**PUBLIC ACT 268 of 2013** 





**ANALYSIS** 

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Senate Bill 660 (as enacted)

Sponsor: Senator Roger Kahn, M.D.

Senate Committee: Government Operations

House Committee: Judiciary

Date Completed: 3-31-14

### **CONTENT**

The bill amended Article 7 (Controlled Substances) of the Public Health Code to classify marihuana as a Schedule 2 controlled substance, with Federal authority; and added Article 8 (Pharmaceutical-Grade Cannabis) to provide for the licensure of facilities that manufacture, cultivate, and test pharmaceutical-grade cannabis (PGC); allow facilities to sell PGC to pharmacies; provide for PGC prescriptions; and provide for the issuance of enhanced PGC registration cards to patients. Implementation and enforcement of Article 8 may not begin sooner than 180 days after Federal authority reclassifies marihuana.

# The amendments to Article 7 do the following:

- -- Specify that marihuana, including PGC, is a Schedule 2 controlled substance if it is manufactured, obtained, dispensed, possessed, or grown in compliance with the Code and as authorized by Federal authority.
- -- Include marihuana in Schedule 2 for the purpose of treating a debilitating medical condition as authorized under the Code.

# Article 8 does the following with respect to the licensure of facilities:

- -- Prohibits a person from manufacturing, distributing, prescribing, or dispensing pharmaceutical-grade cannabis without a controlled substance license.
- -- Requires the Department Licensing and Regulatory Affairs (LARA) to license facilities to cultivate, manufacture, and test PGC.
- -- Establishes licensure criteria, and requires an applicant to submit fingerprints and personal history information.
- -- Requires LARA to establish a Pharmaceutical-Grade Cannabis Licensed Facility Registry.
- -- Establishes operating requirements for licensed facilities.
- -- Requires pharmaceutical-grade cannabis to meet specific standards, and requires licensed facilities to irradiate all PGC before delivery.
- -- Limits the liability of a licensed facility in a product liability action.
- -- Allows LARA to charge fees for activities provided under Article 8.
- -- Requires the fees to be deposited into a new "Pharmaceutical-Grade Cannabis Fund".

Article 8 does the following with respect to the delivery and prescription of pharmaceutical-grade cannabis:

Page 1 of 11 sb660/1314

- -- Requires a licensed facility to sell PGC only to a licensed pharmacy, for dispensing only to eligible patients and other licensed facilities.
- -- Allows a physician to recommend the issuance of an "enhanced pharmaceutical-grade cannabis registration card" to a patient; and allows LARA to issue a registration card.
- -- Requires the person receiving a card to be at least 18 years old, unless he or she is recommended by two physicians.
- -- Requires a person to surrender his or her registry ID card issued under the Michigan Medical Marihuana Act before receiving an enhanced PGC registration card.
- -- Requires the DCH to enter certain information into the Law Enforcement Information Network for each card issued.
- -- Specifies information that a prescription for PGC must include.
- -- Provides that a prescription may not allow an individual to obtain more than 2.5 ounces of PGC.
- -- Restricts access to information submitted to LARA under Article 8.

# **Article 8 does the following with respect to enforcement:**

- -- Requires LARA to inspect licensed facilities.
- -- Allows LARA to delegate its inspection responsibilities to local health departments, which the State must reimburse.
- -- Allows LARA, after an investigation and a hearing, to suspend or revoke a facility's license.
- -- Allows LARA to suspend a facility's license without a hearing, in an emergency.
- -- Establishes misdemeanor penalties for violations of Article 8.
- -- Provides that a licensed facility, or an owner, operator, officer, director, manager, or employee of a facility is not subject to arrest, prosecution, or penalty, and may not be denied any right or privilege, for the cultivation, distribution, and sale of PGC under Article 8.
- -- Preempts local ordinances regarding PGC facilities, except limitations on the number allowed and reasonable zoning regulations.

