

Prescription Opioids: Prescriber Education and the Maryland Prescription Drug Monitoring Program

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Opioids are a class of chemically-related drugs that include both legal prescription drugs and illegal drugs such as heroin. Used correctly, prescription opioids are helpful for people suffering from chronic pain or pain from surgery. However, opioids also cause feelings of euphoria and pleasure in addition to the pain relief and can cause physical dependence. This report responds to the Council’s request to examine State and County prescriber education efforts and to review the Maryland Prescription Drug Monitoring Program (PDMP). OLO found that while both the County and the State have made investments towards preventing opioid misuse and overdoses in recent years, prescriber education has not been a focus of their efforts. OLO also found that the Maryland PDMP has implemented or is in the process of implementing the majority of recommended practices for maximizing effectiveness.

Background on Prescription Opioids and the Legal Framework for Prescribing. Opioids that have accepted medical uses are classified as prescription drugs. Federal law establishes that these drugs may only be dispensed upon written prescription of a practitioner who has been licensed by law to administer the drug. In addition, most prescription opioids are also classified as “controlled substances” and are subject to special regulations for prescribing under the United States Controlled Substances Act (CSA).

All opioids, including prescription opioids, carry significant risks due to their potential to cause physical dependence on the drugs, shown below. However, most prescribers receive little training on the appropriate prescribing of opioids. Furthermore, prescription opioids are often “diverted,” or redirected for illegitimate purposes through theft or other illegal practices.

Risks Associated with Prescription Opioid Use

Prescription Opioid Misuse	One in 20 individuals in the United States are estimated to have “misused” prescription opioids in the last year, meaning that they used them in ways not intended by a doctor
Opioid Use Disorders	Nationally, just under one in 100 individuals are estimated to have experienced a prescription opioid use disorder in the last year, meaning they were physically dependent on the drugs and experienced significant impairments as a result of using them
Prescription Opioid Overdoses	Opioids depress the central nervous system functioning and corresponding key physical processes such as respiratory rate; nearly 19,000 individuals in the United States died from drug overdoses involving prescription opioids in 2014

Similar to nationwide trends, Maryland has experienced very large increases in opioid overdoses in recent years – total State opioid-related overdose deaths nearly quadrupled between 2010 and 2016, primarily due to increases in deaths related to heroin and fentanyl. Montgomery County has experienced lower rates of fatal overdoses related to opioids compared with other Maryland counties. However, County trends are similar to Statewide trends in that heroin-related and fentanyl-related deaths have shown sharp increases in recent years.

Prescriber Education in the United States. As part of efforts to address the growing opioid epidemic, the Federal government and other organizations offer a significant number of guidelines and other educational resources to practitioners on responsible prescribing of opioids. OLO identified 32 states, as well as Washington, D.C. that have requirements, either in statute, regulation, or board guidelines, for practitioners to obtain a certain number of opioid or pain management related continuing medical education (CME) credits as a condition of license application or renewal.

Prescriber Education in Maryland and Montgomery County. The Maryland Behavioral Health Administration (BHA) is the agency responsible for addressing substance use issues. The BHA’s primary strategy on opioid prescribing education has been to disseminate prescribing resources and guidelines. In addition, the BHA is working with the University of Maryland, School of Pharmacy to develop a process for identifying and conducting targeted outreach and education. As shown below, two out of the five Maryland State medical boards have established requirements for licensees to complete CME specific to proper prescribing as a condition of license renewal. However, State law expressly prohibits the Board of Physicians from requiring completion of a specific course for license renewal.

Board	Requirement
Board of Physicians	Previous opioid prescribing CME requirement was abolished due to legislation passed by the Maryland General Assembly in 2016
Board of Nursing	No requirement
Board of Dental Examiners	Dentists must complete a two-hour Board-approved course on proper prescribing and disposal of prescription drugs every other renewal cycle
Board of Podiatric Medical Examiners	Beginning with the 2018-2019 renewal cycle, podiatrists will be required to complete one CME credit per renewal cycle on prescribing pain medications
Board of Veterinary Medical Examiners	No requirement

Montgomery County’s efforts specific to opioid misuse prevention have been focused on outreach and education efforts that target the public. Executive Branch staff report that DHHS has completed a prescriber education campaign in the past but found that it was difficult to find methods to contact prescribers.

Maryland Prescription Drug Monitoring Program. Forty-nine states (including Maryland) and the District of Columbia have created prescription drug monitoring programs (PDMPs) in an effort to prevent harmful use of prescription drugs, including prescription opioids. PDMPs collect and store data on the prescribing and dispensing of specified drugs in an electronic database, which is used to (1) inform prescribing and dispensing decisions, (2) support the investigative efforts of law enforcement, professional licensing boards and other bodies, and (3) inform public health efforts. Maryland’s PDMP was established in 2011 by Maryland statute and became fully operational in December of 2013.

The evidence on the effectiveness of PDMPs in reducing prescription drug misuse is mixed, but experts have identified a variety of recommended practices for improving data quality and increasing utilization. Maryland’s PDMP has implemented or is in the process of implementing the majority of recommended practices. Of note, Maryland enacted mandates in 2016 that that will require all prescribers to register for the PDMP by July 2017 and access prescription monitoring data before initially prescribing certain drugs (including opioids) by July 2018.

