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S.B. 261
134th General Assembly

Bill Analysis

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Version: As Passed by the Senate

Primary Sponsor: Sen. S. Huffman

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SUMMARY

- “Creates the Division of Marijuana Control (DMC) within the Department of Commerce for the purpose of overseeing Ohio’s Medical Marijuana Program.
- Transfers the portions of the Medical Marijuana Program currently overseen by the Board of Pharmacy to DMC, including registration of patients and the licensure and oversight of dispensaries.
- Expands the types of medical conditions that are eligible for treatment with medical marijuana.
- Requires DMC to endeavor to achieve a ratio of at least one licensed retail dispensary per 1,000 registered patients up to the first 300,000 registered patients and then adding additional retail dispensaries on an as-needed basis.
- Allows licensed dispensaries to advertise, on social media or otherwise, without receiving prior approval from DMC.
- Allows licensed dispensaries to display products on advertisements and within the dispensary.
- Requires DMC to establish a new cultivator license category called stand-alone processor.
- Creates two levels of cultivator licenses, with level I cultivating up to 50,000 square feet and level II cultivating up to 6,000 square feet.
- Enables cultivators to request an expansion of their cultivated area, with level I being able to cultivate up to 75,000 square feet and level II up to 20,000 square feet.
- Allows marijuana products that fail laboratory testing or that falls outside of typical testing results to be retested.
- Allows tested samples to be sold.

- Expands the permissible forms of medical marijuana that may be dispensed to include pills, capsules and suppositories, oral pouches, oral strips, oral or topical sprays, salves, lotions, or similar items, and inhalers.
- Increases the permissible tetrahydrocannabinol (THC) content of extracts, from not more than 70% to 90%.
- Enables physicians to recommend medical marijuana via telemedicine.
- Allows a physician that is the medical director of a dispensary to be certified to recommend medical marijuana.

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DETAILED ANALYSIS

Overview

The bill creates a new Division of Marijuana Control (DMC) within the Department of Commerce. The purpose of DMC is to oversee and administer Ohio’s Medical Marijuana Control Program. As such, the majority of responsibilities the State Board of Pharmacy has with regard to the medical marijuana program are transferred to DMC. These transferred responsibilities include: patient and caregiver registration, approval and oversight of retail dispensary licensees, oversight of licensee taxation, criminal records checks for license applicants and

employees, investigations of violations of the Medical Marijuana Law, entering into reciprocity agreements with other states, and maintenance of a toll-free telephone line for responding to inquiries related to the Medical Marijuana Program. It also changes references in the Revised Code as necessary to accommodate these changes.¹

Transition provisions

Not later than 60 days after the bill's effective date, the Department of Commerce and the State Board of Pharmacy must transfer regulation of the Medical Marijuana Control Program to DMC. Until the transfer is complete, the Board retains regulatory authority over licensing of retail dispensaries, registering patients and caregivers, and related duties.²

Upon the completion of the transfer, the Medical Marijuana Control Program in the State Board of Pharmacy is abolished. All of its records, as well of all of its other assets and liabilities relating to the Medical Marijuana Control Program, must be transferred to DMC. DMC is successor to, and assumes the obligations of, the Medical Marijuana Control Program in the State Board of Pharmacy. Any business commenced, but not completed by the Board on the date of the completion of the transfer must be completed by DMC in the same manner, and with the same effect, as if completed by the State Board of Pharmacy. No validation, cure, right, privilege, remedy, obligation, or liability is lost or impaired by reason of the transfer.

Furthermore, DMC is responsible for adopting rules establishing standards and procedures for the Medical Marijuana Control Program. The rules regulating the Medical Marijuana Control Program in existence on the bill's effective date continue in effect until repealed or amended by DMC. However, not later than 90 days after the bill's effective date, DMC must review and propose revisions to the rules related to medical marijuana retail dispensaries.

A license to operate as a retail dispensary, as well as a patient registration, issued by the Board remain in effect for the remainder of the license's or registration's term, unless earlier suspended or revoked. However, the bill authorizes DMC to suspend, suspend without prior hearing, revoke, or refuse to renew a license issued by the Board.³ Until the transfer is complete, the Board will issue renewals; thereafter DMC will issue them.

