SB 199

Department of Legislative Services

Maryland General Assembly
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FISCAL AND POLICY NOTE
Revised

Senate Bill 199 (Senator Conway)
Finance Health and Government Operations

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. DHMH may not deny a license for an opioid maintenance program based on information obtained from the required 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 *a portion* of the required assessments as part of the approval process. Likely significant additional expenditures are incurred, as discussed below; certain elements of the assessment are either not feasible or may be cost prohibitive. Out-year expenditures reflect elimination of one-time costs, inflation, and annualization. Revenues are not affected.

Local Effect: None.

Small Business Effect: Potential meaningful, as discussed below.

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 costs to develop the methodology and assess each application are absorbed by the State. 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. 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. Out-year expenditures reflect eight such assessments each year and inflation.

However, 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. It is also unclear how DHMH might go about evaluating the severity of drug-related crimes because "severity" is not defined and specific crimes are not cited. The Department of Public Safety and Correctional Services (DPSCS) and the Governor's Office of Crime Control and Prevention both advise that zip-code level crime 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. Thus, 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. If feasible to do so, costs would likely be prohibitive.

Small Business Effect: The bill *requires* the process for approval of a license for an opioid maintenance program to include such an assessment; however, because certain elements of the assessment are likely not feasible, the bill may result in a *de facto* barrier to any new opioid maintenance programs being able to become licensed. The bill also specifically *prohibits* DHMH from using the information obtained from the assessment to *deny* a license, but how the assessment is otherwise intended to factor into approval decisions is unclear.

Additional Information

Prior Introductions: None.

Cross File: HB 1134 (Delegate M. Washington) – Rules and Executive Nominations.

Information Source(s): Department of Health and Mental Hygiene, U.S. Centers for Disease Control and Prevention, Department of Legislative Services

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Analysis by: Kathleen P. Kennedy

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