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## Industry consensus on LD1847

1 message

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Senator Hickman, Representative Supica, and the members of the Veterans and Legal Affairs Committee,

Since adjournment last year there have been group calls, meetings, a summit and various opportunities for disparate members of the industry to discuss what we would like to see happen in this program. We all agree on a number of actionable policy points, and I would like to outline those places of agreement for your consideration as you work LD1847.

### TESTING CONSENSUS:

#### **Return OCP's statutory authority to take audit samples at routine inspections and test them for pesticides and residual solvents**

We would like to see the audit testing conceived of in the program rules implemented. We were under the impression, based on what Vern Malloch told the committee last year, that it was a policy choice not to audit test. However, we learned last week that statutory language around that sampling has been revoked. There is consensus that this authority should be returned to statute. In order to test products, we must conceive of what should be tested for. As Representative Osher told the committee last year, there is no clear scientific consensus on what is appropriate to test for and at what limits, to determine safety or lack thereof. However, we all agree prohibited pesticides, and residual solvents should be tested for. Despite the lack of science around limits for inhalation of combustibles, we know that use of these pesticides is prohibited and a violation of state and federal law. Residual solvents are also clearly not intended to be a part of a finished product, and we agree that products should be tested to ensure they do not contain any. The rules state samples are to be taken annually for dispensaries and at the discretion of OCP for caregivers. There is industry consensus that it would be appropriate to take samples during all routine inspections regardless of registration type. Ideally all registrants would have an annual inspection that includes audit sampling.

### TRACKING CONSENSUS:

#### **Records sufficient to conduct a recall and trip tickets that reflect the original source of the material transferred.**

There is consensus that further recordkeeping requirements should be added to statute to clarify the need to be able to conduct a recall. It is also agreed that it would be valuable for trip tickets to disclose the registrant who originally grew and harvested the material being transferred. The portal conceived of in the industry amendment is not objectionable in theory, but it appears to be complicated, expensive and rooted in the stigma that we are not to be trusted.

Some folks think we should go beyond this consensus and others do not, but what I have outlined is where I believe all participants truly agree.

The conservative path is fully implementing the medical program before completely overhauling it or making it look like adult use. In taking a more conservative approach, we ensure that we don't see the loss of thousands of jobs and hundreds of businesses at a time when so many in our state are struggling to meet basic needs. We should also be careful we don't disrupt patients access to the medicine of their choice from the caregiver of their choice. The medical program continues to outperform the adult use program in terms of sales. Patients go out of their way to get a medical card every year so that they can buy from caregivers that produce quality and variety that can't be replicated at scale. METRC and mandatory batch testing require businesses to scale to survive, but we are talking about implementing it on 1,500+ small operators who can't grow more than 30 plants or 500sqft.

I have attached language which addresses these consensus points that I've worked on with Mark Barnett, Matt Bayliss and Paul McCarrier, and have shared with many other industry members including MMCM who supports this path. Additionally, I have included a document outlining considerations regarding microbiological testing, specifically regarding aspergillus.

Maines program is the most socially equitable and accessible medical cannabis program in the country, and I hope that it will continue to be one where the smallest operators can participate and compete based on the quality of their product.

Thank you all for the work you have done to improve this program,

Sincerely,  
Lizzy Hayes

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Alternative solutions to the issues of concern that LD1847 seeks to address.

**Inventory tracking and tracability:** A few statutory changes would make the records required in the medical program more complete, in order to make an audit possible and ensure the ability to recall products. Attached you will find the current recordkeeping requirements from statute with suggested additional language to improve chain of custody transparency. Additionally included is a trip ticket, which accompanies all products transferred, updated to identify the registration number of the person who initially grew and harvested the material.

While it is standard in industries that records be kept to sufficiently tracking inventory, it is not often that a particular software is mandated. In pharmacy licenses, GAP certified facilities, cGMP, HACCP system plans etc, there is only a description of records that must be kept and audited, but not a specific software that must be used.

**Testing of products and facilities:** Recalls in the adult use program have been conducted due to audit tests identifying contaminants in batches of product which had already passed mandatory testing. For this reason audit testing appears to be the most important tool that we have available to protect patients. There is already a requirement to audit test each dispensary annually. The rule does not require but authorizes audit testing at caregiver inspections as well, which should be a policy of the office. We suggest this being added to statute for both caregivers and dispensary registrations.