Any form of medical marijuana approved by the State Board of Pharmacy remains approved until revoked by DMC, after giving notice to the petitioner for that alternate form. DMC must post notice of that revocation on its website.⁴

¹ R.C. 3796.02, 3796.03, 3796.032, 3796.04, repealed, 3796.05, 3796.06, 3796.061, 3796.08, 3796.10, 3796.11, 3796.12, 3796.13, 3796.14, 3796.15, 3796.16, 3796.17, 3796.22, 3796.23, 3796.27, 3796.30, and 4776.01.

² R.C. 3796.08(A)(1).

³ R.C. 3796.14(A)(1)(a).

⁴ Section 4 of the bill.

Expansion of qualifying condition

The bill expands the types of medical conditions that would qualify for treatment with marijuana. Under current law, all of the following are qualifying medical conditions:

- Acquired immune deficiency syndrome;
- Alzheimer’s disease;
- Amyotrophic lateral sclerosis;
- Cancer;
- Chronic traumatic encephalopathy;
- Crohn’s disease;
- Epilepsy or another seizure disorder;
- Fibromyalgia;
- Glaucoma;
- Hepatitis C;
- Inflammatory bowel disease;
- Multiple sclerosis;
- Pain that is either chronic and severe or intractable.
- Parkinson’s disease;
- Positive status for HIV;
- Post-traumatic stress disorder;
- Sickle cell anemia;
- Spinal cord disease or injury;
- Tourette’s syndrome;
- Traumatic brain injury;
- Ulcerative colitis;
- Any other disease or condition added by the State Medical Board; in February 2021, the State Medical Board added:
 - Arthritis;
 - Chronic migraines; and
 - Complex region pain syndrome.

The bill adds the following conditions:

- Arthritis;
- Migraines;
- Autism spectrum disorder;
- Spasticity or chronic muscle spasms;
- Hospice care or terminal illness;
- Opioid use disorder.

The bill also allows physicians to recommend marijuana for treatment for any condition if the physician, in the physician's sole discretion and medical opinion, finds either of the following:

- That the patient's symptoms may reasonably be expected to be relieved from medical marijuana;
- That the patient may otherwise reasonably be expected to benefit from medical marijuana.⁵

Adoption of rules

The bill requires DMC to adopt rules establishing standards and procedures for the medical marijuana control program. As part of the transfer of responsibilities from the State Board of Pharmacy, the Board's duty to adopt rules is transferred to DMC.

The bill tweaks several of the transferred rules:

- The bill transfers from the Board of Pharmacy the duty to adopt rules to establish the number of retail dispensary licenses that will be permitted at any one time. But the bill additionally requires these rules to endeavor to achieve a ratio of at least one retail dispensary per 1,000 registered patients up to the first 300,000 registered patients and then adding additional retail dispensaries on an as-needed basis thereafter, to be evaluated and awarded at least once every two years. When determining the number of retail dispensaries to license during any licensing event, DMC must take into account anticipated growth in patient numbers and patient demand based on sales and market data to ensure that new retail dispensary openings are timed to meet such demand.
- The bill continues the requirement to adopt rules that specify reasons for which a license may be suspended, including without prior hearing, revoked, or not be renewed or issued and the reasons for which a civil penalty may be imposed on a license holder.

⁵ R.C. 3796.01(A)(7) and Ohio Medical Marijuana Control Program, *Frequently Asked Questions*, <https://medicalmarijuana.ohio.gov/faqs> (accessed January 12, 2022).

But the bill does not transfer the requirement to adopt rules that specify reasons for which a registration may be suspended, revoked, or not renewed or issued.

- The bill requires DMC to adopt rules that establish standards and procedures for the testing and retesting of medical marijuana by a licensed laboratory. The bill expands this rule to apply to retesting as well.

The bill also requires DMC to adopt rules that do the following:

- Establish a new category of cultivator license for stand-alone processors and rules for their prompt establishment.
- Allow licensed dispensaries to advertise, on social media or otherwise, without receiving prior approval from DMC, allow licensed dispensaries to display products on advertisements and within the dispensary, and impose a fine or other penalties for licensed entities that fail to comply with these or any other rules DMC adopts pertaining to advertisements.

