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COMMISSION

Cannabis Testing in Maryland Protecting Patient Safety

Cannabis Labs Conference
June 5, 2020

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Deputy Director
Maryland Medical Cannabis Commission

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The Maryland Medical Cannabis Commission develops policies, procedures, and regulations to implement programs that ensure medical cannabis is available to qualifying patients in a safe and effective manner. The Commission oversees all licensing, registration, inspection, and testing measures pertaining to Maryland's medical cannabis program and provides relevant program information to patients, providers, caregivers, growers, dispensaries, processors and independent testing laboratories.

General Assembly establishes the MMCC to oversee academic medical centers growing and dispensing medical cannabis

2013

2014

The GA scraps the academic model and established grower and dispensary licenses;
Authorizes physicians to certify patients for specific conditions

Marijuana is out
Cannabis is in
MMCC may license growers, processors, dispensaries and ITLs
MMCC accepts applications

2015

2016

Dentist, podiatrist, nurse practitioners and certified nurse midwives added to certifying providers
Preapprovals announced for growers, processors and dispensaries

Dispensaries open and begin selling medical cannabis

2017

2018

HB2 passes, altering the makeup of the Commission and expanding the program

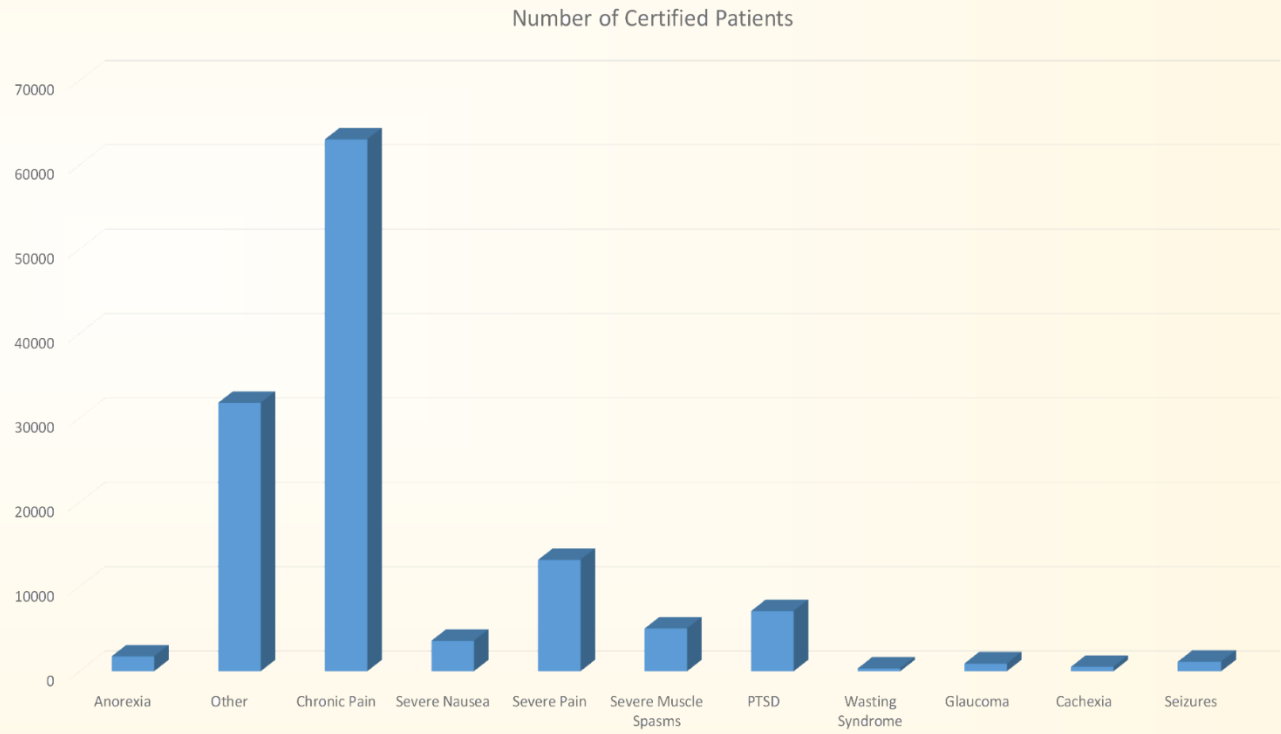
New applications for growers and processors accepted
HB17.SB426 Continues to alter the cannabis landscape

