My name is Scotty Ouellette, and I am registered caregiver and owner/operator of a medical manufacturing laboratory in Maine. I am also in the process of dual certifying my manufacturing laboratory as an Adult Use facility; however, communication back and forth with OCP employees has been very difficult, the process cumbersome, and clear answers impossible to obtain. When the regulatory agency will not follow up to answer questions via phone calls or email, I ask, why do we pay salaries to these government employees paid by money my business and many here funded. Maine Medical is basically funding the OCP media war against Maine Medical. Then I ask, how will these Proposed Rules help this situation? It is a very big disappointment to realize if these rules are passed, these rules will not help, and likely will only make the process and the regulatory agency worse.

These Proposed Rules will yield more power to OCP, and they cannot answer the questions of registrants via phone calls or emails as it is. Blanket statements like "...but not limited to;..." (pp.73-75) will give OCP a blank slate on graduated enforcement. This is not OK. I take issue with biased and subjective guidelines applied haphazardly and subjectively depending on which OCP inspector shows up. A fine example of this is "marketing to those who are under 21 years of age." Inspection criteria for manufacturing laboratories and dispensaries are not available publicly as required by law. (For all registrants, "B. The department shall adopt rules: (1) Establishing standards for compliance with this chapter that are available publicly;" The only publicly available criteria apply to Caregivers and make no mention of fences or locks." Additionally, i can find no objective and measurable criteria to determine whether or not a marketing method will be appealing to those under 21

This entire topic reminds me of the ludicrous imprinted symbol required on some Adult Use products such as fruit chews. While the same fruit chews are available in dozens of legal states with the same exact recipe and process as I make them here in Maine. If the symbol cannot be affixed or embedded in the product serving clearly, then the symbol should not be required as in popcorn or chips. The fruit chews are no more or less appealing to children and pets than are the popcorn or chips. Similar sugar coated fruit chews are marketed in Maine under other labels from other companies. Interesting. This triangular symbol will not stop my dog from eating my medication if I am irresponsible and leave it out. This symbol will not stop a child whose irresponsible adult leaves their medicine accessible to the child. What if the child likes triangles? Hopefully, the child resistant packaging and adult common sense prevail. Why do I mention these issues in Adult Use while testifying at the medical proposed rules hearing"?

Inch by inch, OCP is aligning the two programs. There is nearly nothing "right" about these proposed rules. They are not updated to reflect legislation that becomes law at the end of October; they reflect the OCP attitude of us versus them, again; and they demonstrate OCP's continued disregard for the small businesses they are successfully driving out of business, nor the 106,000 patients these businesses serve. There is NO public outcry from patients for mandatory testing, stamped food products, commercial security fences; advertising ambiguity and un-measurable criteria -- in a world in which we see lottery, alcohol and tobacco ads at ball fields and on vehicles on our public roads sporting fluffy dogs, happy and pretty people, and mythical creatures. We cannot control everything children or those under age 21 observe. No law can replace the need for responsible parenting and responsible pet ownership. I am interested to see the specific criteria by which OCP will determine if something appeals to "under 21."

As for testing, I truly believe the only meaningful testing is random spot check style testing. There is always a way to pass an anticipated and expected test -- such as the x-ray machines used by some so they can pass a mold test that is, by design, nearly impossible to pass any other way. I have tested cannabis before accepting it for processing long before anyone required it (still not required in Maine Medical), and I believe in using products that are not poisoned with pesticides for example, but the best way to know that folks are

not importing or growing pesticide laden products are random spot checks. But what is clearly lacking and clearly needed in OCP's random spot testing is a process by which to deal with negative results.