Finally, the bill additionally permits DMC to revoke a license for failure to secure a certificate of operation within 18 months of provisional licensure. The holder of a provisional license may apply to DMC for not more than two six-month extensions of this deadline. DMC must approve the extension if the license holder demonstrates that the license holder has made a good-faith effort at becoming operational.⁶

Licenses

Cultivator licenses

The bill expands the reasons that must be considered when establishing the number of cultivator licenses that will be permitted at any one time. Under the bill, DMC must additionally consider whether licensed cultivators have expanded to full capacity. Continuing, unchanged, considerations are Ohio's population and the number of patients seeking to use medical marijuana.⁷

The bill also expands what the holder of a valid cultivator license may do. Under current law, a licensed cultivator may cultivate marijuana. The bill expands this to include the acquisition of seeds or clones necessary to begin cultivation of a particular of medical marijuana from another licensed cultivator. In addition to delivering or selling medical marijuana to one or more licensed processor, under the bill, a licensed cultivator may also sell or deliver medical marijuana to other cultivators or retail dispensaries. A cultivator would also be allowed to register cuttings with the Ohio Marijuana Enforcement Tracking Reporting and Compliance System if both of the following are met:

- The cuttings were obtained from a legal, out-of-state cultivator;

⁶ R.C. 3796.03 (with conforming changes in R.C. 109.572 and Section 4) and 3796.04, repealed.

⁷ R.C. 3796.05(A).

- The cuttings have not otherwise been rooted as a clone.⁸

The bill also requires cultivators to do all of the following when processing medical marijuana:

- Package the medical marijuana in accordance with federal child-resistant effectiveness standards;
- Label the medical marijuana packaging with the product's tetrahydrocannabinol (THC) and cannabidiol content;
- Comply with any packaging or labeling requirements established in rules adopted by DMC.⁹

The bill authorizes DMC to issue two levels of cultivator licenses, as follows:

- A level I license holder may be approved to cultivate an area of up to 50,000 square feet;
- A level II license holder may be approved to cultivate an area of up to 6,000 square feet.

When reviewing applicants for a level I license, DMC is required to give preference to level II cultivator license holders.¹⁰

DMC may approve an expansion of an existing facility's marijuana cultivation area, based on cultivator compliance with licensure requirements, if the population of the state, number of patients seeking to use medical marijuana, and data from the drug database regarding patient recommendations and patient usage of medical marijuana support such expansion. If DMC approves an expansion of a facility's marijuana cultivation area, the marijuana cultivation area is not to exceed the following:

- 75,000 square feet for a level I license holder;
- 20,000 square feet for a level II license holder.

A cultivator is prohibited from submitting a request for expansion more than once during any 12-month period. A cultivator seeking to expand its marijuana cultivation area is required to submit an expansion plan, that, at a minimum, does all of the following:

- Includes plans and specifications for the expansion or alteration in accordance with rules adopted by DMC that demonstrate compliance with the requirements of the rules adopted by the Board of Building Standards and the State Fire Marshal;
- Proposes a timeline for completion of the proposed expansion, which, if approved, will become a mandatory condition;

⁸ R.C. 3796.18(A) and METRC, <https://www.metro.com/partner/ohio/> (accessed January 12, 2022).

⁹ R.C. 3796.18(C).

¹⁰ R.C. 3796.18(D) and (H).

- Demonstrates a history of compliance with the Medical Marijuana law and the rules adopted under it, which includes a history of enforcement actions and sanctions issued by the Department of Commerce or law enforcement agencies against the cultivator;
- Provides supporting documentation that the cultivator has consistently met the cultivation requirements established in rules adopted by DMC;
- Demonstrates that the proposed expansion meets the applicable requirements established by the Division in rule and that the cultivator will remain in compliance with the Medical Marijuana law and related rules, if the expansion is permitted.

