

Department of Legislative Services
Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

House Bill 1158 (Delegate Morhaim, *et al.*)

Health and Government Operations and
Judiciary

Medical Marijuana Oversight Commission

This bill makes marijuana a Schedule II controlled dangerous substance and authorizes the medical use of marijuana under specified circumstances. The bill also establishes an independent Medical Marijuana Oversight Commission (MMOC) to register and regulate academic medical centers; certify physicians, growers, dispensing centers, and dispensing pharmacies; and register qualifying patients and their primary caregivers. The commission must adopt regulations to implement the bill by September 1, 2012.

The bill takes effect June 1, 2012.

Fiscal Summary

State Effect: It is assumed that neither revenues nor expenditures are affected in FY 2012, during which time MMOC membership is appointed. Despite the bill's requirement for regulations to be adopted by September 1, 2012, Legislative Services advises that, because the bill requires MMOC to take a number of actions before the program can be fully implemented, the earliest registrants could begin participating in the program is FY 2015. Thus, this estimate assumes that no general fund revenues are generated in FY 2013 or 2014, but that general fund revenues increase significantly beginning in FY 2015 due to fees collected from patients, caregivers, growers, dispensers, and physicians. Although MMOC is required to set fees at a level sufficient to offset the costs of administering the program, fees generated under the bill are unlikely to offset the cost of program administration in the initial years of implementation (due in part to significant one-time start-up costs). In accordance with program growth and corresponding staffing needs, general fund expenditures increase by \$765,800 in FY 2013; and by \$5.1 million in FY 2017.

(in dollars)	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
GF Revenue	-	-	-	-	-
GF Expenditure	\$765,800	\$3,246,000	\$3,065,300	\$3,884,500	\$5,098,900
Net Effect	(\$765,800)	(\$3,246,000)	(-)	(-)	(-)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: Any impact on local government finances is likely minimal and may be offset by fewer violations of current law.

Small Business Effect: Potential meaningful for small growers, dispensing centers, and dispensing pharmacies that participate in the program.

Analysis

Bill Summary:

Medical Marijuana Oversight Commission

MMOC consists of two members from each house of the General Assembly, one member of the public, the Secretary of Health and Mental Hygiene (or the Secretary's designee), two licensed physicians, one licensed nurse, one licensed pharmacist, one scientist who has conducted grant-funded research, two individuals with experience in law enforcement, and an attorney with specified expertise. A member of the commission may not receive compensation as a member of the commission but is entitled to reimbursement for expenses. In addition, the commission is authorized to employ staff (including contractual staff) in accordance with the State budget. The commission is required to consult with experts in performing its duties and must meet at least six times annually.

The commission must report specified information (on an annual or biennial basis, as specified by the bill) to the Governor and the General Assembly beginning October 1, 2013.

Commission Powers, Responsibilities, and Limits on Powers

MMOC is authorized to:

- create subcommittees and appoint advisory committees;
- apply for and accept any funds, property, or services from any person or government agency;

- make agreements with a grantor or payer of funds, property, or services;
- publish and disseminate any information that relates to the medical use of marijuana or related research;
- contract with a qualified, independent third party for any service necessary to carry out the commission's powers and duties;
- inspect any dispensing center, registered grower, or registered pharmacy; and
- suspend or revoke the registrations of any academic medical center, dispensing center, dispensing pharmacy, physician, or registered grower that violates the bill (or regulations issued under the bill).

In addition, the commission is required to (1) keep minutes of each meeting and adopt regulations that relate to the meetings, minutes, and transactions of the commission; and (2) annually prepare a budget proposal and any summary, compilation, or other supplementary report that advances the purposes of the bill.

Regulations adopted by the commission may not require registered academic medical centers or physicians to (1) designate dispensing centers or dispensing pharmacies for patients; (2) possess, cultivate, or distribute marijuana; or (3) have any control over the possession, cultivation, or distribution of marijuana.

