HB 1276

Department of Legislative Services

Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1276 (Delegate Barron, *et al.*)
Health and Government Operations

Health - Patient-Centered Opioid Addiction Treatment Act

This bill requires a certified opioid treatment program (OTP), by January 1, 2018, to establish treatment protocols that are consistent with specified federal standards and that include (1) a requirement that the program conduct a periodic review of a patient's treatment plan with the patient, including consideration of opioid abstinence when appropriate; (2) appropriate clinical use of any drug or treatment approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment, including opioid maintenance therapy, detoxification, overdose reversal, relapse prevention, and long-acting nonaddictive medication-assisted treatment (MAT) medications; (3) appropriate use of overdose reversal, relapse prevention, counseling, and ancillary services; (4) submission of a plan regarding training and experience requirements for providers who treat and manage opiate-dependent patients; (5) a requirement that a provider who prescribes opioid medication must periodically query the Prescription Drug Monitoring Program (PDMP) for patient data; and (6) a requirement to inform a patient about all available FDA-approved opioid treatment medication options and obtain the patient's informed consent before prescribing a medication. An OTP must submit a copy of the required protocols to the Department of Health and Mental Hygiene's (DHMH) Office of Health Care Quality (OHCQ).

Fiscal Summary

State Effect: OHCQ can handle the bill's requirements with existing budgeted resources. Revenues are not affected.

Local Effect: Local health departments (LHDs) that offer OTPs can likely handle the bill's requirements with existing budgeted resources. Revenues are not affected.

Small Business Effect: Minimal.

Analysis

Bill Summary: The bill specifies that "opioid treatment program" has the same meaning as 42 C.F.R. § 10.09.33.01. However, the correct citation for this definition under federal regulations is 42 C.F.R. § 8.2, which defines "opioid treatment program" as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under the federal Controlled Substances Act.

The bill requires OTP programs to establish treatment protocols that are consistent with Section 303 of the federal Comprehensive Addiction and Recovery Act (CARA) and standard medical practices for OTPs.

Current Law/Background:

Comprehensive Addiction and Recovery Act

President Barack Obama signed CARA on July 22, 2016. The law authorizes over $181 million each year in new funding. Among other provisions, CARA:

- authorizes grants to federally qualified health centers, OTPs, and practitioners who offer office-based MAT to expand access to naloxone through co-prescribing;
- reauthorizes funding for the National All Schedules Prescription Electronic Reporting Act for states to improve or maintain a PDMP;
- directs the U.S. Secretary of Health and Human Services to develop recommendations regarding education programs for opioid prescribers;
- authorizes grants to states to expand evidence-based MAT in areas with high rates of opioid and heroin use;
- authorizes grants to state substance abuse agencies to carry out pilot programs for nonresidential treatment of pregnant and postpartum women; and
- authorizes grants to states to implement integrated opioid abuse response initiatives, including expanding availability of MAT and behavioral therapy for opioid addiction.

Section 303 of CARA expands office-based treatment by allowing nurse practitioners and physician assistants to prescribe buprenorphine for opioid addiction for five years (until October 1, 2021). Physician assistants and nurse practitioners must complete 24 hours of training to be eligible for a waiver to prescribe buprenorphine and must be supervised by or work with a qualifying physician if required by state law. Section 303 also specifies the training components for qualifying physicians. Additionally, office-based treatment practitioners must have the capacity (including necessary training) to either provide directly, or by referral, all drugs approved by FDA for the treatment of opioid use disorders, including for maintenance, detoxification, overdose reversal, and relapse prevention.

Opioid Treatment Programs

"Opioid treatment program" is not defined in statute. However, the Code of Maryland Regulations (COMAR) 10.47.02.11 defines "opioid maintenance therapy" as a program that uses pharmacological interventions, including full and partial opiate agonist treatment medications, to provide treatment, support, and recovery to opioid-addicted patients. Such programs must comply with federal regulations as specified under 42 C.F.R. § 8.

OTPs 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 the federal Substance Abuse and Mental Health Services Administration 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, the Behavioral Health Administration (BHA) conducts ongoing annual COMAR and accreditation compliance inspections, and OHCQ conducts renewal inspections every two years.

BHA advises that there are 82 OTPs in the State. With 34 programs, Baltimore City has significantly more programs than other jurisdictions in the State. Anne Arundel County has 9 programs; Baltimore County has 7 programs; and the remaining counties have 5 or fewer programs each. According to BHA, five LHDs (Anne Arundel, Frederick, Montgomery, Prince George's, and Wicomico counties) have OTP programs.

