijuana Fund under section 2430 for the cost of the required 2nd consultation.~~

~~The department shall adopt routine technical rules as defined in Title 5, chapter 375, subchapter 2-A to implement the reimbursement request under this paragraph. [PL 2017, c. 452, §5 (NEW).]~~

~~[PL 2017, c. 452, §5 (NEW).]~~

2-B. Adult and minor patients with substance use disorder. Prior to providing written certification for the medical use of marijuana under this section for a medical diagnosis of substance use disorder that, in the medical provider's professional opinion, may be alleviated by the therapeutic or palliative medical use of marijuana, the

medical provider shall develop a recovery plan with the patient. For purposes of this subsection, "substance use disorder" means a diagnosis related to alcohol or drug abuse covered by Title 5, chapter 521.
[PL 2017, c. 452, §5 (NEW).]

2-C. Bona fide provider-patient relationship. A written certification may be made only in the course of a bona fide medical provider-patient relationship after the medical provider has completed a full assessment of the patient's medical history. ~~If a patient has not provided a medical provider who is not the patient's primary care provider with the name and contact information of the patient's primary care provider, a medical provider shall conduct an in-person consultation with the patient prior to providing a written certification.~~
[PL 2017, c. 452, §5 (NEW).]

Current Statute in regard to Medical Provider continuing education:

8. Continuing medical education. A medical provider who has not previously provided a written certification to a qualifying patient for the medical use of marijuana shall, prior to providing a written certification to a qualifying patient, submit evidence, satisfactory to the department, of successful completion of a one-hour course of continuing medical education relating to medical marijuana within the preceding 24 months.

(Committee Notation: Dr. John Woytowicz strongly urged maintaining this CME requirement above, and the group agreed.)

Security

Rationale

There has been no evidence of chronic major problems with the security measures that have been in place for the past decade (Definition of Enclosed Locked Facility [ELF]). Most participants will already be required by their insurance underwriter, landlord, municipality, etc. to have surveillance, alarms, monitoring, safes, etc. In most Maine homes for example, a child or a pet accessing marijuana is a far more likely issue than armed robbery. Title 22 Statute is sufficient. There is no need for further State mandate when similar issues are already scaled by the private insurance sector and municipalities.

Locks

- Per Statute, all areas where cannabis is cultivated, manufactured and stored must be within an enclosed locked facility (ELF) as per Title 22, Chapter 558C.
- On occasion legislators would like to see firsthand what a caregiver's or manufacturing facility's enclosed locked facility looks like to comprehend how the industry actually works while considering legislation. Current statute is silent on this. Additionally, contractors, patients and employees sometimes have to enter facilities. This requires correction in Title 22, Chapter 558C.

Storage

- No requirements for safes, vaults, etc. for storage of products. As stated, any participant in the program who desires insurance, a storefront, a lease for their business, will be held to higher security standards by these private sectors.

Cultivation Area: Per Statute copied below, fencing need not be opaque. Opaque stockade like fencing does not allow light transmission, and is basically an advertisement to the public as to what is in the garden. Rules mandating opaque fencing are not in alignment with Statute.

> **3. Cultivation area.** "Cultivation area" means an indoor or outdoor area used for cultivation in accordance with this chapter that is enclosed and equipped with locks or other security devices that permit access only by a person authorized to have access to the area under this chapter.
> [PL 2017, c. 452, §3 (AMD).] A registrant's enclosed locked facility may be accessed by the registrant, invited qualified patient(s), invited members of the legislature, contractors hired by the registered caregiver or patient, and employees of the Office of Marijuana Policy for Inspection purposes.

Correction and Enforcement

Rationale:

Industry overlap provides mechanisms for enforcement in many areas. For example, cultivating Caregivers are already required to pass the Department of Agriculture pesticide application class and maintain this certification. These would all encompass Civil Fines/Violations, not criminal. When Law Enforcement is contacted for violations of laws, processes already exist for criminal prosecution.

- It would be a violation of Program STATUTE to not have this certification per Title 22, Chapter 558C, **§2423-A. Authorized conduct for the medical use of marijuana.** There is no need for duplication nor creating the potential for fines and punishment from two government bodies for the same offence.
- Similarly, food manufacture is governed by the Department of Agriculture and food licensing ranging from a simple home kitchen license for producing non-perishables to a commercial kitchen license.
- Violations of these type of issues should be referred to the Department of Agriculture.
- Lastly, our principle is to allow the Office of Marijuana Policy the ability to assist our businesses to come into compliance via education and correction, progressively resorting to warnings, fines, suspension and revocation. We do not believe we should fine a business out of business, but we should educate a business into compliance, especially on patient and public safety matters.