Upon DMC's receipt of a request for expansion, DMC has 30 calendar days to review and approve or deny the request for expansion. If DMC does not deny the request for expansion prior to the expiration of 30 calendar days, the request is deemed approved. If the request is approved, the cultivator is bound to the terms in the request for expansion and must, prior to cultivating medical marijuana in the expanded marijuana cultivation area, pass an inspection conducted in accordance with rules adopted by DMC. A cultivator's failure to comply with the approved request for expansion may result in the revocation of DMC's approval or additional sanctions.¹¹

Retail dispensary licenses

The bill expands what DMC must consider when establishing the number of retail dispensary licenses that will be permitted at any one time to include projected patient growth over the next two years. DMC must continue to consider Ohio's population, the number of patients seeking medical marijuana, and the geographic distribution of dispensary sites in an effort to ensure patient access to medical marijuana.¹²

The bill expands what a licensed retail dispensary may do. Under current law, a dispensary may obtain marijuana from a processor. Under the bill, a dispensary may also obtain marijuana from cultivators. The bill explicitly authorizes dispensaries to *purchase* marijuana from either source. The bill makes corresponding changes with regard to labelling requirements. It also explicitly authorizes a dispensary to obtain or purchase marijuana from another dispensary if the two dispensaries are under common ownership.¹³

Processor license

The bill expands what a licensed medical marijuana processor may do. Under current law, processors may obtain medical marijuana from licensed cultivators. Under the bill they may also acquire it from other processors. They may also physically travel to the location of a cultivator and directly obtain the marijuana from the cultivator.

¹¹ R.C. 3796.18 (E) to (G).

¹² R.C. 3796.05(B).

¹³ R.C. 3796.20(A) and (B).

Under current law they may deliver or sell processed marijuana to one or more retail dispensaries. Under the bill they may also deliver or sell it to cultivators or processors.¹⁴

Laboratory license

The bill expands what a licensed laboratory may do. Under current law, a laboratory may:

- Obtain medical marijuana from one or more cultivators, processors, and retail dispensaries;
- Conduct medical marijuana testing in the manner specified in rule.

Under the bill they may also do the following:

- Conduct research and development testing for cultivators and processors;
- In-process testing for processors;
- Research and development testing for cultivators and processors.¹⁵

Furthermore, the bill authorizes the holders of other license types to use state-licensed labs to conduct in-process product testing for internal use.

Under the bill, retesting is permitted if a product fails testing or if a product test results fall outside of the typical results for that specific product. Retesting may be conducted by a licensed laboratory that is not the original laboratory on a new sample taken from the same batch or lot of product that was originally tested. For purposes of testing product, a “batch or lot” is either of the following:

- All of the plant material of the same strain grown together under the same growing conditions;
- All of the manufactured product of the same type produced from the same oil.

Plant material and products that fall outside of the testing limits for contaminants established by DMC may be refined using a method approved by it.¹⁶

The bill adds a requirement for laboratories testing medical marijuana. Under current law they are required to:

- Test the marijuana for potency, homogeneity, and contamination;
- Prepare a report of the test results.

¹⁴ R.C. 3796.19.

¹⁵ R.C. 3796.21(A).

¹⁶ R.C. 3796.21(B), (C), and (D).

Under the bill, they are also required to collect a sample of a size sufficient to conduct the requested tests, but equaling not more than twice the amount of material needed for such tests.¹⁷

Finally, the bill authorizes marijuana plant material and processed products tested under research and development be sold to patients, but only after all required testing is completed and the product passes testing required for sale.¹⁸

Permissible forms and methods

The bill expands the permissible forms of medical marijuana that may be dispensed to additionally include pills, capsules and suppositories, oral pouches, oral strips, oral or topical sprays, salves, lotions, or similar items, and inhalers. Under continuing law, oils, tinctures, plant material, edibles, patches, and any other form approved by DMC (changed from the Board of Pharmacy) remain permissible forms of marijuana.

In a conforming change, the bill expands the permitted methods of using medical marijuana to apply to the additional permitted forms. Consequently, inhalation, oral administration, and transdermal administration of medical marijuana is permitted. In addition, oral absorption of medical marijuana into the bloodstream, either buccally (between the gum and cheek) or sublingually (under the tongue), is permitted. The smoking or combustion of medical marijuana continues to be prohibited.¹⁹

Petitioning for additional methods of consumption

Under current law, a person may petition the Board of Pharmacy to approve an additional form or method of using medical marijuana. The bill transfers this responsibility to DMC. The bill removes several provisions related to the Board's processing of petitions, including:

- The explicit authorization for the Board to consolidate multiple petitions for similar methods, remaining silent on how DMC is to review these petitions;
- The requirement that the Board consult with experts and review relevant scientific evidence;
- The requirement that the Board make its determination in accordance with related rules;
- A prohibition on appeals regarding a determination by the Board.

