Senator Hickman, Representative Supica, and to the members of the joint standing committee on Veterans and Legal Affairs,

My name is Lizzy Hayes. I am an organic farmer, a medical cannabis caregiver, a medical cannabis patient and I am here today in strong opposition to LD 104.

We have one of the oldest medical programs in the country and one of few, if not the only, where patients can purchase directly from the person growing their medicine. It is a program I am proud to be a part of. There has been consistent messaging that our program does not have tracking and that our products are untested and therefore unsafe.This misinformation erodes public confidence in the medical cannabis industry and I would like to provide some clarity.

Regarding tracking:

There is tracking in the medical program. Registrants are required to track every time that cannabis is transferred into or out of their custody with a "Trip Ticket" (attached) which records the date, time and location of the transfer, the registration number of both parties involved, and description of the material transferred. Additionally we must maintain a transaction log with this same information, and include a photo id # of the person we transfer material to/from. Based on my experience in the National Organic Program, the addition of planting and harvest records (which many cultivators already maintain) and a record of current inventory would be sufficient to do a full trace back audit and mass balance audit.

Regarding testing:

The OCP report *Harmful Contaminants in Maine's Medical Cannabis Program* shows that "50 samples, or 42%, contained at least one contaminant that would have failed testing according to the mandatory testing standards set for Maine's Adult Use Cannabis Program" however 60% of these failures (30/50) were for total yeast and mold, tests which the manufacturer states "are unable to differentiate between pathogenic, beneficial, and benign yeast and molds, making them poor indicators of safety. A low TYM result does not mean a cannabis sample is free of pathogens. A high TYM result doesn't mean a sample is harmful to consumers." Recalls in adult use have been due to failures for TYM, with no evidence of the presence of harmful or dangerous pathogens. This testing is inconsistent with statue which authorizes testing for "Dangerous yeasts, molds and mildew" not testing for TOTAL yeast and mold. These recalls create distrust of products from our state's regulated market and have not demonstrated an ability to impact public health outcomes. Allowing the use of irradiation pre-test puts the utility of the TYM test into question as well.

There are concerns about tests being self-sampled, labs being privately run, inconsistencies in lab results from different labs and in samples from the same batch. Transparency of testing data would enable identification of lab fraud so it could be remedied, but so far the FOIA requests for that data have been denied.

I am hoping lawmakers, stakeholders and the department can collaborate on issues of testing and tracking with conversations based on scientific evidence and pragmatic efforts to honestly assess potential public health risks, rather than creating and promoting an illusion of safety.

I thank you for your consideration and I respectfully ask that you vote ought not to pass on LD104.

SEED TO SALE INVENTORY TRACKING SYSTEM

The inventory tracking system through the use of METRC software comes at a significant cost to the state, is cumbersome to the user, provides no value for the registered operation outside of compliance, and creates excessive waste by requiring single use plastic RFID plant and product tags.

The records which are already required to be kept by registrants would only require the addition of planting, harvest and inventory records (which many operations already maintain) **in order to complete a full audit of the inventory tracking system to ensure traceability, chain of custody and demonstrate that there was no inversion or diversion within a registered operation.** This method of inventory tracking is currently being done by operations in the medical and adult use programs that are certified in MOFGA's MC3 program, a 3rd party verification based on the USDA National Organic Standards.

The MMCP **statute currently requires** records to be kept for all transfers to include:

- Registration number of transferring and receiving parties, or patient medical card #
- Location of transfer
- Time product left registered facility and time of transfer to receiving facility
- Type/form of product, weight/amount of products transferred

For **seed to sale inventory tracking** additional requirements would be needed for:

- Planting records (variety, number of plants, date and location planted)
- Harvest records (variety, number of plants harvested, date & location stored/dried)
- Batch/lot numbers created
- Inventory of finished products

This would enable an inspector to conduct a mass balance audit and a trace-back audit to test the inventory tracking systems ability to demonstrate that all material transferred is produced by a registered facility and that all material was transferred to a registered facility or a qualified patient. This is the process used in over 40,000 farms in the National Organic Program to demonstrate chain of custody and ensure conventional products are not being sold as certified organic.

EXCERPTS FROM THE MC3 STANDARDS(MOFGA CERTIFIED CLEAN CANNABIS):

*requirements which are meant to demonstrate compliance with organic growing standards and are not relevant to tracking have been removed.

Record Keeping and Practices

Record keeping is a regulatory requirement for medical and adult-use cannabis, much of which can also satisfy some of the record keeping requirements of MOFGA's Clean Cannabis Standards. Documentation should include harvest records, allowing for a mass balance and a trace back audit of materials used in production. Crop production logs and receipts for inputs are also required, such as time of harvest and storage method. Records for culls and seconds must be kept.

NOTE: If you use track and trace software for production and sales recordkeeping, you do not need to duplicate records for Clean Cannabis certification. All records must be available for review at inspection or as requested.

For each batch of cannabis, cultivation operations must maintain records that include at a minimum:

Planting records:

a) Form of cannabis planted (e.g., seed, clone, seedlings, etc.);
b) Date(s) that planting took place;
c) Varieties planted;
d) Size of the cultivation area; and
e) Location of the cultivation area.