The bill also amended other articles of the Public Health Code to include references to Article 8 in provisions concerning disciplinary procedures; provisions regulating pharmacy practice; and a prohibition against disciplining health facility employees for reporting malpractice.

The bill repealed sections of the Code that established a marihuana controlled substances therapeutic research program and allowed the appointment of a patient qualification review board (MCL 333.7335 and 333.7336), which have not applied since November 2, 1987.

The bill took effect on December 30, 2013 (although, as indicated above, its implementation is contingent upon Federal reclassification of marihuana).

# Article 7: Reclassification of Marihuana

The Code classifies marihuana as a Schedule 1 controlled substance. Under the bill, marihuana, including pharmaceutical-grade cannabis, continues to be a Schedule 1 controlled substance except as provided below.

The bill specifies that marihuana, including pharmaceutical-grade cannabis, is a Schedule 2 controlled substance if is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the Code and as authorized by Federal authority.

Page 2 of 11 sb660/1314

The bill also includes marihuana in Schedule 2, but only for the purpose of treating a debilitating medical condition as that term is defined in the Michigan Medical Marihuana Act (MMMA) and as authorized under the Code.

(A Schedule 1 controlled substance is a substance that has high potential for abuse and has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision. A substance may be placed in Schedule 2 if it has high potential for abuse; the substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and abuse of the substance may lead to severe psychic or physical dependence.)

The bill defines "pharmaceutical-grade cannabis" as a grade of cannabis that is cultivated for the purposes of Article 8; that is free of chemical residues and is tested by validated methods to determine its cannabinoid levels, specifically, THC and THC acid levels and CBD (cannabidiol) and CBD acid levels and complies with the standards set in Article 8 for its microbial, mycotoxin, and metal contents, including heavy metals; and that meets any other necessary manufacturing practices as prescribed in rules promulgated by LARA.

# Article 7: Controlled Substance License

The Code requires a person to obtain a license issued by the Michigan Board of Pharmacy in order to manufacture, distribute, prescribe, or dispense a controlled substance in Michigan. A licensee may engage in those activities to the extent authorized by the license and in conformity with Article 7.

The bill specifies that a license issued under Article 7 to manufacture, distribute, prescribe, or dispense PGC and the conduct of the licensee are subject to the additional requirements of Article 8.

#### Article 8: Part 81 – General Provisions

<u>Article 7 License</u>. Part 81 prohibits a person from manufacturing, distributing, prescribing, or dispensing PGC without a license to manufacture, distribute, prescribe, or dispense a controlled substance under Article 7.

<u>Fees & Fund</u>. The Director of LARA may charge a reasonable fee for licensing, registration, inspection, testing, investigation, or other activity or service the Department provides under Article 8, in addition to any fee authorized under Article 7. Fees charged under Article 8 must be delivered to the State Treasurer on a monthly basis for deposit in the Pharmaceutical-Grade Cannabis Fund.

Before collecting a fee, LARA must develop and publish a comprehensive schedule of fees. The schedule must include a description of the activity or service and the maximum fee charged for it. The Director must revise the fee schedule from time to time so that the amount collected does not exceed the amount necessary to fund LARA's duties under Article 8.

The Pharmaceutical-Grade Cannabis Fund is created in the State Treasury, and may receive assets or income from any source in addition to the fees. The Department may spend money from the Fund, upon appropriation, only for the direct and indirect costs associated with implementing, administering, and enforcing Article 8. Money in the Fund at the close of the fiscal year will remain in the Fund.

<u>Rules & Implementation</u>. The Department must promulgate rules necessary to carry out Article 8. The rules must address at least all of the subjects listed in Part 81. Among others, these include the following:

Page 3 of 11 sb660/1314

- -- Activities necessary for compliance with Article 8 or activities that constitute a violation.
- -- Activities that constitute unfair, deceptive practices.
- -- Procedures for issuing enhanced PGC registration cards.
- -- Regulation of the manufacture, inventory, storage, disposal, and sale of PGC, and specification of legitimate sources for obtaining seed to cultivate it.
- -- Quarterly reporting by licensed facilities of their inventory.
- -- Health and sanitary requirements for licensed facilities.
- -- Physical security requirements for PGC.
- -- The reporting and transmittal of monthly sales and income tax payments for licensed facilities.
- -- The quantity of PGC plants and dried plant material that a licensed facility may have in its inventory at any time.

