Department of Legislative Services

Maryland General Assembly 2012 Session

FISCAL AND POLICY NOTE

House Bill 1024 (Delegate Morhaim, *et al.*) Health and Government Operations and Judiciary

Medical Marijuana Commission

This bill allows for the investigational use of marijuana for medical purposes. Specifically, the bill establishes the Medical Marijuana Commission to (1) develop requests for applications for academic medical centers to operate programs in the State; (2) approve or deny initial and renewal program applications; and (3) monitor and oversee programs approved for operation.

Fiscal Summary

State Effect: Legislative Services advises that, because the bill requires DHMH and the new commission to take a number of actions before the program can be fully implemented, the earliest patients could benefit through academic centers 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 beginning in FY 2015 due to fees collected from academic medical centers. Because academic medical center program participation is expected be low, as discussed below, fees generated under the bill are unlikely to offset the administrative costs for the commission (as the bill requires). In accordance with a likely timeline for program development and implementation (and accounting for significant start-up expenses), general fund expenditures increase by \$600,600 in FY 2013 and by \$903,500 in FY 2017.

(in dollars)	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
GF Revenue	\$0	\$0	-	-	-
GF Expenditure	\$600,600	\$1,274,400	\$825,600	\$863,600	\$903,500
Net Effect	(\$600,600)	(\$1,274,400)	(\$825,600)	(\$863,600)	(\$903,500)

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 any small growers that provide marijuana to approved programs.

Analysis

Bill Summary:

Medical Marijuana Commission

The commission consists of two members from each house of the General Assembly; two members of the public; three physicians from specified specialties; one nurse, one pharmacist, one scientist, two attorneys (all with specified expertise); and several representatives from specified law enforcement organizations. 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.

Application Process for Academic Medical Centers

The commission must issue a request for applications for academic medical centers to operate medical marijuana compassionate use programs. An "academic medical center" is a hospital 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. An application submitted by an academic medical center must:

- specify the medical conditions to be treated, the criteria by which patients will be included in or excluded from participation, how patients will be assessed for addiction before and during treatment, and the length of treatment and dosage permitted;
- describe the source and type of the marijuana to be used, how health care providers will be eligible to participate and what training they will receive, and the plan for defining and monitoring the success or failure of treatment;
- demonstrate approval of the program by the center's institutional review board;
- include a description of whether and how caregivers will interact with participating patients, a plan for monitoring aggregate data and outcomes and publishing results, and a description of the sources of funding; and

• describe any required training for providers and patients on diversion-related issues, steps the center will take to prevent and monitor diversion, how the program will dispose of any unused marijuana, and how the center and the program will meet any other established criteria.

The commission is required to establish an application review process, as specified by the bill, that includes reviewers with expertise in scientific research and analysis, medical training, and law enforcement. The commission may grant a one-year renewable license to a program and must set application and renewal fees that cover its expenses in reviewing and approving applications and providing program oversight.

The commission must report annually to the Governor and the General Assembly on programs approved to operate under the bill.

Program Limitations and Requirements

An academic medical center that is approved to operate a program under the bill must provide to DHMH, on a daily basis, updated data on patients and caregivers; the center must also make the data available in real time to law enforcement. If a center utilizes caregivers as part of a program, the center is required to limit the number of patients a caregiver is allowed to serve to no more than five and limit the number of caregivers that serve a particular patient to no more than two.

A center must report annually to the commission, as specified by the bill. In addition, a center is required to apply annually to the commission for renewal of approval and is subject to inspection by the commission (which is authorized to rescind approval of a program if the program is found not be in compliance with established conditions of approval).

Licensed Growers

DHMH is required to license medical marijuana growers to operate in the State to provide marijuana to (and only to) programs approved under the bill. The department must establish requirements for security (including a product-tracking system) and for the manufacturing process; a grower must meet these requirements to obtain a license. DHMH is authorized to inspect licensed growers to ensure compliance and may impose penalties upon, or rescind the license of, a grower that does not meet the department's standards for licensure.

An academic medical center may use marijuana obtained only from the federal government or from a medical marijuana grower licensed under the bill.

Protections, Penalties, and Other Legal Considerations

The following persons may not be subject to arrest, prosecution, or any civil administrative penalty – or be denied any right or privilege – for the medical use of marijuana in accordance with the bill: (1) a patient enrolled in an approved program who is in possession of an amount of marijuana that is authorized under the program; (2) a licensed grower (or the grower's employee) who is acting in accordance with the terms of the license; or (3) an academic medical center or employee of the center (or any other person associated with the operation of an approved program), for activities conducted in accordance with the program.