2019

Qualifying Conditions for Treatment with Cannabis

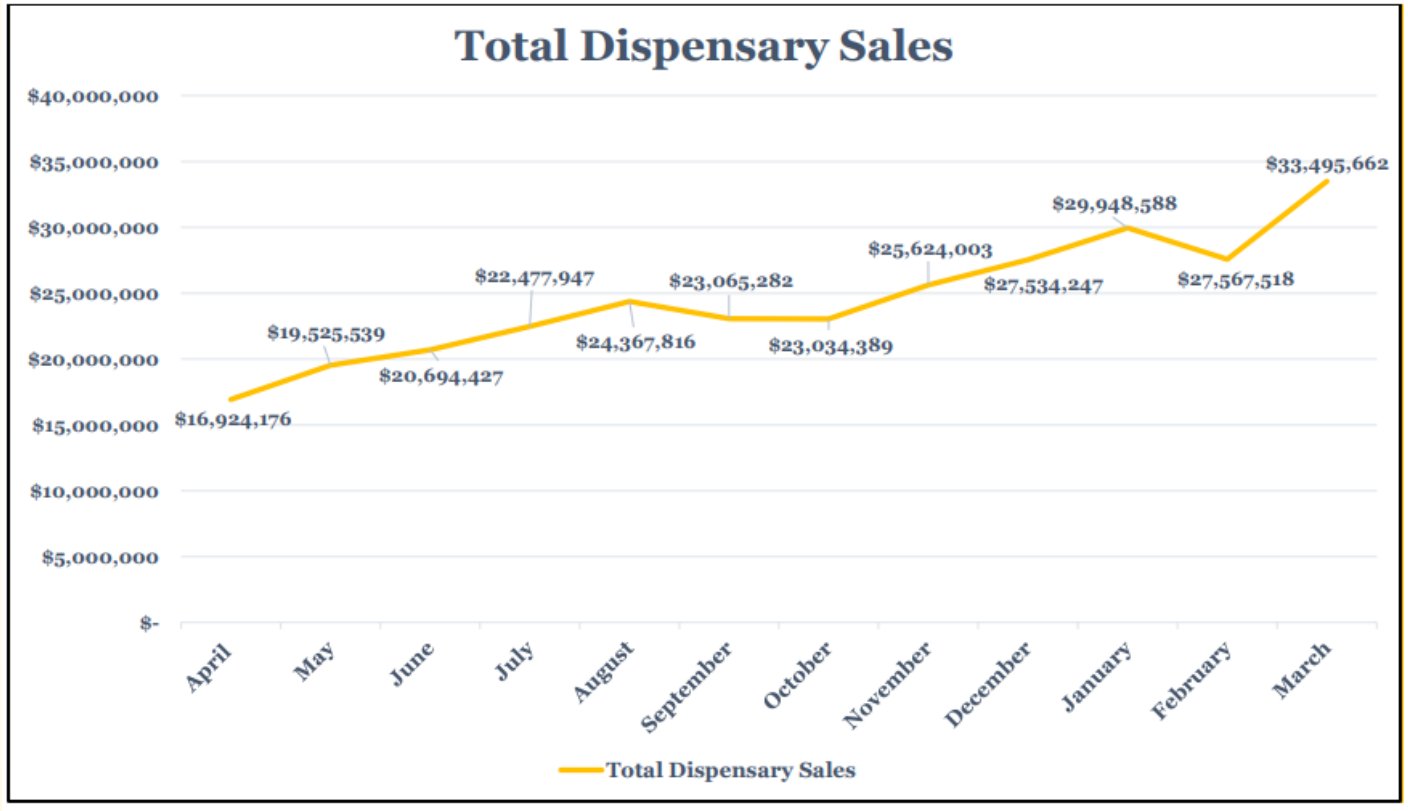
Certified Patient Count: 99,912 (5/20)

- Cachexia
- Anorexia
- Wasting Syndrome
- Severe or Chronic Pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms
- Glaucoma
- PTSD
- Severe condition(s) where other medical treatments are ineffective