OLO’s Recommended Discussion Issues. Overall, OLO finds that additional opportunities exist to prevent opioid misuse at the County and State levels. OLO offers two recommended discussion issues for the Council:

County Role in Prescriber Outreach and Education. Currently, the County’s opioid misuse prevention efforts do not include a prescriber outreach or education component. The Council may wish to discuss with Executive Branch representatives whether opportunities exist to work with State agencies or local chapters of professional associations to link prescribers with educational resources on opioids and the State’s PDMP.

State Law on Prescriber Education. Currently, two out of the five Maryland State medical boards have established requirements for licensees to complete CME specific to proper prescribing as a condition of license renewal, and State law prohibits the Board of Physicians from establishing such a requirement. The Council may wish to discuss with relevant stakeholders in the County the benefits and drawbacks of requiring mandatory prescriber education, including which groups of practitioners should be included. If the Council determines that prescriber education should be mandatory, it could work with State legislators and other stakeholders to establish requirements within State law.

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Introduction

In recent years, the abuse of prescription opioids has become a public health epidemic. According to the Director of the National Institute of Drug Abuse, “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem...including the drastic increases in the number of prescriptions written and dispensed and the greater social acceptability for using medications for different purposes.” This report summarizes two strategies to combat the prescription opioid problem – prescriber education and drug monitoring programs, including best practices and what approaches the state/county are implementing.

OLO staff members Natalia Carrizosa and Kristen Latham completed this study. OLO gathered information through document reviews, data analysis, and interviews with County Executive Branch staff, Maryland State employees, and community members. OLO received a high level of cooperation from everyone involved in this study and appreciates the information and insights shared by all who participated:

State of Maryland

Audrey Clark, James Polek, & Sandra Yankosky, Office of Controlled Substances Administration
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Eva Schwartz, Board of Podiatric Medical Examiners
Deena Speights-Napata & Brian K. Logan, Board of Pharmacy
Sandi Van Horn, Board of Physicians

Montgomery County

Fariba Kassiri, County Executive’s Office
Director Uma Ahluwalia, Raymond Crowel, & Ben Stevenson, Health and Human Services
Steve Chaikin, State’s Attorney’s Office
Director Robert Green, Corrections and Rehabilitation
Chief Russ Hamill, Police Department
Chief Robert Lindsey, Fire and Rescue Services
Elizabeth Rathbone, Montgomery County Public Schools

Other Stakeholders

Judge Marielsa Bernard
Susan D’Antoni & Lynne Diggs, MedChi
April Kaplan, Collaboration Council
Fred Silverman & the Montgomery County Alcohol and Other Drug Abuse Advisory Council
Patricia Winters, Phoenix Rising

Chapter 1. Prescription Opioids and Public Health

Opioids are a class of chemically-related drugs that interact with opioid receptors on nerve cells in the body and brain. Opioids can relieve pain and can cause feelings of euphoria and pleasure. Certain opioids can be legally prescribed by doctors, while others are illicit drugs such as heroin and illegally-produced fentanyl. All opioids, including prescription opioids, carry significant risks.

One in 20 individuals in the United States are estimated to have “misused” prescription opioids in the last year based on a 2015 survey, meaning that they used the drugs in ways not intended by a doctor. Just under one in 100 individuals experienced a prescription opioid use disorder, meaning that they were physically dependent on the drugs and experienced significant impairments as a result of using them. Nationally, 19,000 individuals died from drug overdoses involving prescription opioids in 2014, the most recent year for which data were available.

Compared with the State of Maryland as a whole, Montgomery County has experienced lower numbers of overdose deaths involving prescription opioids and heroin relative to its population. However, County-level trends over time mirror statewide trends, in that heroin-related and fentanyl-related deaths have shown significant increases in the past four years. This chapter provides background information on prescription opioids, opioid misuse, opioid use disorders, and opioid overdose deaths, and is organized as follows:

- **Section A** describes what opioids are and risks associated with them; and
- **Section B** provides data on the problems associated with prescription opioids.

A. Opioid Definition and Risks Associated with Use

The term “opioids” refers to a class of drugs that act by attaching to opioid receptors in the brain and spinal cord and blocking the transmission of pain messages to the brain. Used correctly, opioids are helpful for people suffering from chronic pain or pain from surgery. Opioids also cause initial feelings of euphoria and pleasure in addition to the pain relief.

Opioids include drugs derived naturally from opium, a substance produced by opium poppy plants, or can be synthetic and semi-synthetic drugs produced through chemical synthesis in a laboratory. Specific types of opioids include:

- **Prescription opioids** can be legally prescribed by doctors and include hydrocodone (Vicodin), oxycodone (Oxycontin, Percocet), morphine (Kadian, Avinza), codeine, methadone, and others.
- **Fentanyl** is a special synthetic opioid that doctors can legally prescribe for severe pain, such as advanced cancer pain. Fentanyl is 50 to 100 times more potent than morphine. Fentanyl is also produced and sold illegally, a trend which is on the rise nationally.
- **Heroin** is a semisynthetic opioid derived from morphine that is illegal in the United States and is typically used for recreational purposes.¹

¹ “Opioid Basics,” Centers for Disease Control and Prevention Website, March 14, 2016, < <http://www.cdc.gov/drugoverdose/opioids/index.html> > accessed 10/13/2016.