As an industry, we said, sure, let's do random audit testing. What we omitted and did not realize was absolutely necessary, was what should OCP do with the data? Should we help these businesses figure out where the problem in their process originated? Did they grow this product or where did they purchase it -- where is that transaction log? Is the contamination from the food product with which you prepared your edibles? Neither Maine Medical registrants nor our legislators said, "Do audit testing. Then go to the media and mislead the public into thinking that 57 test results represent half of a 300 million dollar market!" No, not like that. OCP continues to demonstrate that their goal is drive small businesses out of business, support the large corporate interests, and claim to have no power over the massive illegal grow operations rather than refer law enforcement When the small thousands are out of the way, work with law enforcement to get rid of the illegals, and the leftover corporate interests will pick up the market. No, not like that. Sadly, even under new leadership from Colorado, these most recent actions of OCP demonstrate why most of the 106,000 patients, 1800 caregivers and many from the general public reject any Rule that gives OCP more power to destroy the legal small business cannabis markets in Maine.

Thank you for your time. We will see you on the 4th floor at the State House soon I am sure.

Scotty Ouellette
Golden Road Extracts
Also a member of the Maine Cannabis Coalition and Medical Marijuana Caregivers of Maine

- **Ocp has 30 days to act upon a complete application.** Title 22, Chapter 558C, §2425-A. applies to all applications. Throughout the Proposed Rule, OCP refers to timely filed with no regard to the provisions provided in this §2425-A.
- **Telehealth** using a synchronous visit is **explicitly** allowed to be utilized for patient certification per the Act §2423B 9, but is omitted in the Proposed Rule.
- **Terms defined by the Act** and do not need further contradictory definitions in rule, for example *Bonafide Provider Patient Relationship*.
- Medical licensing boards determine what a healthcare provider records in a **Patient Record**. This is not in OCP's scope.
- OCP's reference to compliance with **federal law** in several areas of the Proposed Rule is problematic. The program is contrary to federal law.
- **Patient Confidentiality:** names & identifying information (dob, addresses) are confidential. Several areas of the Proposed Rule disregard this fact.
- **Patient Inspections?** The department may not conduct inspections of a qualifying patient or caregiver operating under §2423-A, subsection 3, C. Ocp makes reference to electrical code for patient cultivation areas and fencing requirements. OCP does not regulate patients in their homes.

- **Revocation.** P. 73-75 Revocation, and sweeping language of **"...but not limited to" (pp 73 AND p.74) must be struck.** "Major violations include, but are not limited to:"
- How does one objectively **quantify marketing to those under the age of 21**? Please provide objective measurement criteria of this in the Proposed Rules.
- **The rules indicate on p. 80 2 c. an appellate may bring ONLY an attorney.** This language restricts an appellate allowing no industry expert, no witness, no employee? OCP did not like industry experts providing support to appellate's fighting for their livelihood in 2022-2023.
- **Pediatric Qualifying Patients.** OCP's Proposed Rule does not align with the Act in regard to pediatric licensing. Redefining parental rights? The Rule needs to mirror the language provided by the Act, Subchapter 2423B.

- "**Municipal authorization** needed. Authorize caregiver retail stores, registered dispensaries, cannabis testing facilities and manufacturing facilities that are not operating on the effective date of this section...[PL 2019, c. 217, §5 (AMD); PL 2021, c. 669, §5 (REV).]" *Municipal authorization* is NOT required of a patient or a caregiver without a storefront in the town. Towns can deal with their setbacks.
- The list of **Authorized Conduct for a Caregiver** on page 35 ought to mirror the list provided on page 41 as the authorized conduct by the Act, Title 22, Chapter 558C is the same.
- **Department Incident Report.** Page 50, under the heading of Dispensary, also illustrates reporting mechanisms by which a dispensary can report illegal activity to OCP via a **Department Incident Report.** Per the Act, this is applicable to "...registered caregivers, dispensaries, cannabis testing and manufacturing facilities..." **This *Department Incident Report* needs to be widely available and all program registrants are required by the Act to report illegal activity, and OCP (and law enforcement) needs to take action on these matters such as illegal grow operations.**
- **Fences and Locks DETER (do not prevent) THEFT.** OCP language in the Proposed Rule indicates a registrant may be concerned reporting a theft because their security system failed. There is nothing in the Act that indicates that cannabis must be **obscured from view** by a 6 foot opaque fence. In some areas of Maine, this immediately signals thieves that one is growing cannabis.
- §2423-A, Q contradicted by P.63 represents a long-standing detail-disagreement with OCP and the industry. Even if OCP employees disagree, the Act clearly states that a **caregiver may be "...organized as any type of legal business** entity under the laws of the State."
- **Inspection Criteria publicly available.** For all registrants, "B. The department shall adopt rules: (1) Establishing standards for compliance with this chapter that are available publicly;" The only publicly available criteria apply to Caregivers (and make no mention of fences or locks). Where does a dispensary find their publicly available criteria?
- OCP is creating an environment in which participants are afraid to even report being a **victim of theft**, for fear they will lose their license or face extraordinary fines for not preventing the said theft.