Enforcement of program rules will be on a stepped scale encompassing the following:

- Warning and plan of correction
- 2nd warning if correction is not made within agreed upon time frame or issue is repeated
- Fine for third occurrence of same problem or failure to remedy per plan of correction
- Doubled fine for fourth occurrence of same problem or failure to remedy per plan of correction
- Suspension of registrant card
- Revocation
- Fines to range from $100-$2000
    - $100 for a failing to properly label product to $2000 for giving medicine to a minor without a patient card or distributing an inherently dangerous substance for example.
- Maximum fine of $10,000 solely for operators utilizing Inherently Hazardous Substances (IHS)

Reference to other agency for violation –

- Pesticide Application Violation: reference to Department of Agriculture
- Food Handling Violation: reference to Department of Agriculture
- Reference to law enforcement if the violation is so warranted.

Categories and Types of Violations:

Record keeping:

- $2,000- No Records kept or records are completely illegible to determine where the harvested marijuana and marijuana products went within the program i.e. to registered caregiver or dispensary or to a patient with their section B number and serial number.
- $500-$1,000- Incomplete records for transfers between program participants
- $100-$499 No copies of records readily available for the department for inspection upon request (maximum fine of $500 over a calendar month)

Diversion:

- $2,000- Transfer to minor(under 18) outside the program. Fine and reference to Law Enforcement about criminal violation.
- $1,000- Transfer to person 18 years of age or older who is not a certified and has never been a certified patient. Could include reference to Law Enforcement
- $500- Transfer to a person 18 years of age or older who is a patient with an expired certification. Could include reference to Law Enforcement.
- $100-$250 Not properly disposing of any plants, harvested marijuana or marijuana products.

Packaging and labeling:

- $2,000- Continued violation of packaging laws that are meant to prevent access to children under 5.
- $500-$1,000 Intentionally deceptive labeling
- $250-$500 Labeling with potency or other lab testing claims without having claims accessible to OMP upon request.
- $100- Not appropriate labeling including absence of label when it comes to the type of product

Public Health and Safety Violation:

- $2,000+ - Public health and safety violation that could cause serious injuries or death.

Housekeeping

Rationale:
Similar to Agriculture, require a 2 year record maintenance. Additionally, appropriate tracking of transfers as required by Title 22, Chapter 558C and as proposed via monthly spreadsheet transmission eliminates the need for an "annual audit."

The renewing registrant is assumed to be in compliance and continuing operations within the program if they have filed for their renewal, but have not yet received said renewal in the mail. This is similar to processes in agriculture and childcare/pre-school.

Manufacturing facilities: in 2018, the two-tiered system for manufacturing was developed and indicated how much material each tier is allowed to have onsite. In just the past 3 years, processing procedures have rapidly advanced facilitating faster, more efficient and safer processing. We consulted with owners of two Tier 2 labs who are available during this work session if needed (Scotty Ouellette & Brett Messer). Depending on the facilities equipment, it is not unreasonable for them to process over 100 pounds a day. Some labs can process up to 100 pounds an hour. We propose that limits be set by rule to allow for faster adjustment as technology advances, starting with minimums of Tier 1 at 200 pounds and Tier 2 at 1000 pounds.

§2430-G. Record keeping; inspections; reporting requirements

1. Tracking; record keeping.

(2) Keep the books and records maintained by the registered caregiver, registered dispensary, marijuana testing facility or manufacturing facility for a period of ~~7~~ 2 years;

~~(3) Complete an annual audit of business transactions of the registered caregiver, registered dispensary, marijuana testing facility or manufacturing facility by an independent 3rd party; and~~

~~(4)~~ (3) Make the books and records maintained under this subsection available to inspection by the department upon the department's demand.

Records kept under this paragraph must avoid identifying qualifying patients. [PL 2017, c. 452, §24 (NEW).]

Statute Update to Title 22, Chapter 558C

There shall be an assumption of compliance if the department is in possession of a renewal application and has not approved or denied it within 28 days.

Manufacturing:

2423-F. Marijuana manufacturing facilities

A person may not manufacture marijuana products or marijuana concentrate or engage in marijuana extraction except as provided in this chapter. [PL 2019, c. 331, §17 (RPR).]

1. Tier 1 manufacturing facility. A tier 1 manufacturing facility registered pursuant to subsection 8 may engage in the activities authorized under subsection 4 in accordance with rules adopted pursuant to subsection 10 and may possess up to ~~40~~ the amount set by rulemaking authority with a minimum threshold of 200 pounds of harvested marijuana.