Risks Associated with Prescription Opioid Use. Data from the 2012 National Health Interview Survey (NHIS) indicated that 23 million adults experienced severe pain over any given three-month period and 25 million adults experienced daily chronic pain in the United States.² Prescription opioids have been shown to be effective for treating short-term and long-term pain for some individuals.³ However, prescription opioid use is also associated with significant risks, described in the following table.

Table 1-1. Risks Associated with Prescription Opioid Use

Problem	Description
Prescription Opioid Misuse (or Nonmedical Use)	Misuse of prescription drugs occurs when individuals take drugs for reasons or in ways not intended by a doctor, such as in greater amounts or for a longer time than intended, and when individuals use drugs that were not prescribed for them. As noted above, opioids can produce a sense of pleasure and euphoria, which can lead to misuse by individuals. Individuals who have misused prescription opioids are substantially more likely than others to begin using heroin, though the vast majority of prescription opioid users do not go on to use heroin. ⁴
Opioid Use Disorders	<p>Opioid use can lead to changes in the brain that result in physical dependence on the drugs, which means that a person can develop a tolerance to the drug and experiences withdrawal symptoms when ceasing use of the drugs. Physical dependence can occur both among patients taking opioid prescriptions as directed as well as individuals who misuse opioids.</p> <p>An opioid use disorder is a condition that causes an individual to experience significant impairments such as health problems, disability, and/or a failure to fulfill work, school or family responsibilities as a result of recurrent drug use. Symptoms of opioid use disorders include:⁵</p> <ul style="list-style-type: none"> • Strong desire for opioids; • Inability to control or reduce use of opioids; • Continued use despite interference with social functioning and fulfillment of obligations; • Spending significant amounts of time to obtain and use opioids; • Use of larger amounts over time; • Development of tolerance, or a diminished response to the drug; and • Withdrawal symptoms when stopping or reducing use, such as vomiting or diarrhea.
Prescription Opioid Overdoses	Opioids depress central nervous system functioning and corresponding key physical processes such as respiratory rate. This can cause the individual to stop breathing, potentially resulting in detrimental damage to the brain and spinal cord and even death. Combining opioids with alcohol and sedative medications further increases the risk of death. ⁶

² "NIH Study Shows Prevalence of Chronic or Severe Pain in U.S. Adults," American Pain Society Website, August 18, 2015, < <http://americanpainsociety.org/about-us/press-room/nih-study-shows-prevalence-of-chronic-or-severe-pain-in-u-s-adults> > accessed 1/27/2017.

³ Huber, E., Robinson, R.C., Noe, C.E., Van Ness, O., "Who Benefits from Opioid Therapy? Rethinking the Question of Opioid Misuse Risk," *Healthcare* 2016, 4, 29, p. 4, < <http://www.mdpi.com/2227-9032/4/2/29> > accessed 1/27/2017.

⁴ Pradip K. Muhuri, P.K., Gfroerer, J.C, Davies, M.C., "Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States," Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality Data Review, August 2013 < <http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm> > accessed 10/26/2016.

⁵ "Substance Use Disorders," Substance Abuse and Mental Health Services Administration Website, October 27, 2015, < <http://www.samhsa.gov/disorders/substance-use> > accessed 10/21/2016.

⁶ "Information sheet on opioid overdose," World Health Organization Website, November 2014, < http://www.who.int/substance_abuse/information-sheet/en/ > accessed 10/25/2016.

B. Data on Prescription Opioid Misuse and Overdose

Several sources of national, state and local data offer information on the prevalence of prescription opioid misuse and opioid use disorders, how individuals who misuse prescription opioids obtain them, and trends in fatal opioid overdoses. In many cases, national data are more complete, more recent and/or more precise than state- or local-level data. The remainder of this section describes data on the public health impacts of prescription opioids, including national data as well as state- and local-level data where appropriate.

1. Data on Prescription Opioid Misuse and Disorders

The National Survey of Drug Use and Health (NSDUH) is an annual survey sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA). The NSDUH surveys the civilian, noninstitutionalized population of the United States aged 12 years and older and includes questions regarding prescription drug misuse for several categories of prescription “psychotherapeutic” drugs, including pain relievers such as prescription opioids. The 2015 survey collected data from 68,073 interviews.⁷

Data from the 2015 NSDUH displayed in Table 1-2 below indicate that nationally, approximately one in 20 individuals aged 12 and over misused prescription pain relievers in the last year. The data show that individuals aged 18 to 25 and individuals experiencing mental illness are more likely than other groups to misuse prescription opioids, one in 12 and one in nine, respectively. Just under one in 100 individuals experienced a prescription pain reliever use disorder, according to survey data.