Registration of Academic Medical Centers and Certifying Physicians

A "registered academic medical center" is a commission-approved program that operates a medical residency program for physicians and conducts research that is overseen by the U.S. Department of Health and Human Services and involves human subjects. MMOC must approve a center's application for registration if the center meets specified requirements and submits a satisfactory proposal, which must include:

- a list of medical providers who intend to participate in the program and the qualifications of those providers;
- the criteria for a patient's inclusion in or exclusion from the program;
- the center's plan for screening a patient for dependence;
- the center's plan for the ongoing assessment and follow-up care for a patient and for collecting and analyzing data;
- a list of any clinical trials or additional research related to medical marijuana that the center intends to pursue; and
- a letter of approval from an institutional review board for any proposed research activity.

MMOC must approve as a certifying physician an individual who completes a specified training program (as established by the commission in consultation with specified

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experts), meets the bill's other requirements, and submits satisfactory application materials, which must include:

- the criteria for including a patient under the care of the physician for purposes of the bill;
- the criteria the physician will use to exclude patients from the physician's care for purposes of the bill;
- the physician's plan for screening a patient for dependence; and
- the physician's plan for the ongoing assessment and follow-up care of a patient and for collecting and analyzing data.

MMOC is encouraged to approve satisfactory applications for registration – of centers and, as specified by the bill, of physicians – that include specified chronic or debilitating diseases or medical conditions (or the treatment of those diseases or conditions, if they produce specified symptoms). In addition, the commission may approve applications for registration that include any other condition that is severe and resistant to conventional medicine if (1) the failure of approved medications to provide relief has been documented; and (2) the symptoms can reasonably be expected to be relieved by the medical use of marijuana.

A registration for a center or a physician expires after one year unless it is renewed; the commission must grant or deny an application for the renewal of a registration based on performance. The commission is required to set a reasonable fee for processing applications for registration.

A registrant is required to report specified information to the commission on an annual basis and within 60 days of the expiration of registration. In addition, a center must prepare a lay summary of its annual report for the public.

Registered Growers

MMOC must require an applicant for registration as a grower to provide specified information related to security measures, diversion policies, location, accounting, and training. The commission is required to approve the fewest number of registered growers as is reasonable.

A registered grower must (1) meet security and safety standards that may be verified by the commission; (2) submit to pharmacological testing; and (3) unless the grower is also a registered academic medical center, conduct criminal history records checks on employees. A registered grower is prohibited from (1) holding any other registration under the bill unless the grower is also a registered academic medical center; (2) being a

certifying physician; or (3) hiring employees who have been convicted of specified crimes, as specified by the bill.

After consulting with the Maryland Department of Agriculture and the Department of State Police (DSP), the commission must adopt regulations for growers to follow regarding specified security features, labeling requirements, location, and tracking. In addition, the commission may establish a fee for registration and renewal applications for growers. The commission must grant or deny the renewal of registration based on performance.

Distribution of Marijuana

The following entities may apply to register with the commission to distribute marijuana for medical purposes: (1) a pharmacy that is registered with the State Board of Pharmacy; (2) a dispensing center; or (3) an academic medical center. MMOC must require an applicant for registration as a dispensing center or dispensing pharmacy to provide an application fee as well as specified information related to security measures, diversion policies, location, accounting, and training. The commission is required to approve or deny the application of a dispensing center or dispensing pharmacy within 60 days after receipt of a completed application and may set reasonable limits on the number of registered dispensing centers in the State or in a geographic area.

An academic medical center is not required to register as a dispensing center and may instead apply to dispense marijuana by submitting specified information to the commission regarding training, informed consent, and diversion policies. Otherwise, an entity (not including a registered pharmacy) seeking to operate as a registered dispensing center must perform a criminal history record check and periodic drug testing for each employee as specified by the bill and is prohibited from hiring individuals who have been convicted of specified crimes. In addition, a registered dispensing center is prohibited from (1) holding any other registration under the bill unless the dispensing center is also a registered academic medical center; or (2) being a certifying physician.

Each approved registered dispensing pharmacy and dispensing center must maintain confidential internal records of each marijuana dispensing transaction. A qualifying patient may be registered at only one pharmacy or center at any time. The commission must establish procedures to allow a patient to (for a \$15 fee) change the pharmacy or center designated by the patient. However, the commission may limit the number of times a patient may change such a designation to once every 30 days.

