S.B. 261* 134th General Assembly

Occupational Regulation Report

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Primary Sponsor: Sen. Stephen A. Huffman

Impacted Professions: Medical marijuana cultivators, processors, laboratories, caregivers, retail dispensaries, and physicians

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LSC is required by law to issue a report for each introduced bill that substantially changes or enacts an occupational regulation. The report must: (1) explain the bill's regulatory framework in the context of Ohio's statutory policy of using the least restrictive regulation necessary to protect consumers, (2) compare the regulatory schemes governing the same occupation in other states, and (3) examine the bill's potential impact on employment, consumer choice, market competition, and cost to government.¹

LEAST RESTRICTIVE REGULATION COMPARISON Ohio's general regulatory policy

The general policy of the state is reliance on market competition and private remedies to protect the interests of consumers in commercial transactions involving the sale of goods or services. For circumstances in which the General Assembly determines that additional safeguards are necessary to protect consumers from "present, significant, and substantiated harms that threaten health, safety, or welfare," the state's expressed intent is to enact the "least restrictive regulation that will adequately protect consumers from such harms."²

The degree of "restrictiveness" of an occupational regulation is prescribed by statute. The following graphic identifies each type of occupational regulation expressly mentioned in the state's policy by least to most restrictive:

^{*} This report addresses the "As Introduced" version of S.B. 261. It does not account for changes that may have been adopted after the bill's introduction.

¹ R.C. 103.26, not in the bill.

² R.C. 4798.01 and 4798.02, neither in the bill.



*CSPL – The Consumer Sales Practices Law

The bill modifies existing licensure requirements for medical marijuana cultivators, processors, testing laboratories, retail dispensaries, and physicians (certificate to recommend). It also makes changes to an inspection requirement and several process regulations that apply to those professions. In addition, the bill modifies an existing registration requirement for medical marijuana caregivers.

The cultivator, processor, testing laboratory, and retail dispensary licenses appear to function primarily as "business licenses" which, by definition, are excluded from the state's occupational regulation policy.³ However, since it is possible for an individual to apply for and obtain such a license, they are reviewed as occupational licenses for the purposes of this report.

Necessity of regulations

Senator Stephen Huffman, the bill's primary sponsor, testified that S.B. 261 is intended to update and improve the state's medical marijuana laws based on efficiencies gleaned in the five years since the laws were enacted in 2016. He suggests that moving regulation of dispensaries, patients, and caregivers from the Board of Pharmacy to the newly created Division of Marijuana Control (DMC) within the Department of Commerce will "streamline rules and regulations" and "simplify the compliance process for businesses within the industry." Senator Huffman asserts that there are too few licensed retail dispensaries in Ohio – approximately one for every 6,000 registered patients – and that the bill's changes to the guidelines for determining the aggregate limit on the number of available licenses will increase that number and allow the industry to keep up with patient demand. He testified that codifying the current administrative rules respecting Level I and Level II cultivator licenses, and increasing the square footage that may be cultivated by Level II license holders following an application for expansion "should allow more product to come into the market and lower prices for patients." Senator Huffman reports that the bill's new stand-alone processor license is intended to allow licensed processors to maintain a small growing area.

³ See, R.C. 4798.01, not in the bill.

Senator Huffman's testimony expresses concern that Ohio patients pay a much higher rate for medical marijuana (about \$310 per ounce) than patients in the surrounding states. He suggests that applying "free market principles to a highly regulated business" will improve the current state of affairs for both licensed practitioners and consumers.⁴

Restrictiveness of regulations

License provisions

Licensure is the most restrictive of all regulatory options identified within the state's continuum of regulations. Accordingly, the state's policy prescribes a narrow range of situations in which required licensure is appropriate; specifically, when all of the following circumstances are present: (1) the occupation involves providing a service regulated by both state and federal law, (2) the licensing framework allows individuals licensed in other states and territories to practice in Ohio, and (3) the licensing requirement is based on uniform national laws, practices, and examinations that have been adopted by at least 50 U.S. states and territories.⁵

Marijuana is classified as a Schedule I substance under the Controlled Substance Act and, consequently, distribution of marijuana is a federal offense.⁶ Nonetheless, the United States Attorney General grants federal prosecutors discretion in how to prioritize enforcement of federal marijuana laws and, in recent years, prosecutors have declined to pursue charges against persons using, cultivating, or distributing marijuana in accordance with state law. Thirty-six states (including Ohio) have enacted laws allowing for cultivation, distribution, and use of marijuana under limited circumstances. The remaining 14 states still prohibit such activities.⁷

Ohio does not allow out-of-state license holders to cultivate, process, or sell marijuana in this state. Such an arrangement would present logistical issues in the context of the state's limits on the aggregate number of available licenses. Ohio's medical marijuana licenses do not appear to be based on a uniform national law. However, the license types and regulatory structure are pretty similar to Michigan, Pennsylvania, and West Virginia; the three surrounding states that have enacted medical marijuana laws.