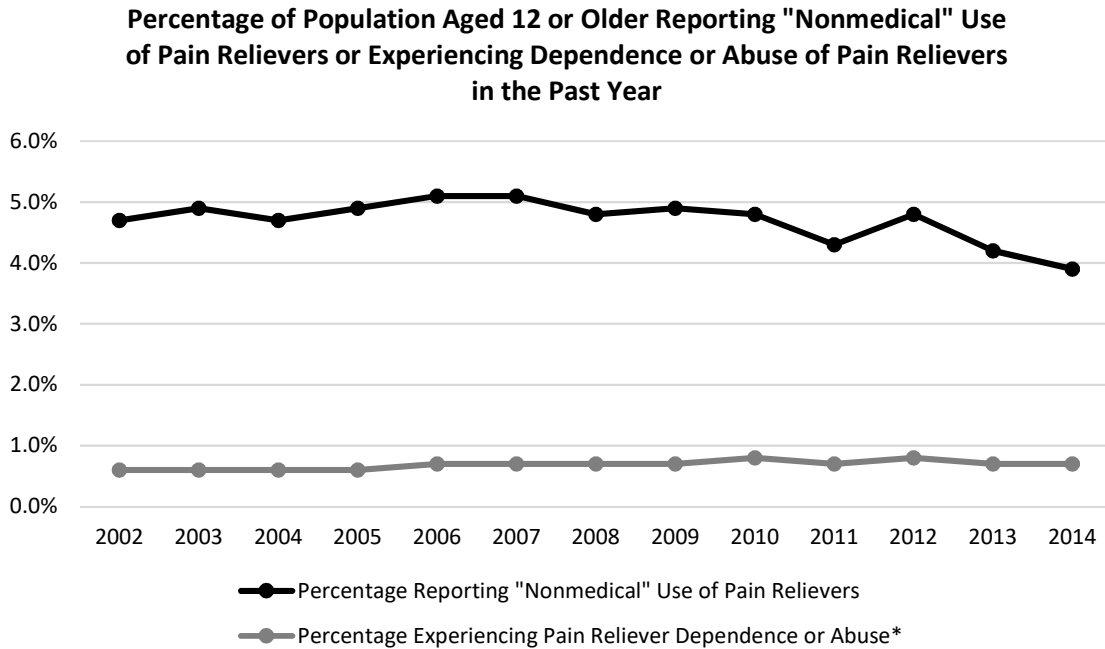
Table 1-2. 2015 National Prevalence Rates for Past-Year Prescription Pain Reliever Misuse and Use Disorders

Population Group	National Prevalence Rate
Prescription Pain Reliever Misuse	
Population Age 12 and Older	5%
Ages 12-17	4%
Ages 18-25	9%
Ages 26 or older	4%
Individuals Aged 18 or Older By Mental Illness Status	
No Mental Illness (82.1% of population)	3%
Any Mental Illness (17.9% of population)	11%
Serious Mental Illness (4.0% of population)	15%
Prescription Pain Reliever Use Disorder	
Population Age 12 and Older	<1%

Source: “Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health,” Substance Abuse and Mental Health Services Administration

⁷ “Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health,” Substance Abuse and Mental Health Services Administration NSDUH Data Review, September 2016, < <http://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.pdf> >.

The chart below displays trend data on “nonmedical” use of pain relievers and pain reliever “dependence” and “abuse” for previous years. Because of changes to the survey, 2015 data are not comparable with data from previous years. In particular, previous surveys asked respondents about “nonmedical use” of prescription drugs instead of “misuse” of prescription drugs.⁸ Additionally, while the 2015 survey estimates the number of individuals experiencing substance use “disorders,” previous surveys instead estimate levels of substance “dependence” and “abuse.” The data below show that “nonmedical” use of prescription pain relievers decreased somewhat between 2007 and 2014. Trend data on pain reliever dependence or abuse do not show a clear upward or downward trend over time.



Source: Results from the 2014 National Survey on Drug Use and Health: Detailed Tables, SAMHSA, Tables 7.2B and 7.50B

The NSDUH also asks questions regarding how individuals who misused prescription drugs obtained those drugs. The data indicate that most individuals who misused prescription pain relievers obtained them from either health care providers or friends and relatives. However, one source of state-level data contradicts this finding. Data from the 2015 Maryland Public Opinion Survey on Opioids, a non-representative online survey of nearly 7,000 Maryland residents, indicated that drug dealers were the primary source of drugs for individuals who reported misusing prescription opioids, followed by “stealing from family” and “friends providing.”⁹