The Department may begin promulgation of the rules at the time marihuana, including PGC, is rescheduled by Federal authority. As noted above, however, implementation and enforcement of Article 8 may not occur sooner than 180 days after that Federal authority reschedules marihuana.

<u>Registry</u>. The Department must establish a Pharmaceutical-Grade Cannabis Licensed Facility Registry, which is to be an online database that contains information regarding the facilities licensed under Part 82. Information in the database must be made available to the public.

<u>Annual Report</u>. By January 31 each year, LARA must submit to the Legislature an annual report for the previous calendar year. The report must contain the following information:

- -- The total amount of fees collected under Article 8.
- -- All costs related to performing the duties of the Department under Article 8.
- -- Fines, suspensions, or license revocations that LARA imposed under Article 8.
- -- Any other information LARA considers appropriate.

MMMA. Articles 7 and 8 do not apply to conduct permitted under the Michigan Medical Marihuana Act.

#### Article 8: Part 81A - Prescribing & Dispensing Pharmaceutical-Grade Cannabis

<u>Physician Recommendation; Issuance of Card</u>. If a physician determines that his or her patient is likely to receive therapeutic or palliative benefit from the use of PGC to treat or alleviate the patient's debilitating medical condition or its symptom, the physician may recommend the issuance of an enhanced PGC registration card to the patient as an eligible patient.

The Department may issue an enhanced PGC registration card to an eligible patient who is recommended by a physician to obtain a card, who is 18 years of age or older, and who properly applies for the card. Also, LARA may issue an enhanced PGC registration card to an eligible patient who is younger than 18, who is recommended by two physicians, and who properly applies for the card, or whose parent or guardian properly applies on the patient's behalf.

Before issuing a card, LARA must determine whether the individual has previously been convicted of a felony for illegally manufacturing, creating, distributing, possessing, or using a controlled substance, or conspiring or attempting to do so, in this State or elsewhere. The Department may not issue a registration card to the individual who has such a conviction.

If an individual has a registry identification card as defined in the MMMA, LARA must require the person to surrender that card before issuing an enhanced PGC registration card to him or her.

Page 4 of 11 sb660/1314

<u>LEIN Information</u>. The Department must ensure that the following information for each registration card is entered into the Law Enforcement Information Network (LEIN): the card registration number; the name and address of the individual to whom the card is issued; the date the card was issued and its expiration date; and the name and address of the physician who authorized the issuance of the card.

This requirement does not authorize LARA to enter into LEIN any information regarding the diagnosis supporting issuance of the card or any medical information regarding the individual.

<u>Prescription for PGC</u>. Section 8154 requires each prescription for PGC to contain the following information:

- -- The date the prescription is written and the date it is filled.
- -- The dosage and instructions for use.
- -- The name, address, and Federal Drug Enforcement Administration number of the dispensing pharmacy and the initials of the pharmacist who fills the prescription.
- -- The name, address, and birth date of the eligible patient for whom PGC is prescribed.
- -- The product brand name, if specified.

A prescription for PGC may not allow the individual to whom it is issued to obtain more than 2.5 ounces of PGC. Pharmaceutical-grade cannabis must be kept only in the original packaging or container provided by the manufacturer or by the dispensing pharmacy.

<u>Electronic Monitoring</u>. The Department must require the use of the electronic monitoring system established under the Code for monitoring PGC dispensed as a Schedule 2 controlled substance. (The Code required LARA by rule to establish that system for monitoring Schedule 2, 3, 4, and 5 controlled substances dispensed by licensed pharmacists and dispensing prescribers. The rules must provide an electronic format for reporting data, including patient identifiers, name and quantity of the controlled substance dispensed, date, prescriber, and dispenser. The Department may provide the data to specified individuals and entities. Except as otherwise provided, the information submitted may be used only for bona fide drug-related criminal or disciplinary investigatory or evidentiary purposes. As a rule, the reporting is mandatory.)