[PL 2019, c. 331, §17 (RPR).]

2. Tier 2 manufacturing facility. A tier 2 manufacturing facility registered pursuant to subsection 8 may engage in the activities authorized under subsection 4 in accordance with rules adopted pursuant to

subsection 10 and may possess up to ~~200~~ the amount set by rulemaking authority with a minimum threshold of 1000 pounds of harvested marijuana.

Dr. John Woytowicz Testimony

Hello members of the VLA committee:

I am enclosing the following recommendations for LD 1242 regarding the bona fide doctor-patient relationship that will heretofore refer to as the "Bona fide clinician (MD, DO, ND, NP, PA) -patient relationship.

1. An encounter for certification can be face to face, by video or by phone as is the standard for any medical service

2. A HIPPA agreement will be signed as is customary for any clinical service rendered by a health care provider.

3. A discussion of the reasons for the medical use of cannabis, and the risks and benefits, will occur between the clinician and patient.

4. A physical exam can be performed if appropriate.

5. Maintenance of a secure medical record.

6. A certifying clinician should be available for future consultation and advice, as well as recertification if possible.

7. Recommendation for a certification of a pediatric patient will be made with the consent of a parent(s) or guardian.

8. The medical diagnoses for a pediatric patient will not be restricted. The certifying clinician will make a recommendation for certification that reflects the scope of their clinical practice.

9. When the patient (adult or pediatric) lacks a primary care provider an effort to recommend someone available in the community is encouraged.

10. Verification of the residence in state of Maine is required by making a copy of a driver's license or state ID, or proof of residence of the parent(s) or guardian for a pediatric patient

11. CME (continuing medical education) on the use of medical cannabis is strongly encouraged based on the available of the CME resources. One hour of CME every 2 years is recommended.

12. Urine drug screen (UDS) is required only if a risk assessment deems it appropriate.

John Woytowicz, MD, ABIHM
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CONSENSUS POSITION ON BILLS

LD 939
We believe the provisions of this bill are largely uncontroversial. We can support the removal of Item 6 regarding co-mingling of marketing, a compromise on Item 8 of recordkeeping requirements of 3 years rather than 2, and a clarification of the definition of 'third party audits' rather than removal if the Committee chooses not to move forward with our proposal for tracking of product.

LD 1242
We believe the Administrative Procedures Act is clear in defining major substantive versus routine technical rulemaking and that this session's work has further made it clear these policy areas are major substantive per those definitions. Item 2 is not necessary if this Committee moves forward with its own Rule proposal and scraps the OMP's Proposed Rule that faced complete rejection by Maine's medical cannabis community. Item 3 is likely best considered under other statutes governing such activity, though this process within the OMP has been neither clean nor effective to date. Item 4, see above. Item 5 is handled by our proposed tracking solution which will satisfy statute.

LD 1319
There is consensus on the need for an economic impact study of any Proposed Rule to be done in conjunction with the Proposal per the Administrative Procedures Act. There is also generally consensus on the lack of a need for rulemaking quantified in the moratorium proposal, but we believe this Committee's work this session could obviate the need for an explicit moratorium. There are other components of LD1319 that the Committee may choose to push forward regarding residency and the lack of availability of an application process since 2018 inception.

LD 353/421
There is consensus around the need for a more graduated/alternative avenue for growth for businesses within the MMMP rather than the existing dispensary model, which is a product of corporate lobbying to make conduct within the program more difficult and reserved for a select few to begin with. These two bills provide alternative paths to growth that could be fruitful for discussion moving forward and could be more achievable for the vast majority of industry participants in Maine.

LD 882
There is consensus around the need for a more nuanced set of enforcement tools for the OMP in its regulation of the MMMP, though we do not support 882 as proposed by the OMP. Fine levels are staggeringly and punitively high and leave far too much ambiguity in determining the severity of infractions, especially around the classification of 'Major Threats to Public Safety'. For example, in the OMP's Proposed Rule, entering something into their proposed tracking software improperly would constitute a 'major violation affecting public safety', as if cannabis is a nuclear-armed torpedo. This bill should not move forward if such sweeping interpretive powers are left up to OMP.

We are unconvinced the OMP has need of administrative holds as it seems to already have the tools necessary to embargo product where a public health or safety question is raised. Crucially, they are completely out of step with how all other program enforcement is handled in Maine.

--End of Document--

Susan Meehan
Maine Cannabis Coalition

Just in case the original file is lost too far down in your emails, or was not brought to your attention correctly, I have re-submitted the 18 page document that was sent you to the Committee on May 16, 2021. Thank you for all the work.