S.B. 261 appears to primarily decrease the restrictiveness of Ohio's existing medical marijuana licenses. For example, the bill increases the scope of permissible activities for license holders, eases conflict of interest restrictions for physicians possessing a certificate to recommend, and allows DMC to issue temporary work permits to employees of licensed cultivators, processors, and dispensaries who are awaiting the results of a criminal background check. Only the bill's provision authorizing DMC to revoke the license of a cultivator, processor,

⁴ Senator Stephen Huffman, S.B. 261 Sponsor Testimony, Senate Small Business and Economic Development committee, November 17, 2021.

⁵ R.C. 4798.02, not in the bill.

⁶ See, 21 United States Code (U.S.C.) 812.

⁷ National Conference of State Legislatures (NCSL), State Medical Cannabis Laws, updated November 29, 2021.

or dispensary that does not secure a certificate of operation within 18 months of provisional licensure, the establishment of new sub-licenses for cultivators, and the authorization for the State Medical Board to require training for dispensary employees appear to increase the restrictiveness of the state's license requirements. The bill's revisions to the guidelines for determining the aggregate license limitation appear likely to increase the number of available licenses in the short-term, but the long-term impact is unclear.

Registration provisions

The state's general policy provides that a registration requirement is the appropriate means by which to protect consumers "against potential damages by transient providers."⁸ The purpose served by the state's existing registration requirement for medical marijuana patients and caregivers are not specified. However, the bill does not appear to affect the restrictiveness of those requirements. The bill moves administration of the patient and caregiver registration from the Board of Pharmacy to DMC. Under current law, the Board of Pharmacy is required to adopt rules specifying reasons for which a registration may be suspended, revoked, not renewed, or not issued. The bill requires DMC to promulgate a similar rule for licenses, but does not reference registrations. It is not clear what (if any) impact this will have on the rules adopted by DMC.

Inspection provisions

The state's general policy provides that an inspection requirement is the appropriate means by which to protect consumers from "unsanitary facilities" and to address general health, safety, or welfare concerns.⁹ There is no expressed rationale for the state's existing requirement that license holders allow periodic inspections by the licensing board. The bill appears to decrease the restrictiveness of this requirement by not expressly allowing DMC inspect the facility of a license holder without notice. The Board of Pharmacy and the Department of Commerce have that authority under current law.

Process regulations

The state's general policy does not specify when a process regulation is the appropriate means of protecting consumers. Presumably, process regulations are preferred when market competition, ratings and reviews, private certifications, private causes of action, and actions under the Consumer Sales Practice Act are not sufficient to achieve the intent of the regulation. The bill generally reduces the restrictiveness of existing process regulations, for example, by allowing physicians to issue a medical marijuana recommendation via telemedicine. The bill does establish several new process regulations for medical marijuana cultivators related to packaging and labeling. However, these new regulations are consistent with those that apply to processors under continuing law and appear to be implemented to accommodate the bill's authorization for cultivators to deliver medical marijuana directly to a dispensary.

⁸ R.C. 4798.02(B)(4).

⁹ R.C. 4798.02(B)(2).

IMPACT STATEMENT

Opportunities for employment

As noted above, S.B. 261 contains a few provisions which might reduce opportunities for employment, such as (1) authorizing DMC to revoke the license of a cultivator, processor, or dispensary that does not secure a certificate of operation within 18 months of provisional licensure, (2) establishing new sub-licenses for cultivators, and (3) authorizing for the State Medical Board to require training for dispensary employees. But such effects are very likely to be offset by those of other provisions of the bill, such as (1) expanding the list of medical conditions for which medical marijuana may be prescribed, (2) revising guidelines for determining the aggregate license limitation, and (3) creation of the stand-alone processor license. These provisions are more likely to reduce the restrictiveness of regulation. The net effect of the bill is most likely to increase total employment in the industry.

As of December 2021, the Ohio Medical Marijuana Control Program had approved medical marijuana retail dispensaries in 56 physical locations. The Department of Commerce had also approved 27 active cultivator licenses and 7 provisional cultivator licenses.