General Misalignment of Title 22, Chapter 558C ("The Act") and OCP Proposed Rule

In general, OCP has failed to encompass 2023 new legislation that will take effect at the end of October 2023. This includes the "timely application," in which Title 22, Chapter 558C now calls for very specific

deadlines of 30 days from receipt. The Proposed Rules propose vague allusions as to "timely." Other areas in which OCP has not properly encompassed changes in legislation include the comprehensive Proposed Rule definition of Bonafide Provider Patient Relationship (pp.30-31), a comprehensive Rule-based list of what constitutes a patient record(p.31), and an apparent "overlooking" of the new, explicit TELEHEALTH authorization. Healthcare providers are not regulated by OCP and do not need OCP to mandate what a complete patient record encompasses. Especially during covid, Telehealth has been a valuable tool in Maine and nationwide for years. In Maine's vast geography and shortage of primary care providers and specialists, Telehealth has proven critical to patient care not only in the medical cannabis industry, but also in general. Telehealth has increased access to patients immensely. OCP cannot disregard access to patients in Maine to Telehealth. Further, definitions listed in the Proposed Rule (pp17-23) must align with the definitions found in Title 22, Chapter 558C, the Act, and the Act very clearly allows access to Telehealth. Legislative intent on this matter is very clear – the intent is to ensure access to this widely accepted practice of Telehealth, even to the point of clearly defining asynchronous versus synchronous encounters. OCP needs to review subchapter 2423 B 9. Along the same lines, p.35 of Proposed Rule mentions "authorized sources" including "registered caregiver, a qualifying patient, a dispensary." Are there other authorized sources?

OCP's reference to compliance with federal law in several areas of the Proposed Rule is problematic as the entire program is contrary to federal law. See page 66 for an example. Any reference to participants being in compliance with federal law needs to be removed from this Rule. Similarly, punctuation on p. 66 is unclear in regard to visiting qualifying patients. [p. 66, 10 (1)]. P 69 of the Proposed Rule in regard to patient confidentiality, this language needs work, "electronic copies of records" – this needs to be clear that they must redact identifying patient information including names, dobs, addresses of patients before taking photos/digital copy.

Please review all packaging and labeling requirements in the Act, specifically, §2429-A. Packaging and labeling requirements. On p. 75, the "under 21" language is far too subjective. Please let us know how we can market exclusively to those who are over age 21 (and/or are qualified patients)? In clear objective, measurable standards?

P. 75 Fines. These are excessive. Fines ought to be used to punish repeat offenders and to dissuade actions that endanger the public. They should not be so high as to regulate a company directly out of business. On p. 77, OCP has not considered new laws that take effect at the end of October, 2023 that ensure rapid notification to registrants of program violations discovered in an inspection. An example of compliance encouraging compliance and assisting a business to be in compliance is a licensed kitchen inspection. The goal of the Department of Agriculture is to work with a registrant to regulate them into compliance and license their kitchen. The goal of OCP ought to be to encourage compliance and help registrants into compliance rather than help them out of business.