Plant records

a) Each plant must be assigned a plant code unique to that plant. This code is recorded when materials are harvested from the plant. This is required to facilitate traceability of cannabis ingredients back to the plant.

Harvest records:

a) Identity of each variety/strain harvested;
b) Date of harvest;
c) Total weight of cannabis waste resulting from the harvest;
d) Net weight of cured, trimmed harvested cannabis (gross weight less waste), and;
e) Lot code for each harvest.

Production Records:

a) Identify the product made;
b) Date of finished product production;
c) Total number of finished product units and unit weights, and;
d) Any incidental loss incurred during production.
e) Lot codes must be applied to each finished unit. Finished product lot codes must be traceable to harvest lot codes and back to plant codes and plant origin.

Sales records:

a) Receipts showing sales of inventory produced, including wholesale transactions, that can be traced back to production and lots, and;
b) Receipts showing any caregiver to caregiver or caregiver to dispensary sales

Recordkeeping
All aspects of certified clean cannabis production must be verifiable with records. Purchase, production, inventory and sales records are all necessary.
Your inspector must be able to complete both a trace-back and a mass balance audit:

A trace-back audit verifies that records are sufficient to track finished products back to the ingredients used to produce them. To conduct this audit, the inspector will choose a finished product and will trace the product lot numbers through the production system to the ingredient lot number received or the harvest date. Please make sure that all necessary records and lot numbers are in place to support a trace-back audit, including purchase receipts with lots noted.

A mass balance audit verifies that sufficient quantities of MC3 Verified and organic ingredients are produced or purchased and match the amount used in the production of finished products. To conduct this audit, your inspector will examine inventory records of both ingredients and finished product, production records, and sales records. Using your ingredient inventory records the inspector will determine the expected amount of ingredient used over a time period, using batch/production records and finished product inventory the inspector will determine the actual amount of ingredient used and the expected amount of finished product sold. Finally, the inspector will verify the expected amount of finished product sold with actual sales records. Please be sure that ingredient inventory, batch/production records, finished product inventory and sales records are in place to support a mass balance audit.

Lot numbers. The ability to track products and ingredients through handling and processing is vital to assure product compliance. Using lot numbers to track products and ingredients allows for a successful audit trail. Each ingredient received should either have a lot number with it or should be assigned a lot number. Any time MC3 or organic ingredients are combined or blended, a lot number must be assigned to the finished product. If an ingredient is purchased from several sources, the production or batch record should list the source and lot number of each ingredient. Lot numbers can be used to facilitate a product recall if there is a complaint or a food safety issue after a product is produced and/or sold.

EXCERPT FROM MOFGA CERTIFICATION SERVICE PROGRAM RULE:

Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(b) 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 certified 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 certified operation;

(3) Include audit trail documentation for agricultural products handled or produced by the certified operation and identify agricultural products on these records as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," or similar terms, as applicable;

(4) Be maintained for not less than 5 years beyond their creation; and

(5) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

INSPECTORS

The inspector's role is to be an impartial and independent reporter of your operation's practices and procedures used to implement the OSP. Information gathered during an inspection is considered confidential and is meant for application evaluation only. Everyone involved in inspection and/or application evaluation has signed an inspector contract, which requires non-disclosure of information to any third party or use of confidential information for personal gain.

- The inspector may tour the farm or plant and review audit trails. A mass balance and traceability exercise may be done.
- Inspectors may provide sufficient information to persons seeking certification to enable them to understand the Requirements of the Rule.
- An inspector may be instructed by MCS to make unannounced inspection visits.
- An inspector may be instructed by MCS to take samples for residue tests at MCS's expense.

Inspector Qualifications

Inspectors shall be professional, objective observers competent to evaluate and report on the conditions and practices on the farm and to verify information submitted in the application. The inspector shall have professional training or equivalent experience in agriculture and organic farming and/or processing practices per the regulations at 205.501. MCS inspectors must enroll in formal inspector training and complete annual training each year. There shall be no conflict of interest in that the inspector shall be financially independent of both the farmer's and the buyer's interests...MCS conducts annual performance evaluations of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services.In addition,MCS conducts witness audit inspections (field evaluations)of all inspectors at least every 3 years and has procedures in place to improve on any deficiencies identified.

§543-A. Cider

1. Restriction on product labeled as cider. A person may not sell, advertise, offer or expose for sale any product labeled as "cider" if that product does not require refrigeration from pressing through purchase or has been heated.
[PL 2021, c. 111, §1 (AMD).]

2. Accepted processing methods. All cider sold, advertised, offered or exposed for sale must be treated by ultraviolet light or pressed under a state-approved hazard and critical control plan unless the cider bears a warning label in accordance with subsection 3. A state-approved hazard and critical control plan must prohibit the pressing of apples that have dropped from the trees for use in cider.
[PL 2021, c. 111, §2 (AMD).]