Medical Cannabis Products Available to Maryland Patients

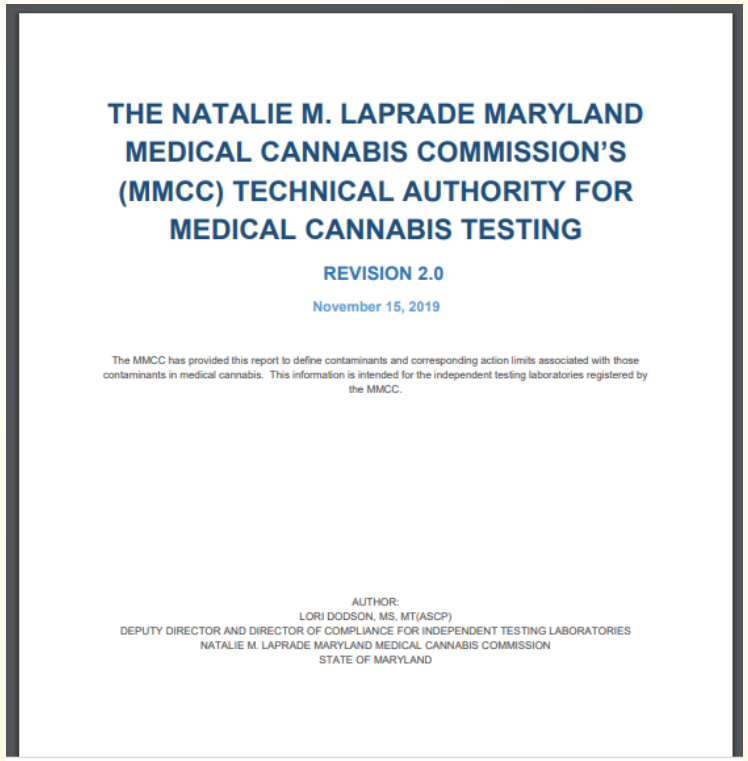
- Flower/ Pre-rolls
- Extracts, Oils, and Tinctures
- Vape Cartridges
- Capsules and Patches (transdermal, suppository)
- Lotions, Ointments (topical)
- Edible Cannabis Products – available summer 2020



How Do We Ensure Products Are Free From Contaminants?

Independent Testing Laboratory Program
Laboratory Registration Requirements-COMAR 10.62

- Must register with the Commission (6 registered currently)
- Must be accredited w/in one year by a third-party accreditation body that adheres to ISO17025
- Must be INDEPENDENT
- Must adhere to the Technical Authority for Medical Cannabis Testing
- Representative Sampling (10lbs. batch limit for flower products)
- Comprehensive End-product Compliance Testing



THE NATALIE M. LAPRADE MARYLAND MEDICAL CANNABIS COMMISSION'S (MMCC) TECHNICAL AUTHORITY FOR MEDICAL CANNABIS TESTING

REVISION 2.0

November 15, 2019

The MMCC has provided this report to define contaminants and corresponding action limits associated with those contaminants in medical cannabis. This information is intended for the independent testing laboratories registered by the MMCC.

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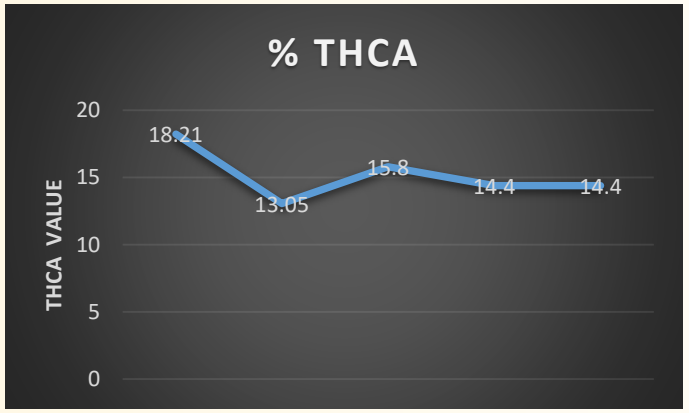
NATALIE M. LAPRADE MARYLAND MEDICAL CANNABIS COMMISSION
STATE OF MARYLAND