<u>Information Access; Confidentiality</u>. The Director of LARA may permit access to information submitted to it under Article 8 only to the following:

- -- Employees and agents of LARA authorized by the Director.
- -- Employees of State, county, and other local law enforcement entities authorized by the Board of Pharmacy for the purpose of cooperating and assisting a governmental agency that is responsible for the enforcement of laws relating to controlled substances or a prescribing physician concerning an individual suspected of attempting to obtain a controlled substance by fraud, deceit, or misrepresentation.
- -- A person with whom LARA has entered into a contractual agreement for the administration of Section 8154.

Information submitted to LARA under Section 8154 will be confidential, but may be released to people authorized by the Director to conduct research studies or to others authorized by the Director.

Except as otherwise provided in Part 81A, information submitted to LARA under Section 8154 may be used only for bona fide drug-related criminal investigatory or evidentiary purposes or for investigatory or evidentiary purposes in connection with the functions of one or more of the licensing boards created in Article 15 (Occupations).

Page 5 of 11 sb660/1314

The identity of an eligible patient that is submitted to LARA must be removed from the system for retrieval of the information, and must be destroyed and made irretrievable by the end of the calendar year after the year in which the information is submitted. A patient identity that is necessary for use in a specific ongoing investigation, however, may be retained until the end of the year in which the need for retention ends.

### Article 8: Part 82 - Facility Licensing

<u>Licensing Requirement</u>. To protect the health, safety, and welfare of Michigan residents, LARA must license facilities under Article 8 to cultivate, manufacture, and test PGC in this State. The Department also must implement, administer, and enforce Article 8 to ensure that a safe, pure, dosage-consistent grade of PGC is available to eligible patients who are residents of Michigan.

Article 8 defines "pharmaceutical-grade cannabis licensed facility" as any secure entity, operation, or facility at or through which PGC is manufactured, cultivated, and tested in this State for lawful medical use as provided for in Article 8 and the MMMA. The term does not include a qualifying patient or primary caregiver who possesses or cultivates marihuana in the manner prescribed in the MMMA or an eligible patient who possesses PGC as prescribed in Article 8.

<u>License to Operate Facility</u>. The Department may not issue a license to an applicant to operate a PGC licensed facility unless LARA is satisfied that all of the following requirements are met:

- -- All fees required under Article 8 have been paid.
- -- The applicant will operate the facility in compliance with Article 8.
- -- The applicant is an adult of good moral character.
- -- The applicant is not delinquent in filing any tax returns; paying any taxes, interest, or penalties; paying any judgments due to a governmental agency; repaying government-issued student loans; or paying child support.
- -- The applicant will not hire or contract with any individual without conducting a criminal history check.
- -- The premises were inspected and the inspection and operations did not reveal any reason to deny the license.
- -- The criminal history check of the applicant did not reveal any felony convictions or any convictions involving a controlled substance.

<u>Criminal History Check</u>. Upon applying for issuance or renewal of a PGC licensed facility license, an applicant must submit a set of his or her fingerprints and file personal history information concerning his or her qualifications for a license. The Department must submit the fingerprints to the Michigan Department of State Police (MSP) for criminal history checks, and the MSP must forward the prints to the FBI. Fingerprints must be submitted as prescribed by the State Police and will be subject to normal fingerprinting fees.

If an applicant has twice submitted to a fingerprint-based criminal history check and his or her prints are unclassifiable, LARA also may acquire a name-based criminal history check for the individual.

The Department must use the information resulting from the fingerprint-based criminal history check to investigate and determine whether an applicant is qualified to hold a license under Article 8.

