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FISCAL AND POLICY NOTE
Revised

House Bill 490

(Delegate Morhaim, *et al.*)

Health and Government Operations

Judicial Proceedings

Natalie M. LaPrade Medical Cannabis Commission - Miscellaneous Revisions

This emergency bill renames the Natalie M. LaPrade Medical Marijuana Commission and Fund to be the Natalie M. LaPrade Medical Cannabis Commission and Fund; alters the purpose and membership of the commission; and generally replaces references to “medical marijuana” with “medical cannabis.” The bill repeals the commission’s authority to approve academic medical centers to operate programs and makes conforming changes to remove all references to academic medical centers throughout the commission’s statute. The bill adds definitions of “processor,” “processor agent,” and “independent testing laboratory,” and it establishes requirements for licensure or registration for each such entity. The bill establishes that a person is not prohibited from concurrently being licensed as a grower, a dispensary, or a processor. Finally, the bill makes additional changes to the current program – primarily related to participation by certifying physicians, licensure terms of growers and dispensaries, the commission’s inspection and sanctioning authority related to dispensaries, and immunity provisions.

Fiscal Summary

State Effect: No effect in FY 2015. However, special fund revenues increase – likely minimally but potentially significantly – beginning in FY 2016. Special fund expenditures increase due to expanded regulatory authority by at least \$225,300 in FY 2016 as anticipated in the FY 2016 budget and discussed below. Out-years reflect inflation and growth in licensees.

Local Effect: None.

Small Business Effect: Potential meaningful, as discussed below.

Analysis

Bill Summary:

Expanded Membership and Purpose of the Commission

The bill adds another public member to the commission, thereby increasing total membership to 16, and broadens the types of licensed physicians and law enforcement officials who may serve on the commission. The new purpose of the commission is to develop policies, procedures, guidelines, and regulations to implement programs to make medical cannabis available to qualifying patients in a safe and effective manner.

Qualifying Patients

The bill redefines “qualifying patient” to remove the requirement that a qualifying patient be a resident of the State. A “written certification” from a certifying physician may include a written statement that, in the physician’s professional opinion, a 30-day supply of medical cannabis is inadequate to meet the medical needs of a qualifying patient. Moreover, the requirement that the physician attest to having completed, as part of a written certification, a “full” assessment (of a patient’s medical history and current medical condition) is modified to be “an” assessment.

Certifying Physicians

The bill redefines “certifying physician” to encompass requirements that the individual not only be licensed by the State Board of Physicians, but also have an active, unrestricted license to practice medicine; be in good standing with the board; and have a State controlled dangerous substances (CDS) registration. The bill establishes that the commission must register (rather than approve) a certifying physician that meets the requirements of the statute. It also specifies that the commission may *not* require a certifying physician to meet requirements beyond those delineated in specified provisions of statute to be registered.

The required proposal that a physician must submit to qualify as a certifying physician is altered so that it must include an attestation that a standard patient evaluation will be completed (including a history, a physician examination, a review of symptoms, and other pertinent medical information). The bill repeals the existing requirement that the proposal include reasons for which the physician will exclude a patient and the physician’s plan for screening a patient for dependence before and after issuing a written certification. Likewise, the bill repeals the requirement that a certifying physician submit an annual report to the commission with information related to the physician’s medical cannabis practice. The bill clarifies that a certifying physician may discuss medical cannabis with a patient, not just one who is already a qualifying patient.

The commission is encouraged to approve physician applications for a chronic or debilitating disease or medical condition (or the treatment of one) that produces *chronic* pain in addition to severe pain. Moreover, in its approval of physician applications, the commission may not limit treatment of a particular medical condition to one class of physicians.

Additionally, the bill adds a processor to the restrictions and exemptions relating to a certifying physician (or his or her spouse) receiving gifts or having an ownership interest in a grower or a dispensary. Even so, a certifying physician may receive compensation from a processor if the certifying physician first obtains approval of the commission and discloses the amount received.

Growers

A “grower” is defined as an entity licensed by the commission that (1) cultivates, manufactures, processes, packages, or dispenses medical cannabis *or* processes medical cannabis products and (2) is authorized to provide cannabis to a qualifying patient, caregiver, processor, dispensary, or independent testing laboratory. The bill repeals the requirement that the commission encourage licensing growers located in agricultural zones.