After consulting with the State Board of Pharmacy, DSP, and stakeholders, MMOC must adopt regulations regarding procedures for dispensing, storing, and transporting marijuana under the bill. In addition, the commission is required to establish a reasonable

fee for registration and renewal applications for dispensing centers and dispensing pharmacies. The commission must grant or deny the renewal of registration based on performance.

Registry Identification Cards

MMOC, in consultation with law enforcement, must develop regulations for the issuance of registry identification cards to qualifying patients as specified by the bill. The commission is authorized to establish an application and renewal fee (which may be based on a sliding scale) for the issuance of a card. The commission is required to (1) approve or deny an application for a card within 30 days of receipt; (2) issue a card within five days after approval; and (3) ensure that an individual is not designated as a primary caregiver for more than five qualifying patients. The commission must (and may only) deny an inadequate application as specified by the bill.

A registry identification card must contain specified information as well as the cardholder's photograph. The commission must be made aware of specified changes to a patient or primary caregiver's name or status within 10 days of the change. If the commission revokes a registry identification card, the commission must send notice requiring immediate return of the card and transfer of any marijuana in the registrant's possession to a registered dispensing center or dispensing pharmacy.

The commission must maintain a list (that is confidential except to authorized employees of the commission or of law enforcement, as specified by the bill) of individuals to whom cards have been issued.

An applicant seeking to serve as a primary caregiver must submit to a criminal history records check and is ineligible to serve as a primary caregiver if the applicant has been convicted of specified crimes. The commission must notify the applicant in writing of the applicant's disqualification from serving as a primary caregiver.

Protections, Penalties, and Other Legal Considerations

As specified by the bill, the following persons may not be subject to arrest, prosecution, or any civil or administrative penalty – or be denied any right or privilege – for the medical use of marijuana: (1) a qualifying patient or primary caregiver who holds a valid registry identification card and is in possession of an allowable amount of marijuana acquired in accordance with the bill; (2) a registered grower or grower's employee; (3) under specified circumstances, an individual transporting the qualifying patient's marijuana to a registered dispensing center or dispensing pharmacy; (4) a dispensing pharmacy, a dispensing center, or an employee of a dispensing pharmacy or a dispensing center; (5) a certifying physician; (6) a registered academic medical center or staff of the

center; or (7) a laboratory or laboratory employee conducting testing of medical marijuana.

The possession of (or application for) a registry identification card does not constitute probable cause to search an individual. In addition, an individual may not be subject to arrest or prosecution for being in the presence or vicinity of the medical use of marijuana as authorized by the bill.

A registrant (or an employee of a registrant) that distributes marijuana to an individual who is not a qualifying patient or primary caregiver, as specified by the bill, is guilty of a felony and on conviction is subject to imprisonment for up to seven years and/or a fine of up to \$7,000. In addition, a person who knowingly gives false information or makes a material misstatement in an application under the bill is guilty of a misdemeanor and on conviction is subject to imprisonment for up to one year and/or a fine of up to \$1,000.

The bill may not be construed to authorize any individual to engage in (and does not prevent the imposition of any civil, criminal, or other penalties for) any of the following: (1) undertaking any task under the influence of marijuana when doing so would constitute negligence or professional malpractice; (2) operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of marijuana; or (3) smoking marijuana in any public place, in a motor vehicle, or on a private property that is subject to specified policies prohibiting the smoking of marijuana on the property. Furthermore, the bill may not be construed to provide immunity, to a person who violates the bill, from criminal prosecution for a violation of any law prohibiting or regulating the use, possession, dispensing, distribution, or promotion of controlled dangerous substances, dangerous drugs, detrimental drugs, or harmful drugs (or any conspiracy or attempt to commit any of those offenses).