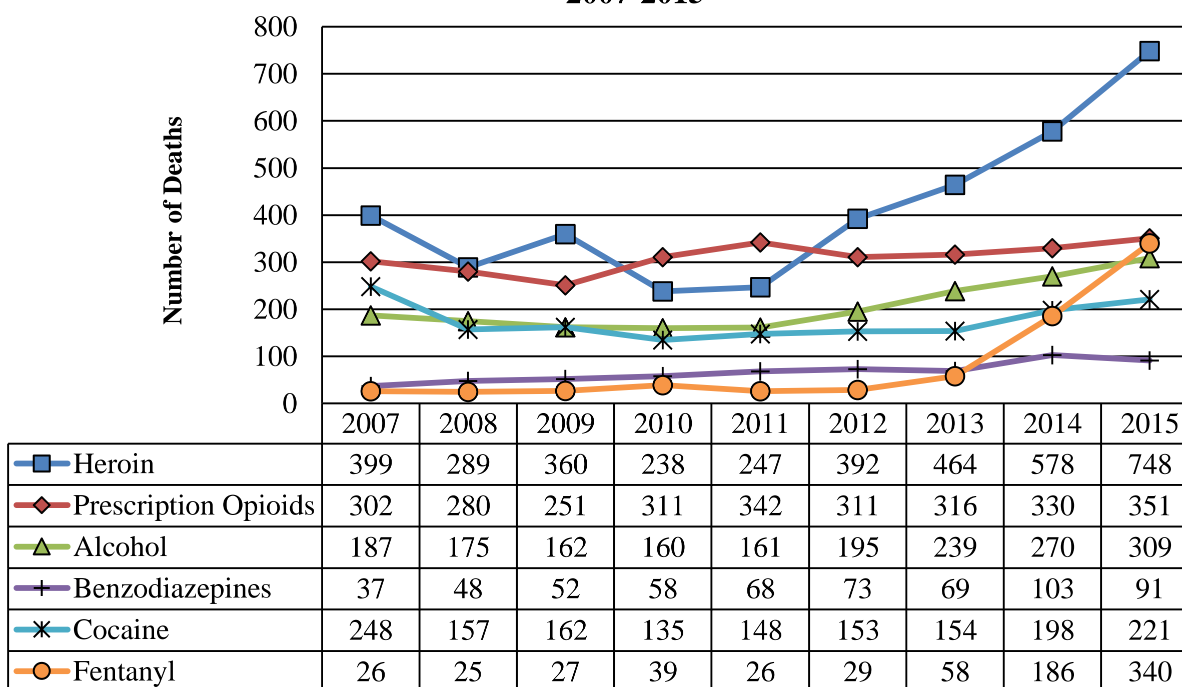
Prescription Drug Monitoring Program

Chapter 166 of 2011 established PDMP with the aim to reduce prescription drug misuse and diversion by creating a secure database of all Schedule II through V controlled dangerous substances prescribed and dispensed in the State. PDMP can make data on prescription opioids available to health care providers, pharmacists, patients, health occupations licensing boards, specific DHMH administrations, law enforcement, and PDMPs in other states. Chapter 147 of 2016 expanded PDMP to require all Maryland-licensed prescribers and pharmacists to register with PDMP by July 1, 2017. Beginning in 2018, providers will be required to use PDMP before prescribing opioids or benzodiazepines, a group of sedative medications that present significant overdose risks, particularly when prescribed and used in combination with opioids.

Opioid-related Deaths

According to DHMH's 2016 report, *Drug and Alcohol-Related Intoxication Deaths in Maryland*, drug- and alcohol-related intoxication deaths in Maryland increased for the fifth year in a row, totaling 1,259 deaths in 2015 – a 21% increase since 2014 and an all-time high. Of all intoxication deaths, 1,089 deaths (86%) were opioid related, including deaths related to heroin, prescription opioids, and nonpharmaceutical fentanyl. Opioid-related deaths increased by 23% between 2014 and 2015 and have more than doubled since 2010. Heroin- and fentanyl-related deaths have risen particularly sharply. The number of heroin-related deaths increased by 29% between 2014 and 2015 and has more than tripled between 2010 and 2015. The number of fentanyl-related deaths increased by 83% between 2014 and 2015 and has increased nearly twelvefold since 2012. **Exhibit 1** shows trends in drug- and alcohol-related intoxication deaths in Maryland from 2007 through 2015.

Exhibit 1
Total Number of Drug- and Alcohol-related Intoxication Deaths By Selected Substances in Maryland
2007-2015



	2007	2008	2009	2010	2011	2012	2013	2014	2015
Heroin	399	289	360	238	247	392	464	578	748
Prescription Opioids	302	280	251	311	342	311	316	330	351
Alcohol	187	175	162	160	161	195	239	270	309
Benzodiazepines	37	48	52	58	68	73	69	103	91
Cocaine	248	157	162	135	148	153	154	198	221
Fentanyl	26	25	27	39	26	29	58	186	340

Source: Department of Health and Mental Hygiene

Preliminary data from DHMH indicates that the number of intoxication deaths increased at an even steeper rate in 2016, with 1,468 deaths from January through September 2016

compared to 904 deaths during the same period in 2015 (a 62% increase). Additionally, for January through September 2016, the number of heroin-related deaths increased 72%, and the number of fentanyl-related deaths increased nearly fourfold compared to the same period in 2015.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Association of County Health Officers; Department of Health and Mental Hygiene; Department of Legislative Services

Fiscal Note History: First Reader - March 6, 2017
fn/ljm

Analysis by: Sasika Subramaniam

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