The bill expands statutory language regarding the authority of licensed medical cannabis growers to authorize growers to provide medical cannabis to licensed processors and registered independent testing laboratories. Additionally, the bill changes the date by which the commission may issue the number of grower licenses necessary to meet the demand for medical cannabis from June 1, 2016, to June 1, 2018, while retaining the limit of 15 licensed growers for initial implementation. On *initial* licensure, a grower license is valid for four years, but a renewal license is still valid for two years.

The bill allows a licensed grower to dispense medical cannabis directly from a grower facility, if that grower is also licensed as a dispensary. The bill also specifies that an entity licensed to grow medical cannabis may grow and process medical cannabis on the same premises.

Dispensaries

The bill clarifies licensure requirements for dispensaries and establishes that a dispensary license is valid for four years on initial licensure and for two years on renewal. The commission must establish requirements for security and product handling procedures, including a product-tracking system, which a dispensary must meet to qualify for a license.

The commission may inspect a licensed dispensary to ensure compliance, and it may impose penalties against, or rescind a dispensary license from, a dispensary that does not meet licensure standards.

A licensed dispensary must submit a quarterly report that includes (1) the number of patients served; (2) the county of residence of each patient served; (3) the medical condition for which the medical cannabis was recommended; (4) the type and amount of medical cannabis dispensed; and (5) a summary of clinical outcomes, including adverse events and any cases of suspected diversion, if available. The quarterly report may not include any personal identifying information of a patient.

Processors and Processor Agents

A processor must be licensed by the commission, and its agents must be registered. A “processor” is newly defined as an entity that (1) transforms medical cannabis into another product or extract and (2) packages and labels medical cannabis. A “processor agent” is a processor’s owner, member, employee, volunteer, officer, or director.

To qualify for licensure, an applicant must submit an application fee and an application that includes (1) the processor’s legal name and physical address; (2) each principal officer and director’s name, address, and date of birth, none of whom may have served as a principal officer or director for a licensee that had its license revoked; and (3) proposed operating procedures that are consistent with regulations. The commission must establish an application review process for granting a processor license that includes the criteria for reviewing, evaluating, and ranking an application. The commission must also establish requirements for security and product handling procedures, including a product-tracking system, which a processor must meet to qualify for a license. A processor license is valid for four years upon initial licensure and for two years on renewal.

The commission may inspect a licensed processor to ensure compliance, and it may impose penalties against, or rescind a processor license from, a processor that does not meet licensure standards.

A processor agent must be at least 21 years old, be registered with the commission prior to working or volunteering for a processor, and obtain a State and national criminal history records check (CHRC). The commission may not register an individual previously convicted of a felony drug offense as a processor agent. A processor must apply to the commission for a registration card for each processor agent by submitting the agent’s name, address, and date of birth. A processor must also notify the commission and return a processor agent’s registration card within one business day after a processor agent ceases to be associated with the processor. On receipt of this notice, the commission must

immediately revoke the registration card of the processor agent and, if the registration card was not returned, notify the Department of State Police.

Independent Testing Laboratories

An “independent testing laboratory” is newly defined as a facility, an entity, or a site that offers or performs tests related to the inspection or testing of cannabis and products containing cannabis.

The commission is required to register *at least one* private independent testing laboratory to test cannabis and products containing cannabis to be sold in the State. To qualify for registration as an independent testing laboratory, a laboratory must (1) meet commission application requirements; (2) pay any required fee; and (3) meet commission-established accreditation, inspection, and testing standards and requirements.

The commission must adopt regulations that establish (1) qualifications for independent laboratory initial registration and renewal; (2) standards of care; (3) the initial and renewal terms for an independent laboratory registration and the renewal procedure; and (4) the bases and processes for denial, revocation, and suspension of a registration of an independent testing laboratory. The commission may inspect a registered independent testing laboratory to ensure statutory compliance.

Protections and Prohibitions

The bill establishes that a licensed processor or a registered processor agent may not be penalized or arrested under State law for acquiring, possessing, processing, transferring, transporting, selling, distributing, or dispensing cannabis and related products, supplies, or educational materials for use by a licensee or a qualifying patient or caregiver.