A person is prohibited from distributing, possessing, manufacturing, or using marijuana that has been diverted from an approved program or from a patient who is enrolled in an approved program. A violator is guilty of a felony and on conviction is subject to (in addition to any existing applicable penalties) imprisonment for up to five years and/or a fine of up to \$10,000.

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).

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

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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 former proposal.

State Fiscal Effect:

Assumptions

Both the University of Maryland Medical System (UMMS) and the Johns Hopkins University (JHU) have advised that they do not intend to participate in the program as academic medical centers. It is unclear how many, if any, other institutions are eligible (and willing) to participate as academic medical centers under the bill. For purposes of this estimate, however, it is assumed that there will be at least one participating academic medical center. Actual program costs could vary significantly from the estimate depending on the extent of participation. Revenues and expenditures do not account for any potential violations of the bill.

Because the bill authorizes, rather than requires, the commission to inspect academic medical centers and DHMH to inspect growers – and given that participation is expected to be low – Legislative Services assumes that additional inspectors are not needed to implement the bill. It is assumed that the commission can be housed within DHMH. To the extent that any inspections are conducted under the bill, Legislative Services assumes that DHMH and the commission can share resources and utilize existing inspectors. Because the bill neither authorizes DHMH to charge a licensing fee for growers nor requires cost-recovery for the grower-licensing process, Legislative Services assumes that no fees are generated from growers under the bill. Thus, general fund expenditures for DHMH, including database development and ongoing maintenance, are not recouped under the bill.

Finally, Legislative Services notes that this estimate differs from DHMH's estimate, which assumes that program participation will be extensive enough to require the department to hire 20 additional staff at a cost of nearly \$1.5 million in fiscal 2013. This estimate instead anticipates less-extensive participation and reflects the phasing in of staff and other costs in accordance with a likely timeline for program development and implementation. All revenues and expenditures are assumed to be general funds.

Future year expenditures reflect staff increases in accordance with the program's implementation, 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 the commission is established and develops regulations to implement the bill. DHMH must also initiate the licensing process for growers and the framework for the required database.

General fund expenditures increase by \$600,570 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 \$500,570 for staffing and operating costs necessary to provide administrative support to the commission and assist with the development of regulations (and, in future years, monitor and oversee approved programs). Staff include one full-time program director, 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 and Establishing Database

Revenues are not generated in fiscal 2014, during which time the commission reviews applications from academic medical centers and DHMH licenses growers.

General fund expenditures increase by \$1.3 million in fiscal 2014. The estimate reflects \$500,000 for software and contractual services associated with the development of a database – to receive data daily from academic medical centers and share it with law enforcement on a real-time basis – and \$774,364 million for ongoing and additional staff, including one full-time systems administrator and one full-time information technology specialist to assist with the development and maintenance of the database.

Fiscal 2015-2017 – Monitoring and Overseeing Approved Programs

General fund revenues increase beginning in fiscal 2015 to reflect fees collected by the commission from academic medical centers. Because participation in the program is

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expected to be low, however, Legislative Services advises that the commission is not likely to be able to comply with the bill's requirement to set its fees at a level sufficient to offset program costs (notwithstanding that some costs, including those associated with the required database, are the responsibility of DHMH rather than the commission) unless it sets its fees at a level that would likely be prohibitively high.

General fund expenditures continue to increase in future years for ongoing expenses. Legislative Services advises that, to the extent that the program participation increases in future years, additional staff may be needed to assist with oversight.

Additional Comments: Although JHU has indicated that it will not participate as an academic medical center, the university has advised that – for any institution that does participate – costs are likely to be significant. Specifically, JHU advises that participation is likely to result in start-up costs to each academic medical center of at least \$2.0 million and ongoing costs of between \$1.5 and \$5.0 million annually (not including potential legal costs or any required fee for participation).

The bill requires DHMH to establish an infrastructure (including a tracking system and a licensing process for growers) to approve and monitor programs operated by academic medical centers. However, JHU and UMMS, the two primary institutions that would be most likely considered as participating academic medical institutions under the bill, have stated that they will not participate. Furthermore, it is unclear how many, if any, other institutions would be eligible (and willing) to participate under the bill. Thus, Legislative Services notes the possibility that – although the bill requires a specified infrastructure to be established and expenditures to be made – ultimately, there may be no programs for that infrastructure to support.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Agriculture, Commission on Criminal Sentencing Policy, 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 **Fiscal Note History:** First Reader - March 8, 2012 ncs/mwc

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