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BILL ANALYSIS

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Senate Bill 660 (as introduced 10-31-13)
Sponsor: Senator Roger Kahn, M.D.
Committee: Government Operations

Date Completed: 11-5-13

CONTENT

The bill would amend the Public Health Code to classify marihuana as a Schedule 2 controlled substance, with Federal authority; provide for the licensure of facilities that manufactured, cultivated, and tested pharmaceutical-grade cannabis (PGC); allow facilities to sell PGC to pharmacists and pharmacies; provide for PGC prescriptions; and provide for the issuance of enhanced PGC registration cards to patients.

Specifically, the bill would amend Article 7 (Controlled Substances) of the Code to do the following:

-- Specify that marihuana, including PGC, would be a Schedule 2 controlled substance if it were 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.

The bill would add Article 8 (Pharmaceutical-Grade Cannabis) to the Code to do the following with respect to the licensure of facilities:

-- Prohibit a person from manufacturing, distributing, prescribing, or dispensing pharmaceutical-grade cannabis without a controlled substance license.
-- Require the Department of Community Health (DCH) to license facilities to cultivate, manufacture, and test PGC.
-- Establish licensure criteria, and require an applicant to submit fingerprints and personal history information.
-- Require the DCH to establish a Pharmaceutical-Grade Cannabis Licensed Facility Registry.
-- Establish operating requirements for licensed facilities.
-- Require pharmaceutical-grade cannabis to meet specific standards, and require licensed facilities to irradiate all PGC before delivery.
-- Limit the liability of a licensed facility in a product liability action.
-- Allow the DCH to charge fees for activities provided under Article 8.
-- Require the fees to be deposited in the "Pharmaceutical-Grade Cannabis Fund", which the bill would create.

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

-- Require a licensed facility to sell PGC only to a licensed pharmacist or retail pharmacy, to be dispensed only to eligible patients and other licensed facilities.
-- Allow a physician to recommend the issuance of an "enhanced pharmaceutical-grade cannabis registration card" to a patient; and allow the DCH to issue a registration card.
-- Require a person to surrender his or her registry ID card issued under the Michigan Medical Marihuana Act before receiving an enhanced PGC registration card.
-- Require the DCH to enter certain information into the Law Enforcement Information Network for each card issued.
-- Specify information that a prescription for PGC would have to include.
-- Provide that a prescription could not allow an individual to obtain more than two ounces of PGC within a 30-day period.
-- Prohibit PGC from being prescribed to an individual under 18 years of age.
-- Restrict access to information submitted to the DCH under Article 8.

Article 8 would do the following with respect to enforcement:

-- Require the DCH to conduct annual inspections of licensed facilities.
-- Allow the DCH to delegate its inspection responsibilities to local health departments, which the State would have to reimburse.
-- Allow the DCH, after an investigation and a hearing, to suspend or revoke a facility's license.
-- Allow the DCH to suspend a facility's license without a hearing, in an emergency.
-- Establish misdemeanor penalties for violations of Article 8.
-- Provide that a licensed facility, or an owner, operator, officer, director, manager, or employee of a facility would not be subject to arrest, prosecution, or penalty, and could not be denied any right or privilege, for the cultivation, distribution, and sale of PGC under Article 8.
-- Preempt local ordinances regarding PGC facilities, except limitations on the number allowed and reasonable zoning regulations.

The bill also would amend 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 would repeal 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.

Article 7: Reclassification of Marihuana

The Code classifies marihuana as a Schedule 1 controlled substance. The Code also includes synthetic equivalents and compounds of those substances in Schedule 1. Under the bill, marihuana, including pharmaceutical-grade cannabis, would continue to be a Schedule 1 controlled substance except as provided below.

The bill specifies that marihuana, including pharmaceutical-grade cannabis, and the synthetic equivalents and compounds, would be Schedule 2 controlled substances if they were manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the Code and as authorized by Federal authority.

The bill also would include 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.)

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 would be subject to the additional requirements of Article 8.

Article 8: Part 81 – General Provisions

Article 7 License. Part 81 would prohibit a person from manufacturing, distributing, prescribing, or dispensing PGC without a license to manufacture, distribute, prescribe, or dispense a controlled substance under Article 7.

Fees & Fund. The DCH Director could charge a reasonable fee for licensing, registration, inspection, testing, or other activity or service the Department provided under Article 8, in addition to any fee authorized under Article 7. Fees charged under Article 8 would have to be delivered to the State Treasurer on a monthly basis for deposit in the proposed Pharmaceutical-Grade Cannabis Fund.

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

The Pharmaceutical-Grade Cannabis Fund would be created in the State Treasury, and could receive assets or income from any source in addition to the fees. The DCH would have to 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 would remain in the Fund.

Rules. The DCH would have to promulgate rules necessary to carry out Article 8. The rules would have to address at least all of the subjects listed in Part 81. Among others, these include the following:

-- Activities necessary for compliance with Article 8 or activities that would constitute a violation.
-- Activities that would 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 could have in its inventory at any time.