The MSP must keep a copy of the fingerprint images and notify LARA if a licensee is arrested or convicted. When notified, LARA must determine whether the individual is still qualified to

Page 6 of 11 sb660/1314

hold a license. When an individual ceases to be a licensee, LARA must notify the State Police.

<u>Delegation of Inspections</u>. The Department may delegate the duty of inspections for approval or renewal of facility licenses to a local health department that has the technical and other capabilities to protect the public health, safety, and welfare in this field. The delegation may not take place unless LARA has first consulted with an ad hoc committee, which it must appoint for this purpose. Membership on the committee must include representatives of LARA, local public health agencies, and an association representing the PGC licensed facilities subject to the inspections.

If delegation occurs, the State will have to reimburse each local health department the full amount of the fees collected.

Relicensure. At least 30 days before an annual license expires, a person operating a PGC licensed facility who is seeking relicensure must apply for license renewal and pay a fee. Upon the applicant's compliance, LARA will have to issue a renewal license.

# Article 8: Part 83 - PGC Licensed Facility Operations

<u>Facility Requirements</u>. A PGC licensed facility must establish legal control of its physical location, which will have to meet all applicable State and local zoning laws.

A licensed facility must maintain on the premises a record of the name, address, and date of birth of each officer, director, partner, member, manager, or employee of the facility. The facility must obtain the individual's identification and have a criminal history check conducted to determine if he or she is qualified to work at or be associated with the facility.

A licensed facility also must give LARA written notice within 10 days after an officer, director, partner, member, manager, or employee ceases to work at or be associated with the facility.

A licensed facility may not acquire, possess, cultivate, deliver, transfer, transport, supply, sell, or dispense PGC for any purpose except as provided in Article 8.

A licensed facility also may not possess more than the amount of PGC plants or dried PGC allowed in its inventory, as prescribed in rules promulgated under Article 8.

A licensed facility must destroy all marihuana that it cultivates or otherwise possesses that is determined not to be pharmaceutical-grade marihuana. A facility must keep records of its activities under this provision in order to verify its compliance to LARA.

<u>PGC Standards</u>. Pharmaceutical-grade marihuana must meet specific standards based on microbiological specifications; mycotoxin specifications; and heavy metal acceptable limits.

A licensed facility must irradiate all PGC in the manner determined by LARA before delivering that cannabis to another person.

<u>Operations</u>: Inspections. A PGC licensed facility may be a profit or nonprofit entity, and may operate on any calendar days of the week.

A facility must prohibit smoking or consumption of marihuana on its premises.

A facility must maintain all records required under Article 8 on the premises. It must make the licensed premises available for inspection and search by LARA, law enforcement officials, and any other State, Federal, or local governmental agency authorized by law or

Page 7 of 11 sb660/1314

Department rule to inspect the premises of the facility during regular business hours and when the premises are occupied by the licensee or an employee. It evidence of a violation of the Code or rules promulgated under it is discovered under this provision, the evidence may be seized and used in an administrative or court proceeding.

<u>Product Liability</u>. In a product liability action against a PGC licensed facility, pharmaceutical-grade cannabis is not defective or unreasonably dangerous, and the facility will not be liable, if the product sold was tested and determined to meet the standards for PGC under Article 8.

# Article 8: Part 84 - Sale & Distribution of Pharmaceutical-Grade Cannabis

A PGC licensed facility may not sell or otherwise distribute PGC except as provided in Part 84.

A licensed facility is prohibited from selling or otherwise distributing PGC directly to the public.

A licensed facility may sell PGC only to a pharmacies licensed in this State to be dispensed only to eligible patients and to other PGC licensed facilities for purposes provided for under Article 8. A label must be affixed to each package and container in which PGC dispensed by a licensed pharmacist or retail pharmacy is contained. The label must show in legible English the name and address of the manufacturer, the date the prescription was filled, the dosage, including the total percentages of THC and CBD, the patient's name, and the name and address of the dispensing pharmacy.

A licensed facility may sell or otherwise distribute PGC to pharmacies for sale or distribution only to eligible patients as provided in Article 8.