Consumer choice and cost and market competition

As compared to the current regulatory framework, the bill will most likely result in increased market competition, a greater number of licensed cultivators and retail dispensaries, and may reduce the market price of medical marijuana products in the state. The extent to which these patterns occur in practice will depend not only on the nature of unmet demand for medical marijuana products, but also on administrative rules promulgated by DMC.

Cost to government

For the fiscal impact of the bill to government, please refer to the LBO fiscal note.

SUMMARY OF PROPOSED REGULATIONS

Overview

The bill makes numerous changes to the law governing persons engaged in the medical marijuana industry. There are currently five occupational licenses and two registration requirements associated with cultivation, processing, sale, administration, and consumption of medical marijuana. Those licenses and registrations are administered by the Department of Commerce, Board of Pharmacy, and State Medical Board. The table below lists each such license and registration, the licensing board that administers it, and the associated professional activities. The table describes the licenses and registrations under current law; the bill's changes are summarized thereafter.

Medical Marijuana Licenses and Registrations					
Title	Type of Regulation	Licensing Board	Authorized Activities		
Cultivator	License	Department of Commerce	Cultivates medical marijuana for delivery or sale to a licensed processor (R.C. 3796.18).		
Processor	License	Department of Commerce	Obtains medical marijuana from a licensed cultivator; packages, labels, or otherwise processes it for sale; and delivers or sells it to a licensed retail dispensary (R.C. 3796.19).		
Testing laboratory	License	Department of Commerce	Obtains medical marijuana from a cultivator, processor, or retail dispensary and conducts testing for potency, homogeneity, and contamination (<i>R.C. 3796.21</i>).		
Patient	Registration	Board of Pharmacy	Possesses and uses medical marijuana to treat a qualifying condition (<i>R.C. 3796.22</i>).		
Caregiver	Registration	Board of Pharmacy	Possesses medical marijuana on behalf of a registered patient and assists the registered patient in use or administration (<i>R.C. 3796.23</i>).		
Retail dispensary	License	Board of Pharmacy	Obtains medical marijuana from a processor and sells it to registered patients or caregivers (<i>R.C. 3796.20</i>).		
Physician	License (certificate to recommend)	State Medical Board	Issues written recommendations for patients to use medical marijuana to treat a qualifying condition (<i>R.C. 4731.30</i>).		

Generally applicable provisions

Division of Marijuana Control (DMC)

The bill creates a new Division of Marijuana Control (DMC) within the Department of Commerce to oversee and administer the state's Medical Marijuana Control Program. The majority of the medical marijuana-related duties previously performed by the Board of Pharmacy - including licensure and oversight of retail dispensaries and registration of patients and caregivers – are transferred by the bill to DMC. Accordingly, under the bill, DMC is responsible for administering all medical marijuana licenses and registrations other than a physician's certificate to recommend, which remains under the auspices of the State Medical Board.¹⁰

Revocation of licenses

The bill permits DMC to revoke any of the licenses it administers if the license holder fails 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 a good-faith effort at becoming operational.¹¹

Inspections and suspensions

The bill limits the authority of DMC, as compared to the authority of the Department of Commerce and Board of Pharmacy under current law, when it comes to suspending a license without a hearing or conducting unannounced inspections. Under current law, The Department and Board are permitted to suspend a license without a hearing via a telephone conference call. Furthermore, the Department and Board may conduct inspections of records and facilities of license holders and license applicants without prior notice. The bill grants DMC authority to suspend a license without a hearing, but does not allow suspension by telephone. With respect to license holders, the bill allows DMC to conduct unannounced inspections of records only (not facilities). However, DMC is permitted to inspect both the records and facilities of license applicants.¹²

Temporary work permits

Continuing law requires employees of licensed cultivators, processors, and dispensaries to obtain a records check to demonstrate that they have not committed certain disqualifying

¹⁰ 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.

¹¹ R.C. 3796.03 (with conforming changes in R.C. 109.572 and Section 4) and 3796.04, repealed.

¹² R.C. 3796.14.

offenses. The bill allows DMC to issue a temporary work permit to a prospective employee if the records check results are not received within ten business days.¹³

Cultivators

Authorized activities

The bill expands the authorized activities that may be performed by a licensed cultivator to include the acquisition of seeds or clones necessary to begin cultivation of a particular medical marijuana from another licensed cultivator. Furthermore, the bill authorizes licensed cultivators to sell or deliver medical marijuana to other licensed cultivators or retail dispensaries. Under certain circumstances, the bill permits licensed cultivators to register cuttings with the Ohio Marijuana Enforcement Tracking Reporting and Compliance System.¹⁴

