

Department of Legislative Services
Maryland General Assembly
2011 Session

FISCAL AND POLICY NOTE

House Bill 1051 (Delegate Carter, *et al.*)
Health and Government Operations

Freestanding Pain Management Clinics - Regulation

This bill prohibits a freestanding pain management clinic from operating in the State on or after October 1, 2012, unless licensed under Title 19 of the Health-General Article. The Secretary of Health and Mental Hygiene must adopt regulations to implement the bill, ensure quality of care and patient safety, and establish administrative penalties.

Fiscal Summary

State Effect: General fund expenditures increase by at least \$59,000 in FY 2012 to hire one full-time health facility surveyor to assist with the development of regulations and the implementation of a licensing process. Future year expenditures reflect annualization and inflation. General fund revenues are not affected in FY 2012 but begin to increase in FY 2013 due to licensing fees paid by freestanding pain management clinics. The bill's penalty provisions are not expected to materially affect governmental finances.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
GF Revenue	\$0	-	-	-	-
GF Expenditure	\$59,000	\$74,300	\$78,000	\$81,900	\$86,000
Net Effect	(\$59,000)	(-)	(-)	(-)	(-)

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

Local Effect: The bill's penalty provisions are not expected to materially affect local government finances.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: “Freestanding pain management clinic” means a publicly or privately owned facility that is physically separate from another licensed or regulated clinic or facility and devotes at least 50% of its services to engaging in the treatment of pain by prescribing controlled dangerous substances (CDS). The bill’s provisions do not apply to (1) a medical or dental school or associated outpatient clinic; (2) a hospital, including any outpatient facility or clinic of a hospital; (3) a licensed hospice care facility; (4) a facility maintained or operated by the State; or (5) a clinic maintained or operated by the federal government.

To qualify for a license to operate a freestanding pain management clinic, an applicant must (1) employ a medical director who is a licensed and board-certified physician; (2) satisfy the Secretary of Health and Mental Hygiene that the clinic will be operated in accordance with the bill’s requirements; and (3) pay an application fee. A license is valid for two years and may be renewed for an additional two-year term. The Secretary must set reasonable application and renewal fees not to exceed the administrative costs of the licensing program.

Neither the owner or operator of a freestanding pain management clinic nor an individual with whom the clinic contracts for services may have (1) been denied, by any jurisdiction, a license to dispense a CDS; (2) had such a license restricted; or (3) been subject to disciplinary action by any licensing entity for conduct that was a result of dependency on drugs or alcohol. In addition, a freestanding pain management clinic may not be wholly or partly owned by an individual who has been convicted of or pled *nolo contendere* to any felony or to a misdemeanor relating to the illegal distribution of drugs. The owner or operator of a freestanding pain management clinic must (1) be on-site during at least 33% of the clinic’s total operating hours; (2) require the clinic’s medical director to review for appropriateness of care at least 33% of the total number of the patient’s files of the clinic; and (3) have a written CDS compliance protocol. The Secretary may deny, suspend, restrict, or revoke a license if an applicant or licensee has been convicted of either a crime involving moral turpitude or a felony that relates to the Maryland Medical Assistance Program.

A violator of any provision of the bill 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. (Each day a violation continues is a separate offense.) In addition, the Secretary may impose an administrative penalty of up to \$1,000.

Current Law: Health care facilities that must be licensed by the Department of Health and Mental Hygiene (DHMH) under Title 19 of the Health-General Article include hospitals, ambulatory surgical facilities, freestanding endoscopy facilities, freestanding

facilities utilizing major medical equipment, kidney dialysis centers, and freestanding birthing centers. Doctor's offices and other freestanding health care clinics are not required to be licensed by DHMH.

The Criminal Law Article specifies that (1) with limited exceptions, an individual must be registered by DHMH before manufacturing, distributing, or dispensing a CDS in the State; and (2) an applicant must register separately each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses CDS.

Background: DHMH advises that it is uncertain as to how many freestanding pain management clinics currently operate in the State.

The growing availability and abuse of prescription drugs has resulted in increased attention paid to clinics that supply large amounts of pain medication. In a recent example from February 2011, federal law enforcement officers arrested 20 individuals (including 5 doctors) as a result of a yearlong undercover operation in Florida into the state's "pill mills," which are alleged to have illegally dispensed large amounts of powerful prescription drugs.

State Fiscal Effect: Legislative Services assumes that the regulations can be developed and adopted in fiscal 2012 so that the licensing process can begin on schedule in fiscal 2013. Therefore, general fund revenues are not affected in fiscal 2012, but begin to increase in fiscal 2013 due to licensing fees collected. The bill specifies that fees collected may not exceed the cost of administering the licensing program. However, it is uncertain (1) how many freestanding pain management clinics operate in the State; (2) how many of these will obtain licensure; and (3) what the fee for licensure will be. Thus, general fund revenues cannot be reliably estimated at this time. Future year revenues would reflect fees collected due to ongoing licensures and biennial renewals.

DHMH advises that the unit that will survey freestanding pain management clinics currently has a staffing deficit of 19 positions. Although the number of such clinics in the State is unknown, it is assumed that the bill's requirements cannot be handled with existing resources and that at least one full-time health facility surveyor is needed to conduct the required inspections and investigations. (Legislative Services also notes that, depending on the actual number of freestanding pain management clinics there are in the State, a greater number of additional new staff could be needed.) Thus, general fund expenditures increase by \$58,993 in fiscal 2012, which accounts for the bill's October 1, 2011 effective date. This estimate reflects the cost of hiring one full-time health facility surveyor to assist with the development of regulations and the implementation of a licensing process.

Health Facility Surveyor	1
Salary and Fringe Benefits	\$52,241
Operating Expenses	2,417
One-time Start-up Costs	<u>4,335</u>
Total FY 2012 State Expenditures	\$58,993

Future year expenditures reflect a full salary with 4.4% annual increases, 3% employee turnover, and 1% annual increases in ongoing operating expenses. In addition, Legislative Services advises that, if there in fact are a large number of freestanding pain management clinics in the State, additional funds may be needed in fiscal 2013 for contractual services to complete initial licensures within the timeframe specified by the bill. (It is assumed that DHMH could handle ongoing licensures and renewals with permanent staff thereafter.)

Legislative Services notes that the Laboratories Administration within DHMH advises that it would be required, under the bill, to issue a CDS registration certificate to any freestanding ambulatory pain management clinic that dispenses CDS and that a full-time pharmacist is therefore needed to implement the bill. However, current law already requires that an individual be so registered before dispensing CDS in the State. In addition, the Laboratories Administration advises that it currently issues CDS registration certificates whether or not a facility is licensed by DHMH. (For example, CDS registration certificates are issued to doctor's offices, which are not required to be licensed by DHMH.) Thus, Legislative advises that a full-time pharmacist is not needed to implement the bill.

Any additional complaints, under the bill, regarding health care practitioners can be handled with existing resources by the relevant health occupations boards.

Small Business Effect: Potential meaningful increase in expenditures for small freestanding pain management clinics that are required to become licensed and that may need to make adjustments to staffing and programming in order to qualify for State licensure.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): *The Washington Post*, Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - March 9, 2011
mc/mwc

Analysis by: Jennifer A. Ellick

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