Product Testing and Laboratory Requirements

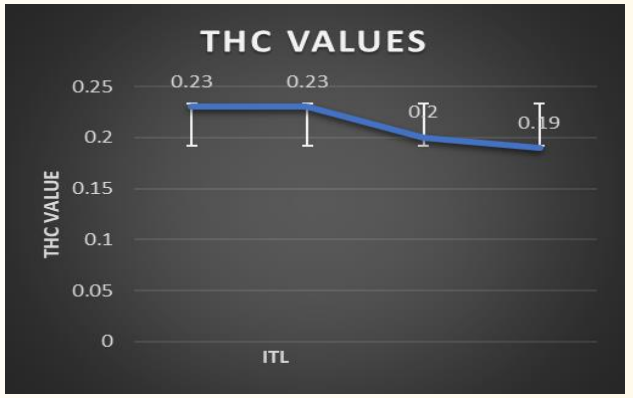
Product Compliance Panel

- Potency/Terpenes/Cannabinoids
- Pesticide Analysis
- Microbiological Impurities
- Water Activity
- Residual Solvent Testing
- Heavy Metal Screen
- Moisture Content
- Foreign Matter Inspection
- Mycotoxin screen

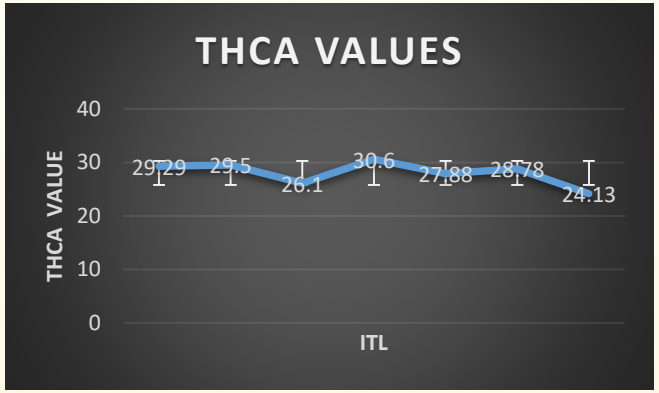
Independent Testing Laboratory Program
Round Robin Testing 2018-2019



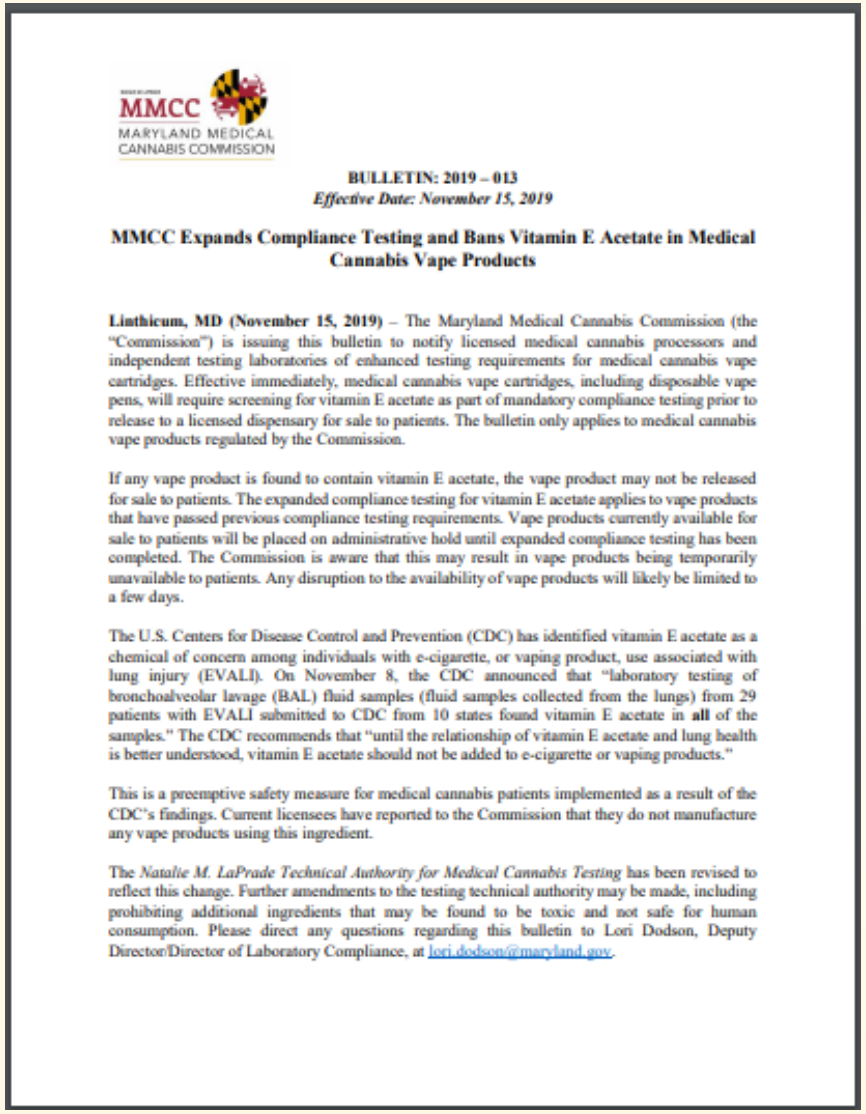
Round Robin 08-2018.
5 ITL's participated.