Packaging and labeling requirements

The bill prescribes several process regulations for cultivators related to packaging and labeling medical marijuana. Such regulations appear to be consistent with those that currently apply to licensed processors, and are likely intended to account for situations in which a cultivator delivers medical marijuana directly to a dispensary.¹⁵

License types

The bill requires DMC to adopt rules establishing a new category of cultivator license for a stand-alone processor, which the bill defines as a licensed processor that obtained its certificate of operation by October 1, 2021, that initially applied for a cultivator license, and was not awarded such a license.¹⁶

The bill codifies a current administrative rule requiring two levels of cultivator licenses: a Level I license for persons who cultivate an area of up to 50,000 square feet, and a Level II license for persons who cultivate an area of up to 6,000 square feet. Under the bill, DMC may expand the license holder's cultivation area to up to 75,000 square feet for a Level I license holder, or 20,000 square feet for a Level II license holder. This differs slightly from the current administrative rule, which allows for an expansion to only 9,000 square feet for Level II license holders.

The bill requires DMC to give preference to Level II license holders when evaluating applications for a Level I cultivator license.¹⁷

¹³ R.C. 3796.13(B)(2).

¹⁴ R.C. 3796.18(A).

¹⁵ R.C. 3796.18(C).

¹⁶ R.C. 3796.01(A)(9) and 3796.03.

¹⁷ R.C. 3796.18(D), (E), (G), and (H); Ohio Administrative Code (O.A.C.) 3796:2-1-09, not in the bill.

Number of licenses

The bill expands the reasons that must be considered in establishing the number of cultivator licenses that will be permitted at any one time. Under the bill, DMC must additionally consider whether currently licensed cultivators have expanded to full capacity. Continuing law requires consideration of Ohio's population and the number of patients seeking to use medical marijuana.¹⁸

Processors

Authorized activities

The bill expands the activities that may be performed by a licensed processor to include acquisition of medical marijuana from other licensed processors and physically traveling to the location of a licensed cultivator for the purpose of directly obtaining medical marijuana (as opposed to merely accepting delivery from a licensed cultivator).¹⁹

Testing laboratories

Authorized activities

The bill expands the authorized activities that may be performed by a licensed testing laboratory to include retesting products that fail testing or fall outside of the typical results for that specific product. ²⁰

Process regulations

The bill allows licensed testing laboratories to use state-licensed labs to conduct in-process product testing for internal use. It also requires such laboratories to collect sample sizes sufficient to conduct the required tests, but equaling not more than twice the amount of material needed for such tests.²¹

Retail dispensaries

Authorized activities

The bill expands the activities that may be performed by a licensed retail dispensary to include obtaining or purchasing marijuana from cultivators or from another licensed retail dispensary under the same ownership.²²

¹⁸ R.C. 3796.05(A).

¹⁹ R.C. 3796.19.

²⁰ R.C. 3796.21.

²¹ R.C. 3796.21.

²² R.C. 3796.20(A) and (B).

Advertising

The bill requires DMC to adopt rules allowing licensed dispensaries to advertise without receiving prior approval from DMC and to display products on advertisements and throughout the dispensary.²³

Number of licenses

The bill expands the reasons that must be considered in 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 the state's population, the number of patients seeking medical marijuana, and the geographic distribution of dispensary sites. The bill requires that DMC 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 add additional retail dispensaries on an as-needed basis thereafter.²⁴

Employee training

The bill allows the State Medical Board to approve a course of education for employees of a licensed dispensary. If the Board adopts the training course, then dispensary employees must take the course.²⁵

Disqualifying offenses

The bill requires DMC to adopt rules specifying which criminal offenses do not disqualify an applicant from holding a retail dispensary license.²⁶

Caregivers

Discipline

The bill does not expressly authorize DMC to adopt rules that specify reasons for which a caregiver registration may be suspended, revoked, not issued, or not renewed. The Board of Pharmacy is required to adopt such rules under current law.²⁷

²³ R.C. 3796.03.

²⁴ R.C. 3796.05(B) and 3796.03(B)(3).

²⁵ R.C. 3796.20(C) and 4731.304.

²⁶ R.C. 3796.03(B)(2).

²⁷ R.C. 3796.04, repealed.

Physicians

Telemedicine

Eliminates a requirement that a physician conduct a physical examination of the patient before recommending medical marijuana and authorizes physicians to recommend medical marijuana via telemedicine.²⁸

Conflict of interest

The bill removes a conflict of interest provision that prohibited physicians from being certified to recommend medical marijuana if the physician has an ownership interest or investment interest in, or receives compensation from a medical marijuana cultivator, processor, or retail dispensary. The bill allows the medical director of a retail dispensary to be certified to recommend medical marijuana.²⁹

²⁸ R.C. 4731.30(C)(1)(b)(i) and 4731.303.