Registry. The DCH would have to establish a Pharmaceutical-Grade Cannabis Licensed Facility Registry, which would be an online database that contained information regarding the facilities licensed under Part 82. Information in the database would have to be made available to the public.

Annual Report. By January 31 each year, the DCH would have submit to the Legislature an annual report for the previous calendar year. The report would have to contain the following information:

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

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

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

Physician Recommendation; Issuance of Card. If a physician determined that his or her patient would likely 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 could recommend the issuance of an enhanced PGC registration card to the patient as an eligible patient.

The DCH could issue an enhanced PGC registration card to an eligible patient who was recommended by a physician and who properly applied for the card. The DCH first would have to determine whether the individual had previously been convicted of illegally manufacturing, creating, distributing, possessing, or using a controlled substance, or conspiring or attempting to do so, in this State or elsewhere. The DCH could not issue a registration card to the individual who had such a conviction.

If an individual had a registry identification card as defined in the MMMA, the DCH would have to require the person to surrender that card before issuing an enhanced PGC registration card to him or her.

LEIN Information. The DCH would have to ensure that the following information for each registration card was entered into the Law Enforcement Information Network (LEIN): the card registration number; the name and address of the individual to whom the card was issued; the date the card was issued; and the name and address of the physician who authorized the issuance of the card.

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

Prescription for PGC. Under Section 8154, each prescription for PGC would have to contain the following information:

-- The date the prescription was written and the date it was 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 filled the prescription.
-- The name, address, and age of the eligible patient for whom PGC was prescribed.
-- The product brand name, if specified.

A prescription for PGC could not allow the individual to whom it was issued to obtain more than two ounces of PGC within a 30-day period. Pharmaceutical-grade cannabis could not be prescribed to an individual less than 18 years of age.

Electronic Monitoring. The DCH would have to 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 the Department of Licensing and Regulatory Affairs 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. That 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.)

Information Access; Confidentiality. The DCH Director would have to permit access to information submitted to it under Article 8 only to the following:

-- Employees and agents of the DCH authorized by the Director.
-- Employees of the Department of State Police authorized by the Board of Pharmacy for the purpose of cooperating and assisting a governmental agency that was 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 the DCH had entered into a contractual agreement for the administration of Section 8154.

Information submitted to the DCH under Section 8154 would be confidential, but could 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 the DCH under Section 8154 could 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).

The identity of an eligible patient that was submitted to the DCH would have to be removed from the system for retrieval of the information, and would have to be destroyed and made irretrievable by the end of the calendar year after the year in which the information was submitted. A patient identity that was necessary for use in a specific ongoing investigation, however, could be retained until the end of the year in which the need for retention ended.

Article 8: Part 82 – Facility Licensing

Licensing Requirement. To protect the health, safety, and welfare of Michigan residents, the DCH would have to license facilities under Article 8 to cultivate, manufacture, and test PGC in this State. The DCH also would have to implement, administer, and enforce Article 8 to ensure that a safe, pure, dosage-consistent grade of PGC was available to eligible patients who were residents of Michigan.

License to Operate Facility. The DCH could not issue a license to an applicant to operate a PGC licensed facility unless the Department was satisfied that all of the following requirements were met:

-- All fees required under Article 8 had been paid.
-- The applicant would operate the facility in compliance with Article 8.
-- The applicant was an adult of good moral character.
-- The applicant was 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 would 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.

Criminal History Check. Upon applying for issuance or renewal of a PGC licensed facility license, an applicant would have to submit a set of his or her fingerprints and file personal history information concerning his or her qualifications for a license. The DCH would have to submit the fingerprints to the Department of State Police for criminal history checks, and the State Police would have to forward the prints to the FBI.

The DCH also could acquire a name-based criminal history check for an applicant who had twice submitted to a fingerprint-based criminal history check and whose prints were unclassifiable.

The DCH would have to use the information resulting from the fingerprint-based criminal history check to investigate and determine whether an applicant was qualified to hold a license under Article 8.

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

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

Relicensure. At least 30 days before an annual license expired, a person operating a PGC licensed facility who was seeking relicensure would have to apply for license renewal and pay a fee. Upon the applicant's compliance, the DCH would have to issue a renewal license.

Article 8: Part 83 – PGC Licensed Facility Operations

Facility Requirements. A PGC licensed facility would have to establish legal control of its physical location, which would have to meet all applicable State and local zoning laws.

A licensed facility would have to give the DCH written notice of the name, address, and date of birth of an officer, director, partner, member, manager, or employee, before the individual was associated with or began working at the facility. The facility would have to have a criminal history check conducted to determine if the individual was qualified to work at or be associated with the facility.

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

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

A licensed facility would be prohibited from possessing 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 would have to destroy all marihuana that it cultivated or otherwise possessed that was determined not to be pharmaceutical-grade marihuana. A facility would have to keep records of its activities under this provision in order to verify its compliance to the DCH.