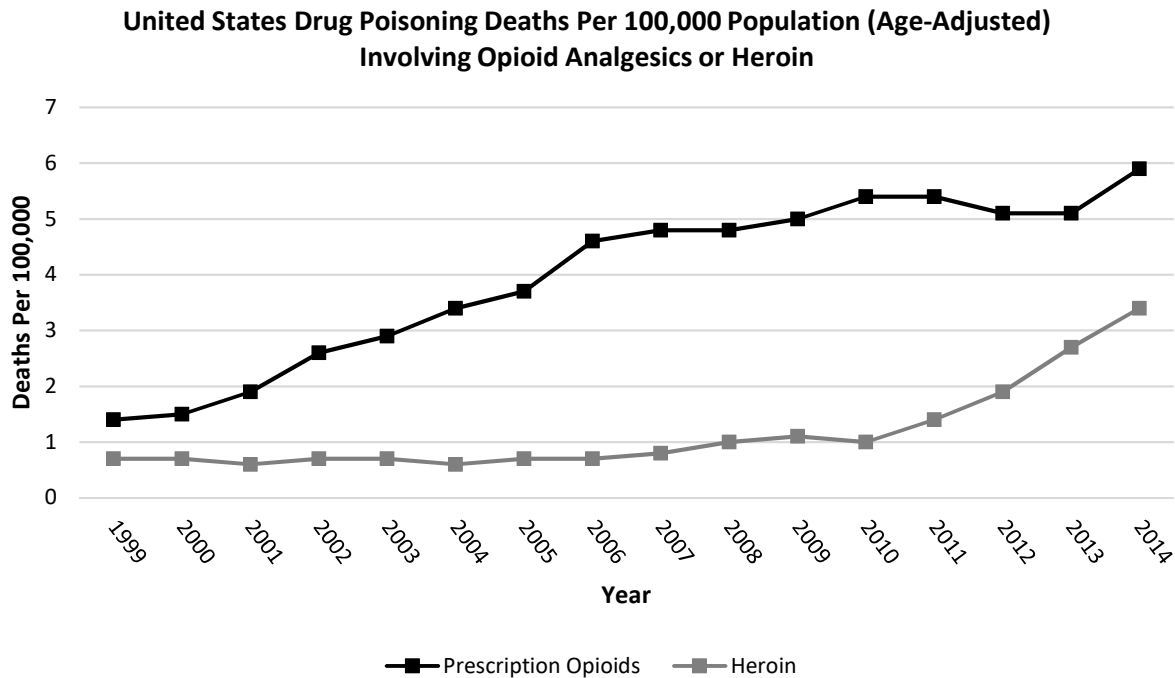
⁸ The terms “misuse” and “nonmedical use” both refer to use of prescription drugs in ways not intended by a doctor. For the 2015 NSDUH, researchers began using the term “misuse” instead of “nonmedical use” in order to capture cases where individuals considered that they were using drugs for the medical purpose for which they are typically prescribed (e.g. pain relief), but where the drugs were not prescribed for them by a doctor.

⁹ *Maryland Public Opinion Survey on Opioids: Summary Report*, University of Maryland School of Pharmacy, p.9 < <https://archive.hshsl.umaryland.edu/bitstream/10713/4875/1/MPOS%20Summary%20Report.pdf> > accessed 10/27/2016.

2. Data on Prescription Opioid Overdoses

As noted earlier, high doses of opioids can depress respiration and cause death. Data from the U.S. Centers for Disease Control (CDC), based on death certificate data, show that nearly 19,000 people died in the United States from drug poisoning involving opioid analgesics and over 10,000 died from drug poisoning involving heroin in 2014.¹⁰ The next chart displays the nationwide trends in opioid analgesic- and heroin-related drug poisoning deaths per 100,000 population (age-adjusted) from 1999 to 2014.

The data show that drug poisoning deaths involving opioid analgesics (prescription opioids and illicit fentanyl) and those involving heroin, adjusted for population growth, both more than quadrupled between 1999 and 2014. Of note, these data include both intentional and unintentional deaths as well as deaths where intention was not determined. Additionally, researchers note that, “some heroin deaths might be misclassified as morphine because morphine and heroin are metabolized similarly, which might result in an underreporting of heroin overdose deaths.”¹¹



Source: National Center for Health Statistics, Centers for Disease Control and Prevention

Maryland Overdose Deaths. The Maryland Department of Health and Mental Hygiene (DHMH) tracks trends in unintentional drug- and alcohol-related intoxication deaths occurring in the State. State law requires that the Office of the Chief Medical Examiner (OCME) investigate certain types of deaths, including those caused by violence, suicide or accident, to determine the cause of death. DHMH uses OCME investigation data along with death certificate data to compile its trend data. Of note, the DHMH data are not comparable with the national

¹⁰ “Number and age-adjusted rates of drug-poisoning deaths involving opioid analgesics and heroin: United States, 1999–2014,” U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, < https://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf > accessed 10/26/2016.

¹¹ Rudd, R.A., Aleshire, N., Zibbell, J.E., & Gladden, R.M., “Increases in Drug and Opioid Overdose Deaths,” Morbidity and Mortality Weekly Report 64(50-51), p. 1,381, < <http://www.cdc.gov/mmwr/pdf/wk/mm6450.pdf> > accessed 10/28/2016.

CDC data described above.¹² The 2016 DHMH report included the following findings regarding unintentional opioid-related deaths in Maryland:¹³

- 89% of all 2016 intoxication deaths in Maryland were opioid-related;
- The total number of opioid-related deaths in the State increased by 70% from 2015 to 2016, from 1,089 to 1,856 deaths, and has nearly quadrupled since 2010;
- Sharp increases in heroin and fentanyl-related deaths are responsible for most of the rise in opioid-related deaths, but prescription opioid related deaths have also increased, in large part as a result of the use of prescription opioids in combination with heroin or fentanyl; and
- Statewide data for 2016 show 20 heroin-related deaths per 100,000 population, seven prescription opioid-related deaths per 100,000 population, and 19 fentanyl-related deaths per 100,000 population.

Montgomery County Overdose Deaths. In 2016, 102 drug- or alcohol-related intoxication deaths occurred in Montgomery County, of which 26 were related to prescription opioids (including prescribed fentanyl), 48 were related to heroin and 43 were related to either prescribed or illicit fentanyl (some deaths are counted more than once due to multiple drugs used).