Round Robin 12-2018.
4 ITL's participated.



Round Robin 12-2019.
7 ITL's participated.



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MARYLAND MEDICAL CANNABIS COMMISSION

BULLETIN: 2019 – 013
Effective Date: November 15, 2019

MMCC Expands Compliance Testing and Bans Vitamin E Acetate in Medical Cannabis Vape Products

Linthicum, MD (November 15, 2019) – The Maryland Medical Cannabis Commission (the "Commission") is issuing this bulletin to notify licensed medical cannabis processors and independent testing laboratories of enhanced testing requirements for medical cannabis vape cartridges. Effective immediately, medical cannabis vape cartridges, including disposable vape pens, will require screening for vitamin E acetate as part of mandatory compliance testing prior to release to a licensed dispensary for sale to patients. The bulletin only applies to medical cannabis vape products regulated by the Commission.

If any vape product is found to contain vitamin E acetate, the vape product may not be released for sale to patients. The expanded compliance testing for vitamin E acetate applies to vape products that have passed previous compliance testing requirements. Vape products currently available for sale to patients will be placed on administrative hold until expanded compliance testing has been completed. The Commission is aware that this may result in vape products being temporarily unavailable to patients. Any disruption to the availability of vape products will likely be limited to a few days.

The U.S. Centers for Disease Control and Prevention (CDC) has identified vitamin E acetate as a chemical of concern among individuals with e-cigarette, or vaping product, use associated with lung injury (EVALI). On November 8, the CDC announced that "laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in **all** of the samples." The CDC recommends that "until the relationship of vitamin E acetate and lung health is better understood, vitamin E acetate should not be added to e-cigarette or vaping products."

This is a preemptive safety measure for medical cannabis patients implemented as a result of the CDC's findings. Current licensees have reported to the Commission that they do not manufacture any vape products using this ingredient.

The *Natalie M. LaPrade Technical Authority for Medical Cannabis Testing* has been revised to reflect this change. Further amendments to the testing technical authority may be made, including prohibiting additional ingredients that may be found to be toxic and not safe for human consumption. Please direct any questions regarding this bulletin to Lori Dodson, Deputy Director/Director of Laboratory Compliance, at lori.dodson@maryland.gov.

Vitamin E Acetate Testing-EVALI:

- 100% of vape products were put on administrative hold and unavailable for sale
- ITL's that were able to perform Vit E Acetate testing collected retention samples from all licensed processors producing vape carts
- A majority of vape samples were tested and resulted w/in 72hours (No detection of Vitamin E Acetate)

Current Focus

- **Rollout and Implementation of Edibles:**
  - Guidance document development
  - Stability studies
  - Method validation
- **Compliance:**
  - Multiple facility inspections per year
  - Metrc audits
- **On-going:**
  - Potency Pilot Study
  - Vape Cartridge Testing
  - Stability (Flower and processed products)
  - Stability (Edibles)
  - Technical Authority Updates
  - Stakeholder Workshops

Current Challenges in the Cannabis Testing Space

- **GARBAGE IN=GARBAGE OUT**
  - Lab Shopping
  - Sampling Bias
- **LACK of STANDARDIZATION**
  - Multiple methods
  - Lack of reference lab availability
- **CHEATING**
  - Manipulating results
  - Additional “drying”
- **COVID-19**
  - Social distancing requirements
  - Decrease in personnel

Any Questions?

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Note: The information presented here is for informational purposes only and not for the purpose of providing legal advice. You should contact your attorney to obtain advice with respect to any particular issue or problem.

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