Fees and Miscellaneous Provisions

Any fees collected under the bill must be used to offset the costs of administering the bill and must be set at an amount high enough to ensure that the total amount of fees assessed, plus contributions and grants collected, is sufficient to cover these costs. MMOC is authorized to distribute any funds received that exceed the amount of funding necessary to fulfill its duties under the bill to in-state academic institutions or registered academic medical centers for specified research. Any funds remaining after such disbursements are made may be provided to the general fund.

The bill must not be construed to require an insurer to reimburse an individual for costs associated with the medical use of marijuana.

The sale of marijuana is subject to specified restrictions with regard to advertising.

Current Law: In a prosecution for the use or possession of marijuana or for the use or possession of drug paraphernalia related to marijuana, it is an affirmative defense that the defendant used or possessed the marijuana or marijuana paraphernalia because (1) the defendant has a debilitating medical condition that has been diagnosed by a physician with whom the defendant has a bona fide physician-patient relationship; (2) the debilitating medical condition is severe and resistant to conventional medicine; and (3) marijuana is likely to provide the defendant with therapeutic or palliative relief from the debilitating medical condition. The affirmative defense may not be used if the defendant was using marijuana in a public place or was in possession of more than one ounce of marijuana.

A “bona fide physician-patient relationship” is a relationship in which the physician has ongoing responsibility for the assessment, care, and treatment of a patient’s medical condition. A “debilitating medical condition” is a chronic or debilitating disease or medical condition or the treatment of a chronic or debilitating disease or medical condition that produces one or more of the following, as documented by a physician with whom the patient has a bona fide physician-patient relationship: (1) cachexia or wasting syndrome; (2) severe or chronic pain; (3) severe nausea; (4) seizures; (5) severe and persistent muscle spasms; or (6) any other condition that is severe and resistant to conventional medicine.

Medical necessity may be used not only as an affirmative defense, but also as a mitigating factor, in a prosecution for the possession or use of marijuana or related paraphernalia. Thus, a defendant who cannot meet the affirmative defense standard for a not guilty verdict may still have medical necessity considered by the court with regard to penalties on conviction. If a court finds that a defendant used or possessed marijuana or related paraphernalia because of medical necessity, the maximum penalty that the court can impose is a fine of up to \$100.

If a court does not find that there was medical necessity, a violator of prohibitions against simple possession or use of marijuana is guilty of a misdemeanor and subject to fines of up to \$1,000 and/or imprisonment for up to one year. A violator of prohibitions against use or possession with intent to use drug paraphernalia is guilty of a misdemeanor and subject to fines of up to \$500; for each subsequent violation, a violator is subject to fines of up to \$2,000 and/or imprisonment for up to two years.

The Board of Physicians may not reprimand, place on probation, or suspend or revoke a license of a licensee for providing a patient with a written statement, medical records, or testimony that, in the licensee’s professional opinion, the patient is likely to receive therapeutic or palliative relief from marijuana.

Background: In 1996, California became the first state to allow the medical use of marijuana. Since then, 15 other states (as well as the District of Columbia) have enacted similar laws. States with medical marijuana laws generally have some form of patient registry and provide protection from arrest for possession of up to a certain amount of marijuana for medical use. Maryland is an exception; although State law allows for medical necessity as an affirmative defense, it does not provide a means for patients to actually obtain marijuana.

Marijuana is classified as a Schedule I controlled substance at the federal level, making distribution a federal offense. In October 2009, the Obama Administration sent a memorandum advising federal prosecutors that it is not an efficient use of resources to prosecute individuals who use marijuana for medical purposes in accordance with state laws. In June 2011, however, the Obama Administration sent another memorandum advising that, while this view of the efficient use of resources had not changed, persons who are in the business of cultivating, selling, or distributing marijuana (and those who knowingly facilitate such activities) are in violation of federal law and are subject to federal enforcement action.

Chapter 215 of 2011 required the Secretary of Health and Mental Hygiene to convene a workgroup to develop a model program for facilitating patient access to marijuana for medical purposes. The Secretary was required to report, by December 1, 2011, on the workgroup's findings, including draft legislation that would establish a program to provide access to marijuana in the State for medical purposes. Due to a lack of consensus, the workgroup ultimately submitted two separate plans for consideration by the General Assembly: one that is based on an investigational use model and another that more closely resembles the traditional medical marijuana program model that is used in other states. The present bill is derived from the latter proposal.

