SB 1060

Department of Legislative Services

Maryland General Assembly
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FISCAL AND POLICY NOTE
First Reader

Senate Bill 1060 (Senator Conway)
Finance

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 (1) conduct an assessment as part of the approval process of an applicant for a license for an opioid maintenance program and (2) issue a written report regarding analysis of decisions to approve or deny a license for an opioid maintenance program. The bill also requires the Secretary to adopt a regulation, by March 31, 2017, that increases the initial application fee for a license for an opioid maintenance program by 10%.

Fiscal Summary

State Effect: General fund expenditures for DHMH increase by *at least* $33,800 in FY 2017 to develop certain components of the assessment methodology and then conduct a *portion* of the required assessments as part of the approval process. Out-year expenditures reflect elimination of one-time costs, inflation, and annualization. It is unclear whether data exists to fulfill other components of the required assessments, as discussed below; costs to track that data are likely significant and are not reflected below. General fund revenues increase by almost $600 annually, beginning in FY 2018, from the 10% increase in the initial application fee.

(in dollars)	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
GF Revenue	$0	$600	$600	$600	$600
GF Expenditure	$33,800	$22,300	$22,500	$22,700	$23,000
Net Effect	($33,800)	($21,700)	($22,000)	($22,200)	($22,400)

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

Local Effect: None.

Small Business Effect: Potential meaningful, as discussed below.

Analysis

Bill Summary: The assessment for the proposed opioid maintenance program must include (1) an appropriate catchment area for the proposed location of the program using a zip code, a one-mile radius, or other metric as determined by the Secretary; (2) the number of existing slots in opioid maintenance programs in the catchment area of the location being applied for and the number of individuals in need of such services in the catchment area; (3) the severity of drug-related crime in that catchment area; (4) the population at risk of opioid addiction in that catchment area; and (5) the need for an opioid maintenance program in the catchment area of the proposed location.

The regulations must also include a requirement that the Secretary issue a written report that provides an analysis of either (1) the sustainability of the opioid maintenance program if a license is approved *or* (2) the saturation of opioid maintenance programs in the catchment area of the proposed location if a license is denied.

The bill also makes conforming changes to existing law relating to licensure of opioid maintenance programs.

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 CFR § 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) 10.47.01.04).

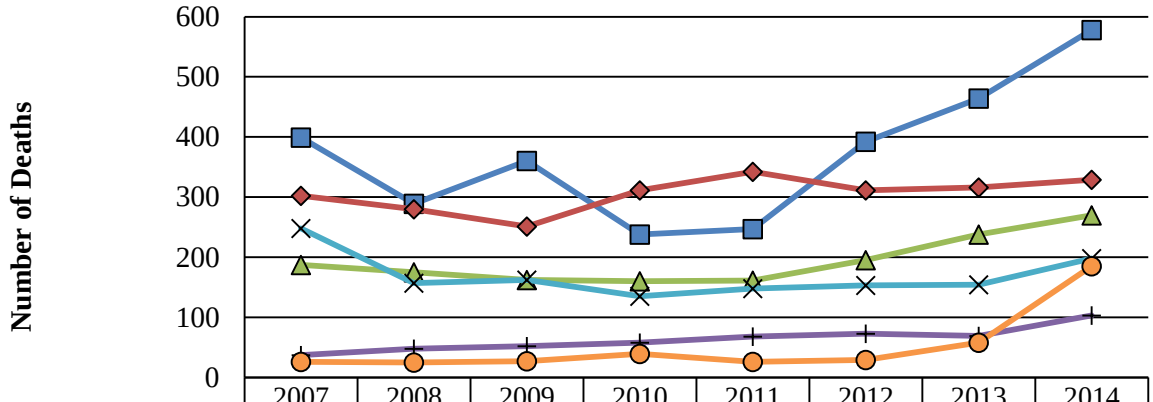
Background: DHMH's 2015 report, titled *Drug and Alcohol-related Intoxication Deaths in Maryland*, indicated that drug- and alcohol-related intoxication deaths in Maryland totaled 1,039 in 2014, a 21% increase since 2013 and a 60% increase since 2010. Of all of the intoxication deaths that occurred, 887 deaths (86%) were opioid related, including

deaths related to heroin, prescription opioids, and nonpharmaceutical fentanyl. Opioid-related deaths increased by 76% between 2010 and 2014.