A licensed facility must report to LARA on a quarterly basis all quantities of PGC sold to licensed pharmacists, retail pharmacies, and other PGC licensed facilities.

#### <u>Article 8: Part 85 - Enforcement</u>

<u>LARA Requirements</u>. The Department is required to enforce Article 8 and the applicable provisions of Article 7, and to conduct at least one inspection of each PGC licensed facility during the term of its license to ensure compliance with the Articles 7 and 8.

<u>License Suspension or Revocation</u>. Upon a finding that there is an emergency requiring immediate action to protect the public health, safety, and welfare, LARA may issue an order to suspend the license of a PGC licensed facility without notice or hearing. The order will be effective immediately. A person subject to the order must comply immediately but, on application to LARA, must be given a hearing within 15 days. On the basis of the hearing, the order must be continued, modified, or dissolved within 30 days after the hearing.

On its own motion or upon receiving a complaint, and after an investigation and a hearing before an administrative law judge at which the licensed facility is given an opportunity to be heard, LARA may suspend or revoke a facility license issued under Article 8. The Department may suspend or revoke the license for any violation by the licensee, a board member, an agent, or an employee, or a violation of any of the terms, conditions, or provisions of the license issued by LARA.

If a license is suspended or revoked, none of the fees paid for it under Article 7 or 8 will be returned to the licensee.

Page 8 of 11 sb660/1314

The Department may summarily suspend a license without notice pending any prosecution, investigation, or public hearing.

Licensing Hearing. In a licensing hearing held by LARA under Article 8, a person may not refuse, upon request of the Department, to testify or provide other information on the ground of self-incrimination. Any testimony or other information produced in the hearing and any information directly or indirectly derived from it may not be used against the person in any criminal prosecution based on a violation of Article 8, except a prosecution for perjury committed while testifying. Continued refusal to testify or provide other information will be grounds for suspension or revocation of a license or registration card issued under Article 8.

<u>Misdemeanor Penalties</u>. An owner, operator, or agent of a PGC licensed facility who knowingly violates Article 8 or who establishes or operates a PGC licensed facility in violation of Article 8, will be guilty of a misdemeanor.

Except as provided below, the penalty is imprisonment for up to 90 days or a maximum fine of \$10,000, or both.

If the person has one prior conviction for violating Article 8, the penalty is imprisonment for up to 180 days or a maximum fine of \$50,000, or both.

If the person has two or more prior convictions for violating Article 8, or intentionally violates the article, the penalty is imprisonment for up to two years or a maximum fine of \$100,000, or both.

<u>Protection against Prosecution, Civil Penalty, or Discipline</u>. Except as otherwise provided in Article 8, a PGC licensed facility, or any owner, operator, officer, director, partner, member, manager, or employee of the facility, will not be subject to arrest, prosecution, or penalty in any manner, including civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, and may not be denied any right or privilege, for the cultivation, distribution, and sale of PGC under Article 8 for use by eligible patients in the manner prescribed by the article.

<u>Local Preemption</u>. A local governmental unit may not enact or enforce an ordinance regarding PGC licensed facilities, although it may limit the number of facilities allowed to operate in the local unit. A local governmental unit also may enact reasonable zoning regulations applicable to PGC facilities based local government zoning, health, and safety laws for the cultivation, distribution, and sale of PGC.

## Article 15: Part 161 – General Provisions

The bill includes references to Article 8 in provisions related to disciplinary proceedings against health professionals and the imposition of sanctions; a requirement that a licensee or registrant report to LARA if he or she knows that another licensee or registrant has committed a violation; provisions that allow a person or governmental entity to make an allegation to LARA if the person or entity believes that a violation exists, and provide for related proceedings; a requirement that LARA report disciplinary actions to the Legislature; and a requirement that LARA adopt guidelines establishing criteria for reinstatement.

The bill also allows LARA to use the Health Professions Regulatory Fund to carry out its powers and duties under Article 8, including the costs of reimbursing the Attorney General for services provided.