3. Warning label. A person selling, advertising, offering or exposing for sale cider that has not been processed in accordance with subsection 2 must affix a label to that product stating: "WARNING: This product has not been pasteurized. It may contain harmful bacteria that can cause serious illness in children, the elderly and persons with weakened immune systems."
[PL 1999, c. 175, §1 (NEW).]

4. Exemption. Hard cider and nonalcoholic carbonated cider labeled as "sparkling cider" are exempt from this section. For purposes of this subsection, "hard cider" means liquor produced by fermentation of the juice of apples or pears, including, but not limited to, flavored, sparkling or carbonated cider, that contains not less than 1/2 of 1% alcohol by volume and "liquor" has the same meaning as in Title 28-A, section 2, subsection 16.
[PL 2023, c. 175, §1 (AMD).]

SECTION HISTORY

PL 1983, c. 220 (NEW). PL 1999, c. 175, §1 (RPR). PL 2021, c. 111, §§1-3 (AMD). PL 2023, c. 175, §1 (AMD).

OFFICE OF CANNABIS POLICY
DEPARTMENT OF ADMINISTRATIVE AND FINANCIAL SERVICES

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.

SECTION 1: Transferring Registrant

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

SECTION 2: Receiving Patient or Registrant

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)	
OR	
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

SECTION 3: Description of Cannabis or Cannabis Products Transported

For each item transported, provide 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.

SECTION 4: Departure Information

This section must be completed by the transferring registrant.

Start Date	Start Time		
Departure Address (Physical)	City	State Maine	ZIP

SECTION 5: Destination Information

This section must be completed by the transferring registrant.

Destination Address (Physical)	City	State Maine	ZIP

SECTION 6: Receiving Registration Signature and Acknowledgment of Receipt

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		

mendations for botanical ingredients established by various national and international bodies. Tests can be performed according to standard pharmacopoeial instructions (e.g., European Pharmacopoeia, United States Pharmacopoeia, among others).

Foreign Organic Matter (crude cannabis material): Not more than 5.0% of stems 3 mm or more in diameter; not more than 2.0% of other foreign matter.

Total Ash (crude cannabis material): Not more than 20.0%.

Acid-insoluble Ash (crude cannabis material): Not more than 4.0%.

Loss on Drying (crude cannabis material): Not more than 10.0% of its weight, determined on 1.000 g of the powdered drug by drying in an oven at 105 °C for 2 h (BMC 2010).

Moisture content of dry material (crude cannabis after packaging): Not more than 15% (BMC 2010).

Microbial and Fungal Limits.

The presence of microbes is typical for all natural products. Unless carefully cultivated, illegal supplies may not meet the prescribed specifications. Conversely, reports in which a causal association between microbial exposure through cannabis use and infections has been established (e.g., Carod Artal 2003) appear to be rare considering the prevalence of use and exposure.

Tolerance limits for microbial and fungal contamination in cannabis and its products should be consistent with applicable state, federal, and international regulations, whenever applicable. Recommended tolerance limits for cannabis products are provided in Table 9 and were based on a review of national and international recommendations for botanical products as well as discussion with a variety of stakeholders (e.g., Washington State). Additional guidance for botanical products is provided in national and international compendia based on oral consumption of finished botanical products. Additionally, more restrictive limits may be adopted for medical use of cannabis, most notably when used by immune compromised individuals. Microbes such as *Aspergillus* spp., for example, can be transmitted through inhalation and are of specific concern in those with specific medical conditions (e.g. chronic granulomatous disease and cystic fibrosis) and when employing specific medical treatments (e.g., immunosuppressive therapies). Reducing total microbial risk may require specific microbial reduction treatment to the greatest level possible without compromising the putative medicinal activity. Appropriate methods for testing microbial loads can be found in the *Bacteriological Analytical Manual* (FDA 2013a).

It is important to note that microbial and fungal values do not typically represent pass or fail criteria. Rather, they are recommended levels when plants are produced under normal circumstances and growing conditions. Individual herbs, such as mints (*Mentha* spp.), which have a high concentration of trichomes, are prone to higher levels of molds than crops with fewer trichomes. As cannabis also possesses high concentrations of trichomes, this may be a factor and recommended limits may require adjustment over time. Higher levels of molds can also occur in seasons of heavy rain without undue damage to the crop and may justify a material exceeding the proposed limits as long as there is no visible damage to the plant and other qualitative specifications are met. Limits must also be appropriately applied to the various preparations being made. Typical microbial and fungal limits may not be relavant to materials that are to

Table 9 Microbial and fungal limits recommended for orally consumed botanical products in the US (CFU/g)

Unprocessed materials[a]	10^3	10^4	10^5	10^6	10^7	Not detected in 1 g
Processed materials[b]	10^3	10^4	10^5	10^6	10^7	Not detected in 1 g
CO_2 and solvent-based extracts	10^3	10^4	10^5	10^6	10^7	Not detected in 1 g

[a] Unprocessed materials include minimally processed crude cannabis preparations such as inflorescences, accumulated resin glands (kief), and compressed resin gland (hashish). [b] Processed materials include various solid or liquid infused edible preparations, oils, topical preparations, and water-processed resin glands (bubble hash). Significant microbial contamination can occur during post-harvesting handling.