State Fiscal Effect:

Assumptions

Based largely upon information gathered from other states (and in particular, from Colorado, which has a population similar to that of Maryland) and accounting for differences, where they exist, between other states' programs and this legislation, Legislative Services relied upon the following assumptions in preparing this estimate:

- Neither revenues nor expenditures are affected in fiscal 2012, during which time MMOC membership is appointed.
- The first qualifying patients and primary caregivers will be registered no earlier than fiscal 2015 given that MMOC, once established, must take certain actions

(including the development of regulations and the review of applications for participation) before the program can be implemented. In addition, MMOC must have in place, before any marijuana is dispensed, a tracking system and an infrastructure for issuing registry identification cards. It is therefore assumed that, consistent with the experience of other states (including Colorado), preparation for implementation is likely to take at least two years.

- The number of registered qualifying patients and primary caregivers is likely to grow significantly in the early years of implementation before reaching a point of saturation after several years. The number of registrants in Colorado, for example, increased from approximately 500 to approximately 110,000 (where the number of registrants has apparently leveled off) in a span of several years. Accordingly, it is assumed that there will be 5,000 registered patients in the first year of implementation; 15,000 in the second year of implementation; and 30,000 in the third year of implementation. It is further assumed, based on other states' experience, that 20% of qualifying patients will require the registration of a primary caregiver.
- Qualifying patients and primary caregivers are likely to pay a registration fee of \$100 (which is similar to the registration fee charged by other states). Legislative Services notes that MMOC may set registration fees on a sliding scale; however, the number of registrants who may pay discounted fees on such a scale cannot reliably be determined. Actual registration fees may vary in accordance with registrants' income levels.
- Because both the University of Maryland Medical System and the Johns Hopkins University have advised that they do not intend to participate in the program as academic medical centers, it is assumed that most or all dispensers will be dispensing centers or dispensing pharmacies rather than academic medical centers.
- MMOC will attempt to set its fees for dispensers, growers, and physicians at levels sufficient to offset the cost of the program.
- The bill authorizes the commission to accept funds from any person or government agency. However, Legislative Services does not anticipate significant additional funds from any source. All revenues and expenditures are assumed to be general funds.
- Any additional payments to the Criminal Justice Information System (CJIS) for criminal history records checks are cost-recovery only. CJIS can handle the bill's requirements with existing resources. Revenues and expenditures do not account for any potential violations of the bill.

Legislative Services notes that fees generated under the bill are unlikely to offset the cost of program administration in the initial years of implementation. This situation is likely unavoidable due to one-time start-up costs, some of which are incurred before any revenues are generated. However, Legislative Services advises that revenues are likely to exceed administration costs within a few years of program implementation. (For point of reference, program revenues in Colorado currently exceed program expenditures by 16.5%, which is the statutory limit.) Legislative Services further advises that the actual rate of growth for the program and the number of registrants could vary significantly from the estimates in this fiscal and policy note; program costs will vary accordingly.

Finally, Legislative Services notes that this estimate differs from the estimate provided by the Department of Health and Mental Hygiene (DHMH), which assumes the need to hire 184 staff at a cost of nearly \$7.8 million in fiscal 2013. The DHMH estimate reflects full implementation of the program in the first year (with more staff than Legislative Services envisions the program ever needing) and does not account for any revenues. The estimates below instead reflect the phasing in of staff and shifting of staff duties in accordance with a more likely timeline for program development, implementation, and growth. Expenditures reflect staff increases in accordance with the program's growth, annual salary increases, employee turnover, and annual increases in ongoing operating expenses.

Fiscal 2013 – Establishing the Commission and Developing Regulations

Revenues are not generated in fiscal 2013, during which time MMOC is established and develops regulations to implement the bill.