**§2430-J. Reporting; record keeping; labels**

The department shall develop, implement and maintain a statewide electronic portal through which registered caregivers, registered dispensaries, cannabis testing facilities and manufacturing facilities may submit to the department the records required pursuant to this chapter. The department may not require records submitted through the portal to contain information identifying qualifying patients. [PL 2023, c. 365, §21 (NEW).]

**1. Required records.** A registered caregiver, a registered dispensary, a cannabis testing facility and a manufacturing facility shall:

~~A. Keep a record of all transfers of cannabis plants and harvested cannabis; [PL 2023, c. 365, §21 (NEW).]~~

A. Maintain records concerning the production, harvesting, and handling. Such records must:

(1) Be adapted to the particular business that the certified operation is conducting;

(2) Fully disclose all activities and transactions of the registered operation, in sufficient detail as to be readily understood and audited; records must span the time of purchase or acquisition, through production, to sale or transport and be traceable back to the last registered operation;

(3) Include audit trail documentation for products handled or produced by the registered operation. Each product received should either have a lot number with it or should be assigned a lot number. Any time harvested materials are combined or blended, a lot number must be assigned to the finished product. If a product is purchased from several sources, the production or batch record should list the source and lot number of each product.

(4) Be sufficient to conduct a product recall.

B. Keep the books and records for a period of 4 years; and [PL 2023, c. 365, §21 (NEW).]

C. Make the books and records maintained under this subsection available for inspection by the department upon the department's request. [PL 2023, c. 365, §21 (NEW).]

[PL 2023, c. 365, §21 (NEW).]

**2. Required label.** A registered caregiver, registered dispensary, cannabis testing facility and manufacturing facility shall accompany all cannabis plants and harvested cannabis being transported pursuant to this chapter with a label that identifies:

A. The person transferring the cannabis plants or harvested cannabis, including the person's registry identification number; [PL 2023, c. 365, §21 (NEW).]

B. The person receiving the cannabis plants or harvested cannabis, including the person's registry identification number or, if the person is not required to register under this chapter, a unique identifier assigned to the person; [PL 2023, c. 365, §21 (NEW).]

C. A description of the cannabis plants or harvested cannabis being transferred, including the amount and form; [PL 2023, c. 365, §21 (NEW).]

D. The time and date of the transfer; and [PL 2023, c. 365, §21 (NEW).]

E. The destination of the cannabis plants or harvested cannabis. [PL 2023, c. 365, §21 (NEW).]

F. The registration number of the person who grew and harvested the material being transferred.

-Add to statute the audit sampling requirements from the program rules for dispensaries.

Previously under Sec. A-20. 22 MRSA §2428, sub-§5:

**5. Inspection.** Registered dispensaries, including all retail and cultivation locations, are subject to inspection at least annually. During an inspection of the registered dispensary, the Department shall collect samples and have them tested for pests, mold, mildew, heavy metals and the presence of pesticides. Additional testing may be conducted. Written results shall be reported to the dispensaries.

-Additionally require audit sampling during inspections for **caregiver** registrations, but won't require them to be annual, as these are done on a rolling basis depending on Office resources.

**Inspection.** Registered caregivers, including all retail and cultivation locations, are subject to inspection. During an inspection of the registered dispensary, the Department shall collect samples and have them tested for pests, mold, mildew, heavy metals and the presence of pesticides. Additional testing may be conducted. Written results shall be reported to the registrants.



# Maine Medical Use of Cannabis Program Trip Ticket

The following information is required as proof of authorized conduct anytime a registered caregiver, registered dispensary, cannabis testing facility, or manufacturing facility transports cannabis or cannabis products for medical use. This form must accompany the cannabis or cannabis products. For more information: <https://www.maine.gov/dafs/ocp/medical-use/applications-forms>.