Revocation. P. 73-75 Revocation, and sweeping language of "but not limited to" (pp 73 AND p.74) must be struck. "Major violations include,~~but are not limited to~~:" OCP has historically demonstrated that we cannot allow OCP a blank slate. The statement on the bottom of p. 73 is a good definition of a major registration violation encompassing will and intent and recklessness. We still feel the "but not limited to" is too powerful and too encompassing, especially when that section refers to revocation of one's registration.

Iii. "(ciii) Engaging in marketing or advertising of cannabis or cannabis products, by or on behalf of a registrant, to individuals under the age of 21 years of age or individuals who are not qualifying patients;" This must be eliminated unless objective criteria can be established to determine what constitutes marketing to those under 21. Same issue on p.75 and anywhere else this is addressed in the Proposed Rule.

P. 80 2 c. An appellate may bring not only an attorney, but also any industry experts or persons who an support their case to an appeal hearing. This language restricts an appellate to bringing only their legal representation. This is a direct aim at appellants who have brought people who are more familiar with industry law and politics than they may be, or people who can better articulate their case, but may not be their actual legal representation. An appellate who is fighting to retain or regain their business, their livelihood, should have the right to bring those who can help them state their case, whether an industry expert of their choosing, patient(s) who support the registrant, or anyone whom they choose.

Pediatric Issues

OCP's Proposed Rule does not align with the Act in regard to pediatric licensing attempting to redefine parental rights over their children and placing undue hardship on a parent to prove they have the right to make decisions for their children. The Act is clear. The Rule needs to mirror the language provided by the Act. Additionally, the Act provides clear instruction about things OCP has failed to mention in the Proposed Rule in regard to after hours parent/guardian contact the healthcare provider access information. P. 32-33 of the Proposed Rules indicates that a minor patient may designate - a minor cannot, but a parent (or guardian) can on their behalf. Please read subchapter 2423B of the Act. P.33 also muddies the water on the Act's acceptance of Digital Images of a patient card. Pp 35-37 of the Proposed Rule presents some unclarity in regard to pediatric school administration and background checks of employees. If a potential employee presents with a valid and unexpired OCP issues Registry Identification Card, said potential employee assumably passed a background check to acquire said card, no? P. 38 also eliminates language for a "Second Primary Caregiver," which historically and practically has been used to certify a secondary caregiver to administer cannabis medication to a registered minor patient on school grounds along with background check criteria for said administration.

Municipal Authority, Patient Confidentiality, trip tickets :

OCP will need to review the Act, subparagraph 2429-D in regard to municipal authority and to whom/what municipal authority applies in the program. There is NO basis in the Act in regard to inspections of patient homes electrical systems, fences or locks.(Any qualifying patient who voluntarily registers with OCP is not making a wise decision)Patients are NOT subject to OCP inspection to ever verify compliance with electrical code. This is out of OCP's scope. Patient confidentiality and very explicit language in the Act protect patients from OCP inspection of their homes.

Additionally, the Act makes no mention of plants visibility or invisibility, nor a fence's opacity or "commercial" designation. Will we be opening up all Maine citizens to random electrical code inspections if we suspect they grow medical or adult use cannabis?

Also in regard to patient confidentiality, trip tickets are required of a "...registered caregiver, registered dispensary, cannabis testing facility and manufacturing facility" must have a label that contains the following information...A retail sale does not need to be accompanied by this label or "trip ticket' as they are known – one does not require OCP permission to travel from the storefront to home or wherever.

Because municipalities explicitly may not limit the number of caregivers, if a caregiver is not operating a storefront within a municipality, OCP does not need to require proof of municipal authority for a caregiver application with no storefronte store to their home in either an Adult Use or Medical sale. In regard to QUALIFYING PATIENTS, the Act is clear: "D. The department may not conduct inspections of a qualifying patient or caregiver operating under section 2423-A, subsection 3, paragraph C." OCP has no authorization to inspect qualifying patient homes, cultivation areas or electrical circuits.

Municipal authority granted per Title 22, Chapter 558C indicates the following, "3. Municipal authorization needed. Authorize caregiver retail stores, registered dispensaries, cannabis testing facilities and manufacturing facilities that are not operating on the effective date of this section...[PL 2019, c. 217, §5 (AMD); PL 2021, c. 669, §5 (REV).]" .