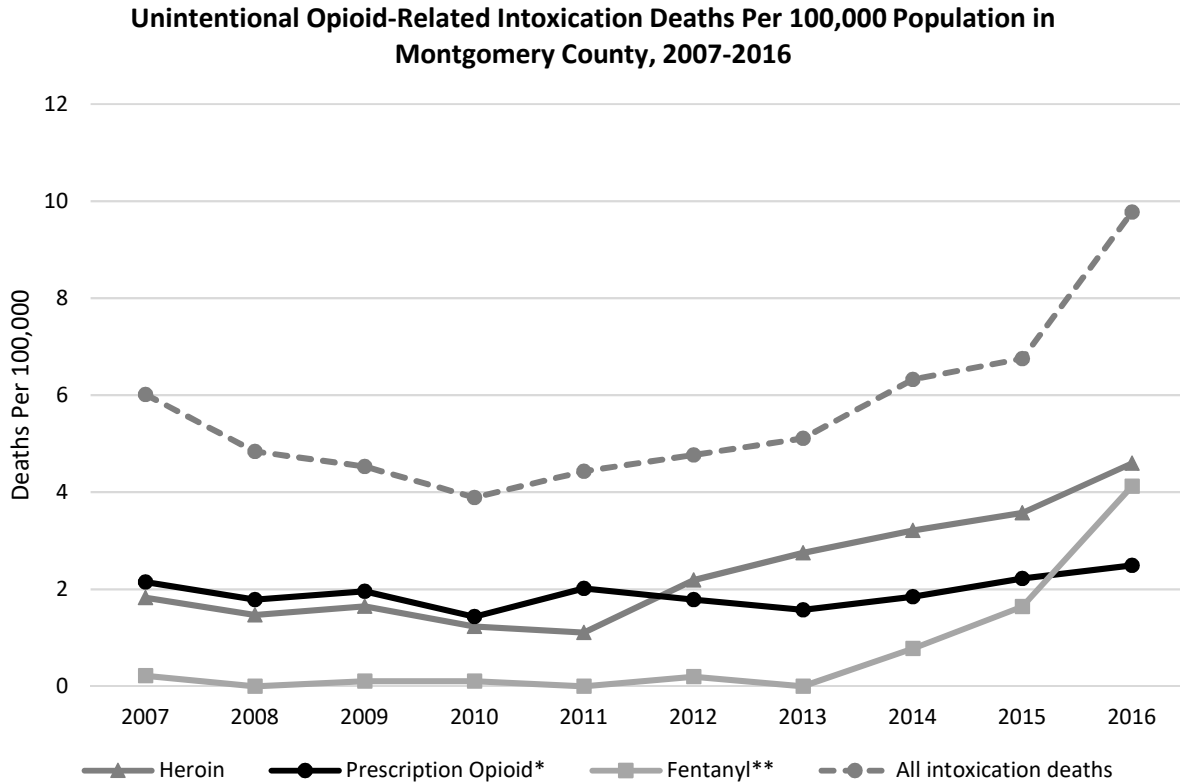
The next chart displays trend data for opioid-related deaths per 100,000 population in Montgomery County from 2007 to 2016. The data show that County trends are similar to Statewide trends in that heroin-related and fentanyl-related deaths have shown significant increases in the past five years.¹⁴ Consistent with this trend, Montgomery County Fire and Rescue Service (MCFRS) staff report that use of naloxone, a drug used to prevent death by counteracting the effects of opioids when a person has overdosed, has increased sharply in the past year, from 36 monthly administrations in FY16 to 57 monthly administrations in FY17.¹⁵

¹² DHMH data are not comparable with the CDC's national level data for three reasons. (1) The DHMH data include only unintentional deaths and deaths where intent was undetermined, whereas the CDC data include deaths regardless of intent. (2) CDC data are based on data from death certificates, which may differ from data based on investigations such as those conducted by the Maryland OCME. (3) DHMH conducted additional analysis to identify heroin-related deaths, as it is not always readily apparent whether heroin or morphine was involved, due to the way that heroin is metabolized by the body; the CDC data only report causes of death listed in death certificates.

¹³ "Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2016," Maryland Department of Health and Mental Hygiene, June 2017, < http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Documents/2015%20Annual%20Report_revised.pdf > accessed 6/15/2017.

¹⁴ Ibid.

¹⁵ MCFRS staff report that it is often not possible to determine whether an individual is experiencing an opioid overdose, but that MCFRS administers Naloxone when an overdose is suspected. As a result, MCFRS administrations of Naloxone may not all be associated with opioid overdoses.



