SB 859

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 859 (Senator Zirkin)
Judicial Proceedings

Natalie M. LaPrade Medical Cannabis Commission - Advertisements

This bill imposes restrictions on advertisements regarding medical cannabis, including (1) requiring any advertising to be consistent with specified federal and State laws; (2) prohibiting specified advertisements from making any statement that is false or misleading in any material way; and (3) requiring any advertising for medical cannabis or medical cannabis products to include a statement that the product is only for use by a qualifying patient. An advertisement that makes a false or misleading statement is an unfair, abusive, or deceptive trade practice under the Maryland Consumer Protection Act (MCPA), subject to MCPA's civil and criminal penalty provisions.

Fiscal Summary

State Effect: Special fund expenditures increase by $87,400 in FY 2020 for staff and training. Out-years reflect annualization and ongoing staff costs. The bill's imposition of existing penalty provisions does not have a material impact on State finances.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	$0	$0	$0	$0	$0
SF Expenditure	87,400	62,700	54,100	55,900	57,800
Net Effect	($87,400)	($62,700)	($54,100)	($55,900)	($57,800)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: All advertisements for medical cannabis, medical cannabis products, or medical cannabis-related services must be consistent with federal regulations governing prescription drug advertising and marketing under 21 C.F.R. 202.1.

Any advertisement for a grower, processor, dispensary, independent testing laboratory, certifying provider, or third-party vendor may not make any statement that is false or misleading in any material way or is otherwise a violation of MCPA.

Current Law/Background:

Natalie M. LaPrade Medical Cannabis Commission

The Natalie M. LaPrade Medical Cannabis Commission is responsible for implementation of the State's medical cannabis program, which is intended to make medical cannabis available to qualifying patients in a safe and effective manner. The program allows for the licensure of growers, processors, and dispensaries and the registration of their agents, as well as registration of independent testing laboratories and their agents. There is a framework to certify health care providers (including physicians, dentists, podiatrists, nurse practitioners, and nurse midwives), qualifying patients, and their caregivers to provide qualifying patients with medical cannabis legally under State law via written certification. Additionally, recent legislation extended legal protections to third-party vendors authorized by the commission to test, transport, or dispose of medical cannabis, medical cannabis products, and medical cannabis waste.

There are no cannabis-specific advertising and marketing restrictions in the State. However, Chapter 598 of 2018, an emergency bill, made a number of significant reforms to Maryland's medical cannabis program, including requiring the commission to submit a report to the General Assembly on potential rules and regulations governing the advertising and marketing of medical cannabis in the State. The commission submitted this report in December 2018.

Maryland Consumer Protection Act

An unfair, abusive, or deceptive trade practice under MCPA includes, among other acts, any false, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers. The prohibition against engaging in any unfair, abusive, or deceptive trade practice encompasses the offer for or actual sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services; the extension of consumer credit; the collection of consumer debt; or the offer for or actual purchase of

consumer goods or consumer realty from a consumer by a merchant whose business includes paying off consumer debt in connection with the purchase of any consumer goods or consumer realty from a consumer.

The Consumer Protection Division of the Office of the Attorney General (OAG) is responsible for enforcing MCPA and investigating the complaints of aggrieved consumers. The division may attempt to conciliate the matter, issue a cease and desist order, or file a civil action in court. A merchant who violates MCPA is subject to a fine of up to $10,000 for each violation and up to $25,000 for each repetition of the same violation. In addition to any civil penalties that may be imposed, any person who violates MCPA is guilty of a misdemeanor and, on conviction, is subject to a fine of up to $1,000 and/or imprisonment for up to one year.

Federal Prescription Drug Advertising and Marketing Restrictions

The U.S. Food and Drug Administration (FDA) protects public health by assuring the safety, effectiveness, and security of a wide range of products, including human prescription drugs. FDA also advances public health by helping people get the accurate, science-based information they need to use medicines appropriately and improve their health. A drug is "prescription only" when medical professionals must supervise its use because patients are not able to use the drug safely on their own. Because of this, the U.S. Congress laid out different requirements for prescription and nonprescription (over-the-counter or OTC) drugs. The U.S. Congress also gave FDA authority to oversee prescription drug advertisements. The Federal Trade Commission oversees advertisements for OTC drugs. According to FDA's website, FDA regulations establish different requirements depending on an advertisement's content and the media for distribution.

Product claim advertisements are the only type of advertisements that name a drug and discuss its benefits and risks. These advertisements must not be false or misleading in any way. FDA encourages companies to use understandable language throughout product claim advertisements that are directed to consumers. All product claim advertisements, regardless of the media in which they appear, must include certain key components within the main part of the advertisement:

- the name of the drug (both the brand name and the generic name);
- at least one FDA-approved use for the drug; and
- the most significant risks of the drug.

Product claim advertisements must also present the benefits and risks of a prescription drug in a balanced fashion. Print product claim advertisements also have to include a brief summary about the drug that generally includes all the risks listed in the drug's approved prescribing information as well as the following statement: "You are encouraged

to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088." Broadcast product claim advertisements (TV, radio, or telephone) have to include the drug's most important risks ("major statement") presented in the audio (that is, spoken) *and either* all the risks listed in the drug's prescribing information *or* a variety of sources for viewers/listeners to find the prescribing information for the drug.

Federal regulations also specify restrictions for reminder advertisements, help-seeking advertisements, other product claim promotional materials, and risk disclosure requirements for different types of advertisements.

State Fiscal Effect: Special fund expenditures for the commission increase by $87,416 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the cost of hiring one full-time permanent enforcement officer to develop regulations, review and approve advertisements, and generally enforce the bill's requirements. It includes a salary, fringe benefits, one-time start-up costs (including attending a training course for four commission employees), and ongoing operating expenses. The information and assumptions used in calculating the estimate are stated below:

- The commission is responsible for enforcing the bill's requirements.
- To enforce the bill, the commission must review advertisements submitted by regulated entities.
- The commission does not have experience with enforcing advertising regulations and cannot absorb the additional responsibilities under the bill with existing budgeted staff and resources.

	FY 2020	**FY 2021**
Position	1.0	-0.5
Salary and Fringe Benefits	$69,857	$62,005
Training Expenses	12,200	-
Operating Expenses	5,359	625
Total State Expenditures	**$87,416**	**$62,650**

Future year expenditures reflect a full salary with annual increases and employee turnover and going operating expenses. However, it is assumed that, as medical cannabis entities come into compliance, the enforcement officer is able to transition from a full-time to a part-time position after the first year.

The Department of Legislative Services notes that the need for the commission to hire an enforcement officer is based largely on the assumption that the commission must review at least a portion of the advertisements used by medical cannabis entities regulated by the

commission. To the extent that a less robust enforcement effort is implemented, the commission's costs may be less.

OAG can handle enforcement related to unfair, abusive, or deceptive advertising under MCPA with existing resources.

Small Business Effect: The bill may meaningfully affect medical cannabis entities' ability to advertise in the State. Many medical cannabis entities are small businesses. Since marijuana remains illegal at the federal level, there are fewer scientific studies regarding the health effects of the use of medical cannabis. Thus, the content of advertisements under the bill is limited, and the restrictions may negatively affect business operations and finances.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Health; U.S. Food and Drug Administration; Department of Legislative Services

Fiscal Note History: First Reader - February 24, 2019
mag/jc

Analysis by: Kathleen P. Kennedy

Direct Inquiries to:
(410) 946-5510
(301) 970-5510