The bill extends existing immunity to a qualifying patient who possesses greater than a 30-day supply of medical cannabis if the qualifying patient has a written certification indicating that a 30-day supply is inadequate to meet his or her medical needs. Additionally, registered grower agents, licensed processors, registered processor agents, and medical facilities where a qualifying patient is receiving treatment are added to the list of entities with civil and criminal immunity under law. Specifically, such entities who act in accordance with the statute related to the medical cannabis program are not subject to arrest, prosecution, or any civil or administrative penalty (including a civil penalty or disciplinary action by a professional licensing board), and they may not be denied any right or privilege for the medical use of cannabis.

A medical facility is not required to report to the commission any disciplinary action it takes against a certifying physician, including revocation of privileges after that certifying physician has been approved by the commission.

The bill specifically exempts vaporizing cannabis from the general statement that the commission statute 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, smoking marijuana or cannabis on private property that is (1) rented from a landlord and is subject to a policy prohibiting smoking of marijuana or cannabis on the property or (2) is subject to a specified policy (adopted by the governing body of either a council of unit owners of a condominium or a homeowners association) prohibiting the smoking of marijuana or cannabis on the property of an attached dwelling.

Current Law: Chapter 403 of 2013 established, and Chapters 240 and 256 of 2014 expanded, the Natalie M. LaPrade Medical Marijuana Commission and Fund to implement and administer a medical marijuana program in Maryland. The program allows for approval, licensing, and registration of participating academic medical centers, growers, dispensaries, and grower and dispenser agents. The program establishes a framework to certify physicians and qualifying patients (and their caregivers) to provide qualifying patients with medical marijuana legally under State law. The commission proposed regulations in December 2014, but those regulations are on hold with the Joint Committee on Administrative, Executive, and Legislative Review (AELR Committee) and the program is not yet operational. Although medical marijuana may be ready for distribution by the end of fiscal 2016, it is more likely that medical marijuana will be available for patients the following year.

Membership and Purpose of the Commission

The commission is an independent commission that functions with the Department of Health and Mental Hygiene (DHMH). It has 15 members – the Secretary of Health and Mental Hygiene (or the Secretary’s designee) and 14 members who have specified experience or expertise and are appointed by the Governor. The purpose of the commission is to (1) develop requests for applications for academic medical centers to operate programs in accordance with statute; (2) approve or deny applications for programs; (3) approve or deny applications for renewal of programs; (4) monitor and oversee programs approved for operation; (5) approve certifying physicians; (6) publish and disseminate any information that relates to the medical use of marijuana and related research; and (7) research issues related to the medical use of marijuana.

Approval of Academic Medical Centers

The commission must annually 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 statute, that includes reviewers with expertise in scientific research and analysis, medical training, and law enforcement. The commission may grant a one-year renewable approval to a program and must set application and renewal fees that cover its expenses in reviewing and approving applications and providing program oversight. Regulations proposed in December 2014 (and currently on hold with the AELR Committee) establish an initial application fee of \$1,000 and licensing and annual renewal fees of \$1,000 for academic medical centers.

The commission may approve no more than five programs to operate at one time.

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

Academic Medical Center Program Limitations and Requirements

An academic medical center that is approved to operate a program must provide to the commission, on a daily basis, updated data on patients and caregivers; the commission

must then 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. In addition, a center that wishes to continue the program has to apply annually to the commission for renewal of approval. A center is also subject to inspection by the commission (which is authorized to rescind approval of a program if the program is found to not be in compliance with established conditions of approval).

Qualifying Patients and Their Caregivers

A “qualifying patient” is someone who either has been provided a written certification by a certifying physician in accordance with a bona fide physician-patient relationship or is enrolled in a research program with a registered academic medical center. Additionally, if younger than age 18, a qualifying patient must have a caregiver. A “caregiver” is a person who has agreed to assist with a qualifying patient’s medical use of marijuana and, for a qualifying patient younger than age 18, a parent or legal guardian. A caregiver may serve no more than five qualifying patients at a time, and a qualifying patient may have no more than two caregivers.

A qualifying patient may be a patient of the certifying physician or may be referred to the certifying physician, and the certifying physician may discuss medical marijuana with a qualifying patient. Generally, a qualifying patient or caregiver may only obtain medical marijuana from a medical marijuana grower or dispensary licensed by the commission; however, a qualifying patient younger than age 18 may only obtain marijuana through the patient’s caregiver.