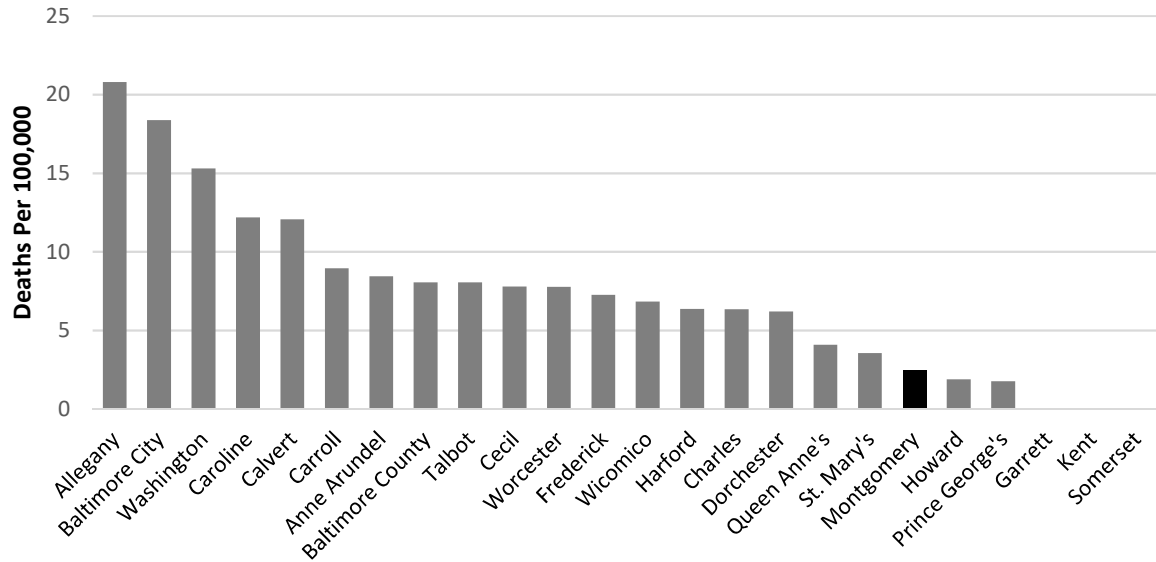
Source: OLO analysis of “Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2016,” Maryland Department of Health and Mental Hygiene; U.S. Census Bureau, Annual Estimates of the Resident Population, and American Community Survey 1-Year Total Population Estimates (for 2007-2009)

* Prescription opioids include buprenorphine, codeine, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, pentazocine, propoxyphene, tramadol and prescribed fentanyl

** Includes both prescribed and illicit fentanyl

However, overall, Montgomery County has experienced lower rates of fatal overdoses involving opioids relative to its population compared with most other Maryland counties. The chart on the following page compares the number of fatal overdoses involving prescription opioids per 100,000 population in Montgomery County with other Maryland counties.

2016 Unintentional Fatal Overdoses Related to Prescription Opioids Per 100,000 Population by Maryland County



Source: OLO analysis of “Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2016,” Maryland Department of Health and Mental Hygiene, Revised September 2016, Table 3; and U.S. Census Bureau, Annual Estimates of the Resident Population: July 1, 2016

* Three counties, Garrett, Kent and Somerset, had no fatal prescription opioid overdoses in 2016

Chapter 2. Legal Framework for Opioid Prescribing

As shown in Chapter 1, prescription opioids are associated with several risks. Because of these risks, the drugs are classified as both prescription drugs and controlled substances as defined in Federal and state laws. The Federal and Maryland State governments regulate the use of controlled substances for legitimate medical, scientific, research, and industrial purposes, while aiming to prevent the substances from being diverted for illegal purposes. This chapter summarizes the current legislative framework for the classification and prescribing of prescription opioids in the United States and Maryland:

- **Section A** summarizes the legal classifications of prescription opioids; and
- **Section B** outlines who can legally prescribe opioids and prescribing rules.

A. Legal Classification of Prescription Opioids

As noted earlier, the term “opioids” refers to a class of drugs that includes legal drugs used to treat pain. The rules regarding how each opioid can be used depend on each drug’s legal classification. Those opioids that have accepted medical uses are classified as prescription drugs and are therefore subject to the Federal and state laws and regulations that apply to prescription drugs. Additionally, most prescription opioids are also classified as “controlled substances” in Federal and state law and are subject to special regulations.

Prescription Drugs. The Federal Food, Drug, and Cosmetic Act of 1938 and its amendments define prescription drugs as drugs that are intended for use by humans or animals, but which are only safe to use under the professional supervision of a licensed practitioner. The law establishes that these drugs may only be dispensed upon written prescription of a practitioner who has been licensed by law to administer the drug. The Secretary of Health and Human Services has the authority to exempt specific drugs from these requirements if the Secretary deems that they are not necessary to protect public health.¹

The U.S. Food and Drug Administration (FDA) in the Department of Health and Human Services is the federal agency responsible for evaluating drugs to determine whether they must be sold as prescription medicines or whether they can be sold “over-the-counter,” meaning that a prescription is not required.² All major drugs containing opioids are currently classified as prescription drugs.³

Controlled Substances. A controlled substance is a drug or chemical that has been designated as such because of its potential for misuse. Controlled substances can be legal or illegal. In the United States, the Controlled Substances Act of 1970 (CSA) provides the legal framework for controlled substances.⁴ This Act consolidated several laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. The Act established federal drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated and gives authority to the Drug Enforcement Agency (DEA) to monitor and control legal and illegal substances.

¹ 21 U.S.C. §353 (2017).

² “Frequently Asked Questions About CDER,” U.S. Food and Drug Administration Website, updated 6/27/2016, < <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/> > accessed 5/2/2017.

³ “Drugs@FDA: FDA Approved Drug Products,” U.S. Food and Drug Administration Website, < <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> > accessed 5/2/2017.

⁴ <https://www.deadiversion.usdoj.gov/21cfr/21usc/>.