PGC Standards. Pharmaceutical-grade marihuana would have to meet specific standards based on microbiological specifications; mycotoxin specifications; and heavy metal acceptable limits.

A licensed facility would have to irradiate all PGC in the manner determined by the DCH before delivering that cannabis to another person.

Operations; Inspections. A PGC licensed facility could be a profit or nonprofit entity, and could operate on any calendar days of the week.

A facility would have to prohibit smoking or consumption of marihuana on its premises.

A facility would have to maintain all records required under Article 8 on the premises. It would have to make the licensed premises available for inspection and search by the DCH, law enforcement officials, and any other State, Federal, or local governmental agency authorized by law or Department rule to inspect the premises of the facility during regular business hours and when the premises were occupied by the licensee or an employee. Evidence of a violation of the Code or rules promulgated under it discovered under this provision could be seized and used in an administrative or court proceeding.

Product Liability. In a product liability action against a PGC licensed facility, pharmaceutical-grade cannabis would not be defective or unreasonably dangerous, and the facility would not be liable, if the product sold were 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 could not sell or otherwise distribute PGC except as provided in Part 84.

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

A licensed facility could sell PGC only to a licensed pharmacist or retail pharmacy to be dispensed only to eligible patients and to other PGC licensed facilities for purposes provided for under Article 8. A label would have to be affixed to each package and container in which PGC dispensed by a licensed pharmacist or retail pharmacy was contained. The label would have to 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 (delta-9-tetrahydrocannabinol and tetrahydrocannabinol acid) and CBD (cannabidiol and cannabidiol acid), the patient's name, and the name and address of the dispensing pharmacist.

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

A licensed facility would have to report to the DCH on a quarterly basis all quantities of PGC sold to licensed pharmacists, retail pharmacies, and other PGC licensed facilities.

Article 8: Part 85 – Enforcement

DCH Requirements. The DCH would be required to enforce Article 8 and the applicable provisions of Article 7, and to conduct annual inspections of PGC licensed facilities to ensure compliance with the requirements of Articles 7 and 8.

License Suspension or Revocation. Upon a finding that there was an emergency requiring immediate action to protect the public health, safety, and welfare, the DCH could issue an order to suspend the license of a PGC licensed facility without notice or hearing. The order would be effective immediately. A person subject to the order would have to comply immediately but, on application to the DCH, would have to be given a hearing within 15 days. On the basis of the hearing, the order would have to 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 was given an opportunity to be heard, the DCH could suspend or revoke a facility license issued under Article 8. The DCH could 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 the DCH.

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

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

Licensing Hearing. In a licensing hearing held by the DCH under Article 8, a person could 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 could 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 would be grounds for suspension or revocation of a license or registration card issued under Article 8.

Misdemeanor Penalties. An owner, operator, or agent of a PGC licensed facility who knowingly violated Article 8 or who established or operated a PGC licensed facility in violation of Article 8, would be guilty of a misdemeanor.

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

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

If the person had two or more prior convictions for violating Article 8, or intentionally violated the article, the penalty would be imprisonment for up to two years or a maximum fine of $100,000, or both.

Protection against Prosecution, Civil Penalty, or Discipline. 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, would 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 could 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.

Local Preemption. A local governmental unit could not enact or enforce an ordinance regarding PGC licensed facilities, although it could limit the number of facilities allowed to operate in the local unit. A local governmental unit also could 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 would include 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 the Department of Licensing and Regulatory Affairs (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 believe 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 would allow 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.

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 would refer to Article 8.

The Board of Pharmacy may impose sanctions against a person licensed under Part 177 on various grounds. The bill would include 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 would add controlled substances as defined in Article 8 to the list.

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 would refer to Article 8.

MCL 333.7212 et al. Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

The fiscal impact of Senate Bill 660 is contingent upon the reclassification of marihuana as a Schedule 2 controlled substance, which would not occur unless authorized by the Federal

government. The analysis below assumes that marihuana would be reclassified. Otherwise, the bill would have no fiscal impact on State or local government.

The bill would allow the Department of Community Health to charge "reasonable" fees for licensing, registration, inspection, testing, and other activities related to the production and distribution of pharmaceutical-grade cannabis. The Department would be required to set the fees at such a level that the revenue collected did not exceed the amount necessary to fund the Department's activities.

The bill is written so that there would be no net fiscal impact on the DCH or local health departments. The DCH would 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 were 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 would be offset by the fees charged.

The bill would permit the DCH 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 approved and the State reimbursed the local public health department the full amount of fees collected. As such there would be no anticipated net fiscal impact on local government from the delegation of inspections.

The bill could have a negative fiscal impact on the Department of Licensing and Regulatory Affairs. This Department currently administers 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, individuals who wished to obtain pharmaceutical-grade cannabis would have to surrender their registry card under the Michigan Medical Marihuana Act and instead obtain an enhanced registration card from the DCH. This would cause an indeterminate loss of revenue for LARA as some registrants changed registration card types, but this revenue loss would 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 would serve to reduce the rate at which surplus funds accrue.

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

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