The commission is required to develop identification cards for qualifying patients and their caregivers. DHMH has to adopt regulations establishing the requirements for identification cards that are provided by the commission. A certifying physician must provide each written certification to the commission, at which point, the commission must issue an identification card to each qualifying patient or caregiver named in the certification. The commission must also develop and maintain a website that provides information on (1) how an individual can obtain medical marijuana in the State; (2) how an individual can find a certifying physician; and (3) contact information for licensed medical marijuana growers and licensed dispensaries.

Although statute does not specifically authorize a fee for identification cards, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) established an application process for qualifying patients and their caregivers

and payment of a required fee, which is set in the proposed regulations at \$100. A lesser fee may be charged, however, based on need as determined by the commission.

Certifying Physicians

The commission must approve a certifying physician who meets all requirements and who submits a satisfactory application. Information that must be included in a certifying physician's proposal includes (1) reasons for including a patient under the care of the physician; (2) reasons for which the physician will exclude a patient; (3) the physician's plan for screening a patient for dependence before and after issuing a written certification; and (4) the physician's plan for ongoing assessment and follow-up care.

Statute encourages the commission to approve physician applications for chronic and debilitating diseases or medical conditions that result in a patient being admitted into hospice or receiving palliative care or diseases or conditions that produce (1) cachexia, anorexia, or wasting syndrome; (2) severe pain; (3) severe nausea; (4) seizures; or (5) severe or persistent muscle spasms. The commission is authorized to approve applications for other conditions as well, if the condition is severe, is one for which other medical treatments have been ineffective, and the symptoms can reasonably be expected to be relieved by the medical use of marijuana.

Although not specified in statute, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) specify that a certifying physician may only treat qualifying patients with post-traumatic stress disorder (PTSD) if the certifying physician is a board-certified psychiatrist.

A certifying physician must submit an annual report that includes the number of patients served, the county of residence of each patient, any medical condition for which medical marijuana was recommended, and a summary of the clinical outcomes. An annual report may not include identifying information about patients.

A certifying physician may apply to the commission for approval biennially, and the commission must grant or deny a renewal based on the physician's performance in complying with regulations adopted by the commission. Likewise, the commission, in its annual report to the Governor and General Assembly, must include information on physicians certified.

A certifying physician or the spouse of a certifying physician may not receive any gifts from or have an ownership interest in a medical marijuana grower or dispensary. A certifying physician may receive compensation from a medical marijuana grower or dispensary if the certifying physician (1) obtains the approval of the commission before

receiving compensation and (2) discloses the amount of compensation received to the commission.

Licensed Medical Marijuana Growers and Their Agents

The commission must license medical marijuana growers that meet all requirements established by the commission to operate in the State. The commission may issue licenses to no more than 15 medical marijuana growers; however, beginning June 1, 2016, the commission may issue the number of licenses necessary to meet the demand for medical marijuana by qualifying patients and caregivers issued identification cards in an affordable, accessible, secure, and efficient manner. An applicant may not be issued more than one license. Each initial and renewal license is valid for two years. A grower must pay an application fee in an amount determined by the commission and must meet all requirements set by the commission.

Regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) set the application fee for a grower license at \$6,000 (payable in two installments: \$2,000 at Stage 1 of the application process and \$4,000 at Stage 2) and the biennial license fee at \$250,000 (payable in \$125,000 installments annually). The regulations also would allow for a combination grower-dispensary license to be held, with fees set at a higher level to reflect the amount of fees for both growers and dispensaries combined.

The commission has to establish an application review process for granting medical marijuana grower licenses in which applications are reviewed, evaluated, and ranked based on criteria established by the commission. The commission must:

- encourage licensing medical marijuana growers that grow strains of marijuana, including strains with high cannabidiol content, with demonstrated success in alleviating symptoms of specific diseases or conditions;
- encourage licensing medical marijuana growers that prepare medical marijuana in a range of routes of administration;
- encourage licensing medical marijuana growers located in agricultural zones; and
- actively seek to achieve racial, ethnic, and geographic diversity when licensing medical marijuana growers and encourage applicants who qualify as a minority business enterprise; beginning June 1, 2016, a licensed grower must report annually to the commission on the minority owners and employees of the grower.

An entity that seeks a medical marijuana grower license must also meet local zoning and planning requirements.