Caregiver Authorized Conduct:

OCP's disregard for the basis that built Maine's Medical Cannabis Program is clear when comparing page 35 to page 41 of the Proposed Rule. The list of Authorized Conduct for a Caregiver on page 35 ought to mirror the list provided on page 41 as the authorized conduct by the Act, Title 22, Chapter 558C is the same. P.50 of the Proposed Rule illustrates another example of OCP's disregard for caregivers. Transaction logs are required to be kept by all caregivers and dispensaries operating within the program. These logs are key to Maine's Cannabis Council's proposed alternative to Metrc in the medical program, an alternative that would function a lot like Maine's GAP program (Good Agricultural Practices) and Maine's Hemp program.

Page 50, under the heading of Dispensary, also illustrates reporting mechanisms by which a dispensary can report illegal activity to OCP via a Department Incident Report. Per the Act, this is applicable to "...registered caregivers, dispensaries, cannabis testing and manufacturing facilities..." This Department Incident Report needs to be widely available and program registrants are required by the Act to report illegal activity, and OCP (and or law enforcement) needs to take action on these matters such as illegal grow operations. While we realize that OCP has no authority over illegal operations, law enforcement does. Encouraging registrants to report illegal activity, and use of the published and available Criteria for Registered Caregiver Inspections form can help OCP to develop a partnership and learning experience with registrants. While OCP does not have authority over illegal operations, when a OCP registrant buys or sells from an unregistered cultivator, OCP has authority over that registrant, and this ought to be a violation endangering public safety (supporting the illicit market).

Inspection criteria are to be available publicly per the Act; however, we only see criteria for Caregiver inspections. Per the Act, this law applies to all registrant inspections and criteria are to be publicly available. "B. The department shall adopt rules: (1) Establishing standards for compliance with this chapter that are available publicly;" Further, good leadership would perhaps establish the goal of inspections to encourage and develop compliance with program rule and law, not to regulate segments of the industry out of business. If people are afraid of repercussions rather than anticipating assistance in solving a problem, they are less likely to report or be honest about a problem.

P.63 represents a long-standing detail-disagreement with OCP and the industry. Even if OCP employees disagree, the Act clearly states that a caregiver may be "...organized as any type of legal business entity under the laws of the State." (Subchapter 2423-A, Q." OCP may want to require the business name and/or any DBA names from a caregiver? Along the same lines are the references to timely filed applications, especially for renewal. Title 22, Chapter 558C, §2425-A. applies to all applications. Throughout the Proposed Rule, OCP refers to timely filed with no regard to the provisions provided in this subparagraph 2425-A.

Cultivation Area (Fences and locks)

The Act:3. Cultivation area. "Cultivation area" means an indoor or outdoor area used for cultivation of mature cannabis plants, immature cannabis plants or seedlings 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. A cultivation area may include multiple indoor or outdoor

areas, whether contiguous or noncontiguous, on the same parcel or tract of land. [PL 2021, c. 662, §2 (AMD); PL 2021, c. 669, §5 (REV).]

The Act is clear that OCP shall implement security measures (to be approved by the legislative committee of oversight, currently the Veterans and Legal Affairs Committee). To require that fences be "commercial grade", fencing is just not Maine – many of us do it ourselves. Chain Link fencing covered with opaque material? A wooden frame fence? The fence must deter access to unauthorized persons, permitting access only by a person authorized to have said access. Locks, fences and any security measure can be defeated – perhaps unless they are protected by the 20k soldiers who protect Fort Knox. As is commonly heard, "locks keep out honest people." We can require fences and locks, but even the second best of systems can be defeated. Anything controlled electronically can be hacked, even government databases such as OCP. The language on p. 28 in regard to locks is impossible to attain. "...commercial grade locks sufficient to prevent theft..." perhaps DETER theft, rather than PREVENT theft may be more appropriate language. No lock can 100% prevent a determined thief. One cannot PREVENT unauthorized access or theft no matter the lock or fence within the boundaries of the law. May I install an electric fence, for example? This language needs to be realistic using terms like *deter* rather than *prevent.* Additionally, none of these provisions are subject to OCP inspection or verification on private patient-only property (not a caregiver). OCP is creating an environment in which participants are afraid to even report being a victim of theft, for fear they will lose their license or face extraordinary fines for not preventing the said theft. Additionally, there is nothing in the Act that indicates that cannabis must be obscured from view by a 6 foot opaque fence. In some areas of Maine, this immediately signals thieves that one is growing cannabis. .