¹⁷ R.C. 3796.21(E).

¹⁸ R.C. 3796.21(F).

¹⁹ R.C. 3796.06(A) and (B).

Under the bill, DMC must make a determination on a petition within 60 days. The current law prohibition against seeking a petition to approve consumption of medical marijuana by smoking or combustion is maintained.²⁰

Dosage of medical marijuana

With respect to THC content, the bill increases the permissible THC of extracts from not more than 70% to 90%. Plant material continues to be capped at 35%. Also, the bill requires that a 90-day supply of plant material have a weight of not less than nine ounces.²¹

Inspections without notice

Under current law, the Department of Commerce and the Board of Pharmacy are authorized to take certain actions without notice to a licensee or applicant for a license. Under current law, the Board is authorized to suspend a retail dispensary license without a hearing via a telephone conference call. This authority is repealed under the bill and not transferred to DMC.²²

Equity study

The bill requires the State Board of Pharmacy and the Department of Commerce to collaborate on conducting an equity study of the medical cannabis industry and the medical cannabis market to determine whether there is a compelling interest to implement remedial measures, which may include applying the requirements of the Minority Business Enterprise Program, to assist minorities and women in the medical cannabis industry.²³

Physician medical marijuana certification and the State Medical Board

The bill makes changes to the law governing physicians certified to recommend marijuana as a treatment. Under current law, physicians are required to conduct a physical examination of the patient before recommending marijuana. Under the bill, this requirement is removed and physicians are authorized to recommend marijuana via telemedicine.²⁴

Furthermore, the bill partially removes a conflict of interest provision related to such physicians. Under current law, physicians are prohibited from being certified to recommend marijuana if the physician has an ownership interest or investment interest in, or a

²⁰ R.C. 3796.061.

²¹ R.C. 3796.06(D) and (E).

²² R.C. 3796.14(B).

²³ R.C. 3796.35.

²⁴ R.C. 4731.30(C)(1)(b)(i) and 4731.303.

compensation arrangement with, a medical marijuana license holder. The bill allows the medical director of a dispensary to be certified to recommend medical marijuana.²⁵

Finally, the bill authorizes the State Medical Board to approve a course of education for employees of a medical marijuana dispensary. If the Board adopts the training course, then dispensary employees must take the course.²⁶

Closed-loop payment system

The bill repeals the authority of the Department of Commerce to establish a closed-loop payment processing system under which the state creates accounts to be used only by registered patients and caregivers at licensed dispensaries, as well as by all license holders under the Medical Marijuana Control Program. The authority to create the closed-loop system was granted in 2016, and it does not appear that the Department has established such a system.²⁷

Records checks for employees

Under continuing law, employees of licensees must obtain a records check to demonstrate that the person has not committed various crimes. The bill allows a temporary work permit to be issued if the records check results are not received by DMC within ten business days.²⁸

Definitions

The bill makes the following definitions:

Marijuana cultivation area means the boundaries of the enclosed areas in which medical marijuana is cultivated during the vegetative stage and flowering stage of the cultivation process. For purposes of calculating the marijuana cultivation area square footage, “marijuana cultivation area” does not include enclosed areas used solely for the storage and maintenance of mother plants, clones, or seedlings.

Recommending physician means a physician certified to recommend medical marijuana for the treatment of a qualifying medical condition.

Stand-alone processor means a licensed processor that has obtained its certificate of operation by October 1, 2021, and initially applied for a cultivator license and was not awarded a provisional license.²⁹

²⁵ R.C. 4731.30(I).

²⁶ R.C. 3796.20(C) and 4731.304.

²⁷ R.C. 3796.031.

²⁸ R.C. 3796.13(B)(2).

²⁹ R.C. 3796.01.

HISTORY

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