

Department of Legislative Services  
 Maryland General Assembly  
 2015 Session

FISCAL AND POLICY NOTE

House Bill 1134 (Delegate M. Washington)  
 Rules and Executive Nominations

Public Health - Opioid Maintenance Programs - Licensing

This bill specifies that the Secretary of Health and Mental Hygiene must adopt regulations that require the Department of Health and Mental Hygiene (DHMH) to conduct an assessment, on the zip code level, as part of the approval process of an applicant for a license for an opioid maintenance program. The assessment for the proposed opioid maintenance program must include (1) the number of existing slots in opioid maintenance programs in the zip code of the location being applied for and the number of individuals in need of such services in the zip code; (2) the severity of drug-related crime in that zip code; (3) the population at risk of opioid addiction in that zip code; and (4) the need for an opioid maintenance program in the zip code of the proposed location. The applicant must pay for the cost of the assessment.

Fiscal Summary

**State Effect:** General fund expenditures for DHMH increase by *at least* \$28,700 in FY 2016 to develop the assessment methodology and then conduct required assessments as part of the approval process. Likely significant additional expenditures are incurred, as discussed (but not shown) below. General fund revenues increase to reflect reimbursement of assessment costs. Out-year expenditures and revenues reflect elimination of one-time costs, inflation, and annualization.

(in dollars)	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
GF Revenue	\$15,700	\$21,100	\$21,300	\$21,500	\$21,800
GF Expenditure	\$28,700	\$21,100	\$21,300	\$21,500	\$21,800
Net Effect	(\$13,100)	\$0	\$0	\$0	\$0

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

**Local Effect:** None.

**Small Business Effect:** Meaningful.

## Analysis

**Current Law:** “Opioid maintenance program” means a program that (1) is certified by the State; (2) is authorized to treat patients with opioid dependence with a medication approved by the U.S. Food and Drug Administration (FDA) for opioid dependence; (3) complies with applicable federal and State regulations including those for secure storage and accounting of opioid medication imposed by FDA; and (4) has been granted certification for operation by DHMH, the federal Substance Abuse and Mental Health Services Administration (SAMHSA), and the federal Center for Substance Abuse Treatment.

Opioid maintenance programs must act to reduce the chances of diversion of substances from legitimate treatment use under federal law (42 C.F.R. § 8.12(c)(2)). Further, under Maryland regulations, the substances administered, dispensed, or stored at the clinic must be secure and accounted for (Code of Maryland Regulations (COMAR) 10.47.01.04I).

**Background:** Disputes regarding the location of substance abuse and opioid maintenance programs have been well-litigated at both the state and the federal level based on discriminatory treatment of individuals with disabilities. The Americans with Disabilities Act (ADA) provides that “no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subject to discrimination by any such entity” (42 U.S.C. § 1213). Although “disability” does not include “an individual who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use,” it does encompass an individual who “is participating in a supervised rehabilitation program and is no longer engaging in such use” (42 U.S.C. § 12210).

Case law generally indicates that laws that single out opioid maintenance programs for different zoning procedures are facially discriminatory under ADA. This does not mean that these facilities cannot be regulated at all, or even that laws that have a disparate impact on opioid maintenance programs are facially invalid, so long as they are supported by legitimate nondiscriminatory reasons.

There are 66 opioid maintenance facilities in Maryland and approximately 18,000 individuals actively receiving treatment at these facilities. Opioid maintenance programs in Maryland must complete a rigorous application and inspection process to receive a license and treat patients. Applicants must submit applications to both the Office of Health Care Quality (OHCQ) and the Division of Drug Control within DHMH, as well as to SAMHSA and the U.S. Department of Justice Drug Enforcement Agency (DEA). After reviewing the initial application, OHCQ and DEA conduct inspections to ensure that building standards, security requirements, staffing, and program specifics, etc., meet all requirements. Additionally, programs must obtain national accreditation by a qualifying

accreditation organization. OHCQ conducts another inspection after the program has been operational for six months.

In addition to this initial process, Maryland's Behavioral Health Administration conducts ongoing annual COMAR and accreditation compliance inspections, and OHCQ conducts license renewal inspections every two years.

**State Fiscal Effect:** The bill necessitates that DHMH develop a methodology to conduct the required assessments as part of the approval process. It is assumed that the cost to develop the methodology itself is absorbed by the State but that, as required by the bill, each applicant pays for the cost of the assessment associated with its application by reimbursing DHMH. Thus, general fund expenditures increase by at least \$28,745 in fiscal 2016, reflecting only a likely portion of the costs associated with these assessments. DHMH advises that it may be able to develop a methodology to estimate the prevalence of individuals who are at risk for opioid dependence and in need of opioid maintenance treatment services in a particular zip code. DHMH further advises that it expects eight applications annually to be subject to this assessment process; this estimate assumes just six applications in fiscal 2016 due to the bill's October 1, 2015 effective date. The estimate also assumes that the bill's requirements do not apply to the established license renewal process for the 66 facilities already licensed and operating in Maryland.

Specifically, DHMH advises that it needs to contract with a high-level analyst at an hourly rate of \$65.33 to develop the prevalence methodology noted above; the number of hours estimated to do so is 200, for a cost of \$13,066. This cost is not subject to reimbursement. However, for each such application received, a similarly paid analyst needs approximately 40 hours to review the required data (which must be gathered by DHMH). Thus, each assessment likely costs at least \$2,613; these costs must be reimbursed by the applicants. Out-year expenditures and reimbursement revenues reflect eight such assessments each year and inflation.

The bill also requires assessment of data regarding the "severity of drug-related crime" in the zip code of each proposed location for an opioid maintenance program. It is not clear whether such an assessment can be made, as the Department of Public Safety and Correctional Services (DPSCS) and the Governor's Office of Crime Control and Prevention both advise that this data does not exist. Although DPSCS has the address provided by each individual at intake, it is the address where the individual *resided*, not where the crime was *committed*. Further, DPSCS advises that crimes are tracked by the jurisdiction in which the crime was prosecuted, not necessarily where the crime took place. The additional cost to develop a methodology to track such data and then incorporate it into the assessment cannot be reliably estimated and has not been factored into the estimate above.

**Small Business Effect:** DHMH advises that most of the opioid maintenance facilities in Maryland are small businesses. Thus, it is likely that the bill has a meaningful impact on opioid maintenance program applicants because the costs related to application increase by at least \$2,613, and the amount of time required for DHMH to process license applications increases by at least a week.

**Additional Comments:** The bill is silent on several key points. There is no penalty for failure to perform the assessment as required, and there is no guidance on how the assessment (or each component of the assessment) should factor into the decision to grant or deny a license. Thus, it is unclear whether DHMH can actually use information gathered from the assessment in its approval process since current regulations do not contain location-specific restrictions. Aside from the data availability issue discussed above, it is unclear how DHMH might go about evaluating the severity of drug-related crimes because “severity” is not defined and specific crimes are not cited. However, it is clear that the bill increases the amount of time to evaluate and approve applications for opioid maintenance programs licenses by at least a week and increases costs for applicants significantly.

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### **Additional Information**

**Prior Introductions:** None.

**Cross File:** SB 199 (Senator Conway) - Finance.

**Information Source(s):** Department of Legislative Services

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