Packaging and Labeling.
These are basically per statute and statute requirements are pasted below for reference only. .

Packaging and Labeling, p. 27 versus the Act

9. Packaging and labeling requirements. A manufacturing facility shall package and label its cannabis products and cannabis concentrate prior to transfer from the manufacturing facility in a form intended for use or consumption by a qualifying patient in tamper-evident packaging and with a label that includes the following information: A. The registry identification number of the manufacturing facility; [PL 2019, c. 331, §17 (RPR).] B. Information that allows the provider of the cannabis to the manufacturing facility to confirm that the cannabis provided was used to manufacture the cannabis product or cannabis concentrate transferred back to that provider; [PL 2019, c. 331, §17 (RPR); PL 2021, c. 669, §5 (REV).] C. Ingredients other than material derived from cannabis plants contained in the cannabis product or cannabis concentrate; and [PL 2019, c. 331, §17 (RPR); PL 2021, c. 669, §5 (REV).] D. Any chemicals, solvents or other substances used to manufacture the cannabis product or cannabis concentrate. [PL 2019, c. 331, §17 (RPR); PL 2021, c. 669, §5 (REV).] [PL 2019, c. 331, §17 (RPR); PL 2021, c. 669, §5 (REV).]

§2429-A. Packaging and labeling requirements 1. Packaging requirements. As applicable based on the form of the item sold, harvested cannabis sold in a retail transaction under this chapter must be: A. 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 cannabis at the final point of sale to a qualifying patient; [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] B. 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 cannabis at the final point of sale to a qualifying patient; [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] C. Packaged in a container with an integral measurement component and child-resistant cap if the cannabis product is a multiserving liquid; and [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] D. 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 cannabis products must include a signifier that the package contains harvested cannabis. [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] 2. Packaging prohibitions. Harvested cannabis 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 cannabis was a trademarked product; [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] 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).] [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] 3. Labels. If a registered caregiver, dispensary or manufacturing facility affixes a label on the packaging of any harvested cannabis provided to a qualifying patient and that label includes information about contaminants, the cannabinoid profile or potency of the harvested cannabis, the label must be verified by a cannabis testing facility. This subsection does not apply if there is no cannabis testing facility operating in accordance with section 2423-A, subsection 10. [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).]

2. Rules on signs, advertising and marketing. The department shall adopt rules regarding the placement and use of signs, advertising and marketing by or on behalf of a registered caregiver or dispensary, which may include, but are not limited to: A. A prohibition on health or physical benefit claims in advertising or marketing, including, but not limited to, health or physical benefit claims on

the label or packaging of harvested cannabis; [PL 2017, c. 452, §18 (NEW); PL 2021, c. 669, §5 (REV).] B. A prohibition on unsolicited advertising or marketing on the Internet, including, but not limited to, banner advertisements on mass-market websites; [PL 2017, c. 452, §18 (NEW).] C. A prohibition on opt-in advertising or marketing that does not permit an easy and permanent opt-out feature; and [PL 2017, c. 452, §18 (NEW).] D. A prohibition on advertising or marketing directed toward location-based devices unless such marketing includes a permanent and easy opt-out feature and the owner of the device is 21 years of age or older. [PL 2021, c. 367, §15 (AMD).] [PL 2021, c. 367, §15 (AMD); PL 2021, c. 669, §5 (REV).]