General fund expenditures increase by \$765,849 in fiscal 2013. The estimate includes \$100,000 for the contractual services of a consultant to assist with the development of regulations related to security. It also includes \$665,849 for staffing and operating costs necessary to provide administrative support to the commission and assist with the development of regulations. Staff include one full-time program director, one full-time deputy director, one full-time physician specialist, one full-time staff attorney, three full-time program administrators, one full-time agronomist, one full-time pharmacist, and two full-time administrative aides.

Fiscal 2014 – Reviewing Applications, Installing Tracking System, and Preparing for Implementation

Revenues are not generated in fiscal 2014, during which time MMOC reviews applications, installs a tracking system, and establishes an infrastructure for issuing registry identification cards.

General fund expenditures increase by \$3.2 million in fiscal 2014. The estimate reflects \$500,000 for software and contractual services associated with the development of a tracking system; \$500,000 for equipment and contractual services associated with developing the infrastructure for issuing registry identification cards; and \$2.2 million for ongoing and additional staff, including 2 full-time systems administrators, 2 full-time information technology specialists, 10 full-time inspectors (who can later shift from reviewing applications to conducting inspections), 4 full-time administrative specialists, and 4 full-time administrative aides.

Legislative Services advises that costs associated with the issuance of registration cards could vary widely depending on how cards are issued in practice. (For example, because the bill specifies that MMOC must issue the identification cards, it is unlikely that an existing system which already has unique identifiers such as soundex numbers could be utilized. It is also unclear whether patients would be registered on a centralized or regional basis.)

Fiscal 2015 – First Year of Implementation

General fund revenues increase by at least \$600,000 in fiscal 2015, which reflects the registration by MMOC of 5,000 qualifying patients and 1,000 primary caregivers. General fund revenues also increase significantly to reflect fees collected by MMOC from dispensers, growers, and physicians; although the exact amount of this increase cannot be reliably determined at this time, as discussed above, it is unlikely to completely offset the costs of administering the program.

General fund expenditures increase by \$3.1 million in fiscal 2015 for ongoing expenses and to hire additional staff to conduct inspections and register physicians, qualifying patients, and primary caregivers. The estimate reflects the hiring of two full-time inspectors, six full-time administrative specialists, and three full-time administrative aides.

Fiscal 2016 – Second Year of Implementation

General fund revenues increase by at least \$1.8 million in fiscal 2016, which reflects the registration by MMOC of 15,000 qualifying patients and 3,000 primary caregivers. General fund revenues also increase significantly to reflect fees collected by MMOC from dispensers, growers, and physicians; although the exact amount of this increase cannot be reliably determined at this time, as discussed above, it may not completely offset the costs of administering the program.

General fund expenditures increase by \$3.9 million in fiscal 2016 for ongoing expenses and to hire additional staff in accordance with the growth of the program. The estimate

reflects the hiring of eight full-time administrative specialists, and three full-time administrative aides.

Fiscal 2017 – Third Year of Implementation

General fund revenues increase by at least \$3.6 million in fiscal 2015, which reflects the registration by MMOC of 30,000 qualifying patients and 6,000 primary caregivers. General fund revenues also increase significantly to reflect fees collected by MMOC from dispensers, growers, and physicians; although the exact amount of this increase cannot be reliably determined at this time, as discussed above, it may not completely offset the costs of administering the program.

General fund expenditures increase by \$5.1 million in fiscal 2017 for ongoing expenses and to hire additional staff in accordance with the growth of the program. The estimate reflects the hiring of 12 full-time administrative specialists and 4 full-time administrative aides.

Additional Information

Prior Introductions: None.

Cross File: Although designated as a cross file, SB 995 (Senator Brinkley, *et al.* - Judicial Proceedings) is not identical.

Information Source(s): Cities of Frederick and Havre de Grace; Charles, Frederick, and Montgomery counties; Maryland Department of Agriculture; Commission on Criminal Sentencing Policy; Governor's Office of Crime Control and Prevention; Department of Health and Mental Hygiene; Judiciary (Administrative Office of the Courts); Department of State Police; Office of the Public Defender; Department of Public Safety and Correctional Services; State's Attorneys' Association; University of Maryland Medical System; Department of Legislative Services

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