<b>SECTION 1: Transferring Registrant</b>			
This section must be completed by the transferring registrant.			
Caregiver's Legal Name		Caregiver (CRG) Registry Identification Card Number	
Legal Name of Dispensary Registration Certificate Holder, if applicable		Dispensary (DSP) Registration Certificate Number, if applicable	
<b>SECTION 2: Receiving Patient or Registrant</b>			
This section must be completed anytime cannabis or cannabis products for medical use are transported, including patient delivery and when a registered caregiver, registered dispensary, cannabis testing facility, or manufacturing facility is transporting cannabis or cannabis products from one of its registered locations to a different registered location.			
This section must be completed by the transferring registrant.			
Patient Identification Number/Medical Certification Number (DO NOT LIST NAME)			
<b>OR</b>			
Caregiver's Legal Name		Caregiver (CRG) Registry Identification Card Number	
Legal Name of Dispensary Registration Certificate Holder, if applicable		Dispensary (DSP) Registration Certificate Number, if applicable	
<b>SECTION 3: Description of Cannabis or Cannabis Products Transported</b>			
For each item transported, provide the registration number of the person who grew and harvested the material being transferred, the amount (weight or units), product type (flower, wax, cartridges, etc.), and strain or other further identifying information of the cannabis or cannabis products.			
This section must be completed by the transferring registrant.			
<b>SECTION 4: Departure Information</b>			
This section must be completed by the transferring registrant.			
Start Date		Start Time	
Departure Address (Physical)		City	State Maine
			ZIP
<b>SECTION 5: Destination Information</b>			
This section must be completed by the transferring registrant.			
Destination Address (Physical)		City	State Maine
			ZIP
<b>SECTION 6: Receiving Registration Signature and Acknowledgment of Receipt</b>			
This form is incomplete without a signature by the receiving registrant listed in Section 2. If the person listed in Section 2 is a patient, no signature is required.			
This section must be completed by the receiving registrant.			
Printed Name of Receiving Registrant		Email Address	Phone Number
Date Received		Time Received	
Signature			

To the Veterans and Legal Affairs Committee  
From Lizzy Hayes, caregiver and organic farmer

**An appeal to omit microbial panels from safety testing in cannabis:**

An item introduced in LD1847 is testing products specifically for the fungal spores of aspergillus. I would like to make a case that this test lacks utility, when no guarantee of safety or harm could ever be the conclusion of that test. While only microbe that is known to be present on cannabis that causes human disease is aspergillus, it is important to note that according to the [CDC](#):  
*"Most people do not get sick from Aspergillus. However, it can cause mild to severe illness in certain populations such as people with weakened immune systems or lung diseases....Aspergillus spores are common in indoor and outdoor environments...It may not be possible to completely avoid breathing in some Aspergillus spores."* The same elevated risk exists for these individuals in the food choices they make. Premade deli salads, and unwashed vegetables, brie and other unpasteurized cheeses can also pose harm to immune compromised individuals [according to the CDC](#).

In the book ["Aspergillus and Aspergillosis"](#) it states *"The genus Aspergillus, one of the most ubiquitous and worldwide spread organisms, is saprophytic on all sorts of substrates with various moisture contents and has been demonstrated in such diverse sources as soil, decaying vegetation, air and even water. In addition it is a commonly cultured mold from houses and is especially found in basements, crawl spaces, bedding and house dust."*

From [Innate immunity to Aspergillus species - PubMed](#) it is stated that *"All humans are continuously exposed to inhaled Aspergillus conidia, yet healthy hosts clear the organism without developing disease and without the development of antibody- or cell-mediated acquired immunity to this organism. This suggests that for most healthy humans, innate immunity is sufficient to clear the organism."*

[This study](#) entitled *"Ten-year air sample analysis of Aspergillus prevalence in a university hospital"* found: *"Recovery of Aspergillus spp. at 37 °C in the high-efficiency particulate air (HEPA)-filtered locations was positive for Aspergillus spp. approximately one-third of the time; the rest of the patient care areas were positive half of the time and the outdoor samples were positive 95% of the time."*

It's impossible to guarantee that there are no active aspergillus spores on cannabis even if a sample from a batch passes testing. It would be deceptive to tell medical patients that it is safe to smoke cannabis. Smoking is a health hazard and a choice that must be made as an assumed risk. Unlike Adult Use customers, patients purchasing cannabis in the medical program are required to discuss their cannabis use with a physician, and so we should safely assume that patients with elevated risk factors have been counseled by their medical provider to avoid product types that pose a higher risk.

For those reasons I do not believe pass/fail batch testing for microbiological contaminants is best practice.