



HOUSE COMMITTEE ON APPROPRIATIONS

FISCAL NOTE

HOUSE BILL NO. 2208

PRINTER'S NO. 3078

PRIME SPONSOR: Frankel

COST / (SAVINGS)

FUND	FY 2023/24	FY 2024/25
Medical Marijuana Program Fund	\$0	See Fiscal Impact
General Fund	\$0	See Fiscal Impact

SUMMARY:

Amends the Medical Marijuana Act to improve oversight of Medical Marijuana testing laboratories and impose requirements on each approved lab and powers and duties of the Department of Health.

ANALYSIS:

House Bill 2208 Printer's Number 3078 amends Act 16 of 2016, known as the Medical Marijuana Act, to improve oversight of medical marijuana testing laboratories. The Department of Health (DOH) may designate an independent laboratory as an approved lab to test medical marijuana products for two-year intervals. A lab that is approved by DOH to participate in the program prior to the effective date of this legislation is considered an approved lab until its current approval expires and is subject to the requirements of this act. The DOH shall determine the scope of the accreditation that the approved lab must receive and maintain.

An independent lab may apply for approval to test medical marijuana products and shall be subject to the following fees which will be deposited into the Medical Marijuana Program Fund:

- Initial application fee: \$250 per location
- Annual registration fee: \$125 for each approved laboratory location

An approved lab must maintain written standard operating procedures for all sampling and testing procedures and enter the results of all of the following into the tracking system:

- Compliance testing,
- Stability testing,
- Research and development testing, and
- Quality assurance testing.

The independent lab must submit these as part of the laboratory testing application. The approved lab must notify the department in writing of any modifications to its standard operating procedures at least 30 days prior to the modification.

The legislation requires a grower/processor to contract with an approved lab for:

- Compliance testing: DOH shall establish uniform medical marijuana testing standards and require approved labs to report testing results in a manner determined by DOH, including testing at harvest and at final processing and retesting of failed test results.
- Stability testing: The grower/processor must retain a sample from each medical marijuana product derived from a harvest batch for stability testing to ensure the product's potency and purity. The stability testing is to be done at six-month intervals for the duration of the expiration date period

listed on the product and once within six months of the expiration date.

Additional testing and inspections:

- Research and development: An approved lab may collect samples from grower/processor for research and development.
- Audit testing: The DOH, at its sole discretion, may conduct audit testing of medical marijuana samples collected from grower/processor facility and dispensary facility.
- Inspections: The DOH shall conduct announced or unannounced inspections to determine an approved lab's compliance with its standard operating procedures and this act.
- Quality assurance testing: The DOH shall coordinate announced or unannounced testing for quality assurance and compliance by approved labs at least once a year. Quality assurance testing shall be conducted using industry best practices and standards and shall be uniform among all approved labs. If the results of the test are unsatisfactory, DOH shall initiate an investigation which may include additional testing, review of lab's standard operating procedures, inspection of the lab's facility and equipment, interview with lab personnel, or the submission of a corrective action plan.
 - o Any fees for conducting tests as part of the quality assurance testing shall be the responsibility of each approved lab.
 - o Fees associated with the cost of the medical marijuana samples submitted as part of the testing shall be waived.

The DOH may establish and maintain a State testing lab, which shall be responsible for:

- o Developing and maintaining medical marijuana lab reference library that contains testing methodologies for potency, homogeneity, detection and quantity of contaminants, and solvents.
- o Establishing standard operating procedures for sample collection, preparation, and analysis of medical marijuana for approved labs.
- o Conducting quality assurance testing of approved labs.
- o Resolve problems with approved labs.
- o Conducting audit testing on medical marijuana samples analyzed by approved testing labs.

This legislation allows DOH to hire sufficient staff to ensure compliance with these requirements by approved labs. Additionally, DOH can promulgate regulations related to requirements for approved labs.

The legislation adds an additional member to the Medical Marijuana Act Advisory Board. This member shall be appointed by the Governor and shall have experience and expertise in laboratory science. The newly appointed member shall not be affiliated with, contracted with, an owner of, operator of, or financed by an approved laboratory or medical marijuana organization.

This Act shall take effect in 90 days.

FISCAL IMPACT:

Assuming this legislation is enacted in June, it would take effect in September. Therefore, there is no fiscal impact for 2023/24.

The DOH estimates an increase to administrative costs totaling \$1.2 million as a result of this legislation. DOH estimates \$217,000 in increased personnel costs for two full-time staff and \$1 million in increased operational costs.

The increased administrative costs would be offset by the revenue received from the initial application fees. In 2024/25, the revenue received will depend upon the number of independent laboratories that submit applications each having a \$250 initial application fee. The number of independent labs that will submit an application is currently unable to be determined. Therefore, revenue received by DOH from the initial application fees is currently indeterminate. Therefore, the net fiscal impact to the commonwealth cannot be determined at this time.

Revenue received as a result of the initial application fees is required by this legislation to be deposited into the Medical Marijuana Program Fund. The Medical Marijuana Act appropriates funding for the Medical Marijuana Program, operated by DOH, from this Fund. To the extent the net fiscal impact to the commonwealth exceeds the funding appropriated there would potentially be a need for state General Funds.

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House Appropriations Committee (D)

DATE: May 21, 2024

Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.