The commission must set standards for licensure of medical marijuana growers to ensure public safety and safe access to medical marijuana, which may include a requirement for the posting of security. A licensed grower must ensure that safety precautions established by the commission are followed by any facility operated by the grower. In addition, the commission 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. The commission may inspect growers to ensure compliance and may impose penalties against, or rescind the license of, a grower that does not meet the commission's standards for licensure.

A licensed grower may distribute marijuana at the grower's facility or at a satellite facility of the grower, and marijuana may only be provided to (1) a program operated by an academic medical center; (2) a licensed dispensary; (3) a qualified patient; and (4) a caregiver.

A "medical marijuana grower agent" is an owner, employee, volunteer, officer, or director of a licensed medical marijuana grower. Each medical marijuana grower agent must be registered with the commission before the agent may volunteer or work for a licensed grower, as well as obtain a State and national CHRC. The commission may not register a person who has been convicted of a felony drug offense as a grower agent. The licensed grower must apply to the commission for a registration card for each grower agent by submitting the name, address, and date of birth of the agent. Within one business day after a grower agent ceases to be associated with the grower, the grower must notify the commission and return the agent's registration card. On receipt of this notice, the commission must immediately revoke the registration card of the grower agent and, if the registration card was not returned, notify the Department of State Police.

Although statute does not specifically authorize registration fees for grower agents, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) proposed a \$200 registration fee.

Dispensaries and Their Agents

A "dispensary" is an entity licensed by the commission that acquires, possesses, processes, transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, related products, or educational materials for use by a qualifying patient or caregiver. A "dispensary agent" is an owner, employee, volunteer, officer, or director of a dispensary.

A dispensary must be licensed by the commission; to obtain a dispensary license, an applicant must submit to the commission:

- an application fee in an amount determined by the commission; and
- an application that includes (1) the legal name and physical address of the proposed dispensary; (2) the name, address, and date of birth of each principal officer and each director, none of whom may have served as a principal officer or director for a dispensary that has had its registration certificate revoked; and (3) operating procedures that the dispensary will use, consistent with commission regulations for oversight, including storage of marijuana only in enclosed and locked facilities.

The commission must (1) establish an application review process for granting dispensary licenses in which applications are reviewed, evaluated, and ranked based on criteria established by the commission and (2) actively seek to achieve racial, ethnic, and geographic diversity when licensing dispensaries.

Statute is silent on the term of a dispensary license. However, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) set the application fee for a dispensary license at \$5,000 (payable in two installments: \$1,000 at Stage 1 of the application process and \$4,000 at Stage 2) and provide for biennial licensure with a biennial license fee of \$80,000 (payable in \$40,000 installments annually). The regulations also would allow for a combination grower-dispensary license to be held, with fees set at a higher level to reflect the amount of fees for both growers and dispensaries combined.

A dispensary must apply to the commission for a registration card for each of its agents by submitting the name, address, and date of birth of each agent. A dispensary agent must be at least age 21, be registered with the commission before volunteering or working at the dispensary, and obtain a State and national CHRC. The commission may not register a person who has been convicted of a felony drug offense as a dispensary agent. Within one business day after a dispensary agent ceases to be associated with a dispensary, the dispensary must notify the commission and return the agent's registration card. On receipt of this notice, the commission must immediately revoke the registration card of the agent and notify the Department of State Police if the registration card was not returned to the commission.

Although statute does not specifically authorize registration fees for dispensary agents, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) proposed a \$200 registration fee.

Protections and Prohibitions

The following persons may not be subject to arrest, prosecution, or any civil or administrative penalty (including action by a professional licensing board) – or be denied any right or privilege – for the medical use of marijuana: (1) a qualifying patient (who is

enrolled in an approved program or in possession of an amount of marijuana determined by the commission to constitute a 30-day supply); (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; (4) a certifying physician; (5) a caregiver; (6) a licensed dispensary or a registered dispensary agent; or (7) a hospital or hospice program where a qualifying patient is receiving treatment.

Further, a hospital or hospice program is not required to report to the commission any disciplinary action taken by the hospital or hospice program against a certifying physician, including the revocation of privileges, after the approval of the certifying physician by the commission.

A licensed dispensary or a registered dispensary agent may not be penalized or arrested under State law for acquiring, possessing, processing, transferring, transporting, selling, distributing, or dispensing marijuana, products containing marijuana, related supplies, or educational materials for use by a qualifying patient or caregiver.