Preliminary data from DHMH shows that the number of intoxication deaths continued to increase in 2015, with 889 deaths from January through September 2015 compared to 767 deaths during the same period in 2014 (a 16% increase).

Exhibit 1 shows trends in drug- and alcohol-related intoxication deaths in Maryland from 2007 to 2014.

Exhibit 1
Drug- and Alcohol-related Intoxication Deaths by Selected Substances
2007-2014



	2007	2008	2009	2010	2011	2012	2013	2014
Heroin	399	289	360	238	247	392	464	578
Prescription Opioids	302	280	251	311	342	311	316	329
Alcohol	187	175	162	160	161	195	238	270
Benzodiazepines	37	48	52	58	68	73	69	103
Cocaine	248	157	162	135	148	153	154	198
Fentanyl	26	25	27	39	26	29	58	185

Source: Department of Health and Mental Hygiene

According to DHMH, "opioid maintenance therapy" is the use of narcotic drugs to treat opioid use disorders. The Behavioral Health Administration (BHA) and the Office of Health Care Quality (OHCQ) license and provide joint oversight over opioid maintenance programs.

Opioid maintenance programs must complete a vigorous application and inspection process to receive a license and treat patients. Applicants must submit applications to both 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, BHA conducts ongoing annual COMAR and accreditation compliance inspections, and OHCQ conducts license renewal inspections every two years.

BHA advises that there are 74 licensed opioid maintenance programs in the State. With 32 programs, Baltimore City has significantly more programs than other jurisdictions in the State. Anne Arundel County has 8 licensed programs; the remaining counties have 5 or fewer programs each.

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 USC § 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 USC § 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.

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* $33,796 in fiscal 2017, reflecting only a likely *portion* of the costs associated with these assessments. Costs could also be higher depending on how the Secretary defines the "catchment area" for each proposed location. 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; other metrics, such as a one-mile radius, may

not be feasible. DHMH further advises that it expects eight applications annually to be subject to this assessment process, with just six applications in fiscal 2017 due to the bill's October 1, 2016 effective date. The estimate also assumes that the bill's requirements do not apply to the established license renewal process for the 74 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 $68.97 to develop the prevalence methodology noted above; the number of hours estimated to do so is 250, for a cost of $17,243. 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 $2,759. Out-year expenditures reflect eight such assessments each year and inflation.

The bill also requires assessment of data regarding the "severity of drug-related crime" in the catchment area of each proposed location for an opioid maintenance program. However, depending on the catchment area definition adopted by the Secretary, 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) advises that zip-code-level crime data does not exist. It is also likely that no data exists at the one-mile-radius level. 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*; such addresses are also self-reported and are not required to be provided. DPSCS advises that crimes are tracked by the jurisdiction in which the crime was prosecuted, not necessarily where the crime took place. Thus, some data is available if the catchment area is defined by the *jurisdiction* of the location for a proposed opioid maintenance program. Any 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.

The fee for initial licensure for opioid maintenance programs is $700. The Secretary must adopt regulations that establish a 10% increase in the initial application fee by March 31, 2017. For the purposes of this analysis, it is assumed that this fee increase is likely effective beginning in fiscal 2018. However, to the extent that the Secretary promulgates regulations more quickly, general fund revenues for fiscal 2017 may increase minimally. Thus, general fund revenues increase by $560 annually, beginning in fiscal 2018, from a $70 increase in initial licensure fees for each of the eight estimated new applications.

Small Business Effect: The bill requires the process for approval of a license for an opioid maintenance program to include an assessment of several specified factors. As discussed above, at least one of these factors may not be feasible to assess; thus, the bill may result

in a *de facto* barrier to any new opioid maintenance programs being able to become licensed.

Additional Information

Prior Introductions: HB 861 of 2015, a similar bill, was referred to the House Health and Government Operations Committee, but no further action was taken.

Cross File: HB 1416 (Delegate M. Washington) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Department of Public Safety and Correctional Services, Department of Legislative Services

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