²⁹ R.C. 4731.30(I).

COMPARISON TO OTHER STATES

The table below compares the provisions of the bill that could be construed to increase the restrictiveness of occupational regulations with similar laws regulating medical marijuana professionals in the surrounding states. Three of the five surrounding states allow for cultivation, processing, dispensing, and use of medical marijuana. Each of those states utilizes a licensing framework similar to the one that applies in Ohio. Only Michigan prescribes different classes of cultivator licenses (based on number of plants rather than square footage). Pennsylvania and West Virginia both allow for a medical marijuana license to be suspended if the license holder fails to become operational. All three of the surrounding states that allow medical marijuana require training for dispensary employees.

Medical Marijuana Regulations						
	Ohio	Indiana	Kentucky	Michigan	Pennsylvania	West Virginia
Legality of marijuana	Medical only.	Low-THC CBD only (under 0.3%). No clarification as to the legality of manufacturing CBD. (Indiana Office of the Attorney General, Official Opinion 2017-7, November 21, 2017.)	Prohibited. (Ky. Rev. Stat. 218A.1422, 218A.1423, 534.040, 532.020, 532.090, and 534.030.)	Medical and recreational.	Medical only.	Medical only.
License and registration types	Cultivator, processor, testing laboratory, patient, caregiver, retail dispensary, and physician	N/A	N/A	Grower, operator, processor, provisioning center, secure transporter, and safety compliance	Caregiver, dispensary, grower/possessor, practitioner (i.e., physician), and laboratory (35 Pa.	Grower, processor, dispensary, practitioner, caregiver, and laboratory (W. Va.

Medical Marijuana Regulations							
	Ohio	Indiana	Kentucky	Michigan	Pennsylvania	West Virginia	
	(R.C. Chapter 3796).			facility (Mich. Comp. Laws 333.27401).	Cons. Stat. 10231.103 and 28 Pa. Code 1171.23).	Code 16A-6-1, 16A-4-1, 16A-5-2, and 16A-7-4).	
Classes of cultivator licenses	No separate classifications under current law. Under the bill: Stand-alone processor license; Level I – up to 50,000 square feet (or 75,000 square feet with expansion); Level II – up to 6,000 square feet (or 20,000 square feet with expansion). (<i>R.C. 3796.01,</i> <i>3796.03, and</i> <i>3796.18.</i>)	N/A	N/A	 Three grower license classifications based on number of plants: Class A – 500 plants; Class B – 1,000 plants; Class C – 1,500 plants (Mich. Comp. Laws 333.72501). 	No similar provision.	No similar provision.	

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Medical Marijuana Regulations							
	Ohio	Indiana	Kentucky	Michigan	Pennsylvania	West Virginia	
Revocation of inactive licenses	DMC may revoke any of the licenses it administers if the license holder fails to secure a certificate of operation within 18 months of provisional licensure (<i>R.C.</i> <i>3796.03</i>).	N/A	N/A	No similar provision, but state law does not limit the number of licenses issued.	All license holders must, within six months of licensure, submit evidence that the license holder is operational. If the license holder is not operational by that time and does not comply with its plan for correction (which can last no more than 90 days), then the license may be suspended or revoked. (28 Pa. Code 1141.42.)	All license holders must, within six months of licensure, submit evidence that the license holder is operational. If the license holder is not operational by that time and does not comply with its plan for correction (which can last no more than 90 days), then the license may be suspended or revoked. (W. Va. Code R. 64-109-15.)	
Training for dispensary employees	State Medical Board may approve a course of education for employees of a licensed dispensary. If the Board adopts the	N/A	N/A	All marijuana- related license holders must train employees and maintain a training manual addressing safety, guidelines,	All employees of medical marijuana license holders that have direct contact with patients, caregivers, plants, or seeds must	All employees of medical marijuana license holders that have direct contact with patients, caregivers, plants, or seeds must	

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Medical Marijuana Regulations						
Ohio	Indiana	Kentucky	Michigan	Pennsylvania	West Virginia	
training course, then dispensary employees must take the course. (R.C. 3796.20(C) and 4731.304.)			security protocol, product information, dosage and purchasing limits, and education materials (<i>Mich.</i> <i>Admin. Code R.</i> <i>420.602</i>).	complete a training course within 90 days of starting employment (28 Pa. Code 1141.48).	complete a training course within 90 days or starting employment (W. Va. Code. R. 64- 109-21).	

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