A person may not distribute, possess, manufacture, or use marijuana that has been diverted from a qualifying patient, a caregiver, a licensed grower, or a licensed dispensary. A violator is guilty of a felony and subject to maximum penalties of five years imprisonment, a \$10,000 fine, or both – in addition to any penalties for manufacture, possession, or distribution of marijuana under the Criminal Law Article.

The statute does not 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.

Background: Chapter 403 of 2013 authorized the investigational use of marijuana for medical purposes through research programs operated by academic medical centers in the State. The Act also established the Natalie M. LaPrade Medical Marijuana Commission, as an independent commission within DHMH. The commission initially was established 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.

Due to lack of interest among academic medical centers to participate in the program and pressure from patient advocates to make medical marijuana available beyond only those patients participating in a research study, legislation was introduced in 2014 to expand the medical marijuana program. Chapters 240 and 256 of 2014 expanded the State's medical marijuana program to allow qualifying patients to obtain medical marijuana from persons other than academic medical centers. Specifically, a qualifying patient who has been provided with a written certification from a certifying physician in accordance with a bona fide physician-patient relationship may obtain medical marijuana. A qualifying patient may only obtain marijuana from a grower or dispensary licensed by the commission. The commission is prohibited from licensing more than 15 growers before June 1, 2016; after that date, it may issue the number of licenses necessary to meet the demand. The commission is authorized to set *reasonable* fees to cover its operating costs.

Enactment of Chapters 240 and 256 not only expanded the commission's duties but also increased public interest in the commission, particularly among patient advocates and individuals interested in becoming growers or establishing dispensaries. The location of commission meetings had to be moved to a larger venue in order to accommodate the public. The commission was unable to meet the September 2014 deadline to adopt regulations due to the volume of complicated and controversial issues that were presented when drafting them. Examples of such issues included how to determine a 30-day supply, the type of marijuana that would be authorized (leaf, hemp oil, extracts), requirements for specified continuing education for certifying physicians, whether certifying physicians treating individuals with PTSD must be board-certified psychologists, zoning/location issues for growers and dispensaries, and how to determine licensure categories. The commission submitted proposed regulations in December 2014, and the public comment period ended February 23, 2015. These proposed regulations were placed on hold by the AELR Committee in March 2015.

DHMH's Laboratories Administration Division of Drug Control distributes CDS registrations to qualified health professionals, including physicians. In order to qualify for registration, a physician must obtain a license from the State Board of Physicians and pay a registration fee of \$120. A registration is valid for two years. The Laboratories Administration advises that approximately 3,500 physicians hold a CDS registration.

State Revenues: Although the impact of the bill's provisions on special fund revenues is dependent on several factors and could result in either an increase or a decrease in revenues, the likely effect is a net increase in special fund revenues – possibly as early as the end of fiscal 2016 but more likely beginning in fiscal 2017.

The bill authorizes additional fees for processors and independent testing laboratories and requires that the commission register at least one independent testing laboratory. The commission could, however, register multiple independent testing laboratories. The bill

does not provide any guidance on the number of processor licenses that may be issued. Absent information on how much the licensure and registration fees may be, a reliable estimate of the increased revenues cannot be made at this time. *For illustrative purposes only*, using regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) as a guide and assuming that a processor licensee would pay similar fees to that of a dispensary licensee, each such licensee could pay an application fee of \$5,000 (payable in multiple installments) and the equivalent of \$40,000 in licensing fees annually. There is no comparable fee proposed to that which might apply to registering independent testing laboratories. Nevertheless, the commission advises that it anticipates an increase in special fund revenues of approximately \$20,000 annually.

The bill changes the date by which the commission may issue additional grower licenses as necessary to meet the demand for medical cannabis from June 1, 2016, to June 1, 2018. The commission has recently advised that it does not anticipate issuing additional grower licenses for a few years; thus, this provision likely has no fiscal impact. However, if it were to delay issuance of more than 15 grower licenses, special fund revenues would decrease during that two-year period. As noted earlier, regulations proposed by the commission in December 2014 (and currently on hold with the AELR Committee) would establish an application fee of \$6,000 for each grower (payable in installments at two stages of the application process) and a biennial license fee of \$250,000, payable annually in installments of \$125,000.