Page 9 of 11 sb660/1314

### Article 15: Part 177 – Pharmacy Practice & Drug Control

Part 177 allows a prescription to be transmitted electronically if certain conditions are met, except as otherwise provided under Article 7 and the Federal Food, Drug, and Cosmetic Act. The bill also refers to Article 8.

The Board of Pharmacy may impose sanctions against a person licensed under Part 177 on various grounds. The bill includes noncompliance with Article 8.

Article 177 provides for the Program for Utilization of Unused Prescription Drugs, and lists drugs that may not be accepted for dispensing. The bill includes on the list controlled substances as defined in Article 8.

# Article 17 (Facilities & Agencies): Malpractice Reporting

Article 17 prohibits a health facility or agency from discharging or disciplining, threatening to discharge or discipline, or discriminating against an employee because he or she, or an individual acting on his or her behalf, reports in good faith the malpractice of a health professional or a violation of Article 7, 15, or 17, or a rule promulgated under the article. The bill also refers to Article 8.

Legislative Analyst: Suzanne Lowe

MCL 333.7212 et al.

#### **FISCAL IMPACT**

The fiscal impact of Senate Bill 660 (S-1) is contingent upon the reclassification of marihuana as a Schedule 2 controlled substance, which will not occur unless authorized by the Federal government. The analysis below assumes that marihuana will be reclassified. Otherwise, the bill will have no fiscal impact on State or local government.

The bill allows the Department of Licensing and Regulatory Affairs to charge "reasonable" fees for licensing, registration, inspection, testing, and other activities related to the production and distribution of pharmaceutical-grade cannabis. The Department is required to set the fees at such a level that the revenue collected does not exceed the amount necessary to fund the Department's activities.

The bill is written so that there will be no net fiscal impact on LARA or local health departments. The bill requires LARA to undertake a number of activities, including promulgation of rules, licensing pharmaceutical-grade cannabis facilities, performing background checks on operators and employees, conducting annual inspections of licensed facilities, establishing a licensed facility registry, issuing registration cards, ensuring that registration card data are entered into the Law Enforcement Information Network, monitoring pharmaceutical grade cannabis as a Schedule 2 controlled substance, reporting to the Legislature, and taking action to suspend or revoke licenses through a hearing process. The costs of these activities will be offset by the fees charged.

The bill permits LARA to delegate inspections for approval or renewal of licenses to local public health departments as long as an ad hoc committee including representatives of the local public health departments approves and the State reimburses the local public health departments the full amount of fees collected. As such, there is no anticipated net fiscal impact on local government from the delegation of inspections.

The bill might have a negative fiscal impact on the Medical Marihuana Program (MMP), which issues registry cards to individuals whose doctors have recommended marihuana for the treatment of their symptoms. Registered individuals pay an initial fee of \$100 for a registry card and \$100 to renew the card every two years thereafter. Under the bill,

Page 10 of 11 sb660/1314

individuals who wish to obtain pharmaceutical-grade cannabis will have to surrender their registry card under the Michigan Medical Marihuana Act and instead obtain an enhanced PGC registration card. This will cause an indeterminate loss of revenue for LARA (which administers the MMP) as some registrants change registration card types, but this revenue loss will not substantially affect LARA's operations as the revenue currently generated by the MMP is in excess of what is required to operate the program. A loss of MMP revenue will serve to reduce the rate at which surplus funds accrue.

The bill creates a new misdemeanor for establishing or operating a pharmaceutical-grade cannabis licensed facility in violation of the regulations detailed under the bill. Violators will be guilty of a misdemeanor punishable as described above. There are no data to indicate how many individuals will be convicted of the new offense. Any convictions under the bill will increase the costs of incarceration and community supervision. Any penal fine revenue will benefit public libraries, which are the constitutionally designated recipients of that revenue. Violators charged with or convicted of the misdemeanor also may be charged with any other applicable crime committed while violating the new regulations.

Fiscal Analyst: Josh Sefton

#### S1314\s660es

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.