The bill extends the initial term of licensure for growers from two to four years and establishes a four-year initial licensure term for dispensaries. (Regulations proposed by the commission in December 2014, and currently on hold with the AELR Committee, assumed biennial licensure for both growers and dispensaries.) This longer initial term of licensure could result in acceleration of special fund revenues to fiscal 2016 and 2017, if the fee increases to reflect the longer initial term of licensure. However, the Department of Legislative Services advises that the impact is dependent on whether that fee would have to be paid in full when licensed or would be payable in annual installments, as proposed under regulations currently on hold. Thus, it is not likely that provisions related to the initial term of licensure have an impact on special fund revenues.

Repealing provisions related to academic medical centers has no fiscal impact as the two academic medical centers in the State (The Johns Hopkins University and the University of Maryland Medical System) have repeatedly advised that they have no plans to participate in the medical marijuana program.

State Expenditures: Special fund expenditures for the commission increase due to the additional regulatory authority in the bill. The commission may incur additional expenditures to license processors and register independent testing laboratories as early as the end of fiscal 2016; however, such costs may be deferred to fiscal 2017. It is unclear

whether the staffing complement anticipated for existing licensing activities will be sufficient to handle these additional responsibilities. The commission has been operating with only an executive director, but the fiscal 2016 budget includes funding for nine positions.

The commission has expanded inspection authority under the bill. Previous estimates of commission costs did not assume expenditures for inspections of growers because they are not required under statute and, if conducted, could likely have been handled by commission members initially. However, based on proposed regulations (currently on hold with the AELR Committee), the commission is likely to fully exercise the inspection authority in the bill. Moreover, the fiscal 2016 budget for the commission includes \$66,867 for vehicle purchase, maintenance, and gas for inspection purposes as well as in-state travel expenses for inspectors. The staffing complement in the budget is slightly different than estimated for implementation of Chapters 240 and 456 of 2014, but it is consistent in number and encompasses personnel to conduct inspections. Thus, this analysis assumes costs for inspections are consistent with the budgeted amount and no additional cost for personnel.

Likewise, the fiscal 2016 budget for the commission includes \$158,400 for marijuana laboratory testing associated with inspections. This amounts to \$50 for each sample and assumes that the commission will test each dispensary and growing facility (and, presumably, each processor) once per month. Thus, this analysis assumes similar costs to utilize the required independent testing laboratory for this purpose.

The addition of one commission member increases reimbursement minimally.

The Governor's proposed fiscal 2016 budget fully funded the commission, even as expanded under the bill, at \$1.8 million. As introduced, the fiscal 2016 budget included \$1.0 million in general funds and more than \$800,000 in special funds. This funding split is consistent with previous fiscal and policy notes, which assumed a combination of general funds and special funds would have to be used to implement Chapters 240 and 256 of 2014 and that general funds would cover the majority of start-up costs before medical marijuana growers and dispensaries were fully licensed. Also, previous fiscal and policy notes assumed that sufficient revenue to cover costs might not be able to be attained because of delays in implementation and lower fees than those proposed to be established in the December 2014 regulations (which are currently on hold with the AELR Committee) would likely be charged (due to the "reasonableness" standard of fees in current law and because the only cost-recovery requirement in statute applies to academic medical centers, which are eliminated by the bill).

As passed by the General Assembly, however, the fiscal 2016 budget eliminates the \$1.0 million in general funding for the commission but authorizes the commission to process a budget amendment to provide for these costs with special funds. If insufficient

special fund revenue is collected in fiscal 2016 to do so, the commission is directed to seek a general fund deficiency appropriation with its fiscal 2017 budget submission for approval at the 2016 legislative session. It is likely that some portion of general funding for the commission will have to be maintained in fiscal 2016 and even future years because cost-recovery is not required. Moreover, fees set at a level to cover costs would likely not meet the “reasonableness” standard.

Small Business Impact: Most licensees are likely to be small businesses, and the additional costs associated with expanded inspection authority and testing are likely borne by them through their licensure fees.

Conversely, licensure fees for individual licensees could be reduced because the bill authorizes the collection of new fee revenue from processors and independent testing laboratories, thus likely increasing special fund revenue and spreading the commission costs over a greater number of licensees. Any such impact cannot be reliably quantified.

Setting the initial term of licensure at four years (rather than two years) for all licensees (growers, dispensaries, and processors) could result in higher initial licensure fees. As noted above, this impact will be dependent on whether the fee is due in full upon initial licensure or in annual installments, as proposed under regulations currently on hold with the AELR Committee.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

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