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules (I-V) based on medicinal value, harmfulness, and potential for abuse/addiction (shown in the next table). Table 2-1 summarizes the five schedules of controlled substances. There are opioids in all five schedules.⁵ The following factors affect a drug's schedule:⁶

- Potential for abuse;
- Scientific information available regarding the drug's pharmacological effect;
- Scientific understanding of the drug;
- Historical and current patterns of abuse;
- Magnitude of abuse;
- Possible risks to public health; and
- Risk of developing psychological or physical dependence.

Table 2-1. Descriptions of Federal Schedules of Controlled Substances

Schedule	Characteristics of Substances	Examples (<i>Opioids in Italics</i>)
I	No currently accepted medical use in the United States, no acceptable safe use under medical supervision, and have a high potential for abuse	<i>heroin</i> , cannabis, lysergic acid diethylamide (LSD), and MDMA ("Ecstasy")
II	A currently accepted medical use in treatment but a high potential for abuse which may lead to severe psychological or physical dependence	<i>oxycodone</i> , <i>methadone</i> , <i>fentanyl</i> , amphetamine, cocaine, methamphetamine
III	A currently accepted medical use in treatment with potential for moderate or low physical dependence or high psychological dependence	<i>buprenorphine</i> , benzphetamine, ketamine, anabolic steroids
IV	A currently accepted medical use in treatment and lower potential for abuse compared with drugs in Schedule III	<i>butorphanol</i> , <i>pentazocine</i> , alprazolam (Xanax®), diazepam (Valium®)
V	A currently accepted medical use in treatment and lower potential for abuse compared with drugs in Schedule IV	<i>Codeine and hydrocodone cough suppressants (Robitussin AC, Phenergan with Codeine)</i>

The CSA allows for substances to be added, rescheduled, or decontrolled. Two federal agencies, the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA), determine which substances are added to or removed from the various schedules. An updated and complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15.⁷

Controlled Substances in Maryland. Federal laws and regulations set the minimum requirements for the regulation of controlled substances. States are free to enact more restrictive laws or regulations. Maryland currently recognizes eight additional drugs as controlled substances and places two drugs on higher schedules compared to the DEA list.⁸ These include the following prescription opioids:

- Butalbital, Acetaminophen, caffeine (Fioricet® or Esgic®) – Maryland Schedule III;

⁵ <http://www.buppractice.com/node/452>.

⁶ <https://www.foundationsrecoverynetwork.com/the-difference-between-an-illegal-and-a-controlled-substance/>.

⁷ Section 812 of the CSA lists substances which were controlled when the legislation was first enacted and Section 1308 of the most recent issue of Title 21 of the Code of Federal Regulations lists the current list of controlled substances.

⁸ <http://dhmh.maryland.gov/ocsa/Documents/Supplemental%20CDS%20List%20-%20Maryland.pdf>.

- Dihydrocodeinone (also known as hydrocodone) – Maryland Schedule III;
- Opium – Maryland Schedule III; and
- Pentazocine (on DEA Schedule IV) - Maryland Schedule III.

A. Laws and Regulations Regarding the Prescribing of Opioids

The classifications of prescription opioids as both prescription drugs and controlled substances determine how the drugs can be prescribed and by whom. This section summarizes the Federal and state laws and regulations regarding who is eligible to prescribe opioids and how to prescribe them.

1. Eligibility for Prescribing

In order to prescribe opioids, a practitioner must have the authority to prescribe drugs and be in compliance with rules for prescribers of controlled substances. This section describes which practitioners have the authority to prescribe drugs in Maryland and summarizes rules for controlled substances prescribers.

Authority to Prescribe Prescription Drugs. State laws define which practitioners have the authority to prescribe prescription drugs in a given state. Table 2-2 lists the categories of licensed professionals in Maryland that are authorized by law to prescribe prescription drugs, including opioids.⁹ The table also lists the licensing board that is responsible for licensure and discipline in that occupation.

Table 2-2. Occupations Authorized by Law to Prescribe Prescription Drugs in Maryland

Occupation	Licensing Board
Physicians ¹⁰	Board of Physicians
Physician Assistants (under supervision of physician) ¹¹	Board of Physicians
Dentists ¹²	Board of Dental Examiners
Podiatrists ¹³	Board of Podiatric Medical Examiners
Certified Nurse Practitioners ¹⁴	Board of Nursing
Certified Nurse Midwives ¹⁵	Board of Nursing
Veterinarians ¹⁶	Board of Veterinary Medical Examiners

Registration to Prescribe Controlled Substances. In order to prescribe controlled substances, the law requires that the practitioner register with both the U.S. Drug Enforcement Administration (DEA) and the

⁹ Therapeutically certified optometrists, which are licensed optometrists with an additional certification, may prescribe certain specified topical medications, but are not listed in the table because they may not prescribe oral medications such as prescription opioids (see Md. Health Occupations Code Ann. § 11-404.2).

¹⁰ Md. Health Occupations Code Ann. § 14-101; and Md. Health Occupations Code Ann. § 12-101.

¹¹ Md. Health Occupations Code Ann. § 15-302.2; in order to prescribe drugs, a physician assistant must meet certain requirements regarding education and experience and must include certain elements in a delegation agreement with the supervising physician.

¹² Md. Health Occupations Code Ann. § 12-101.

¹³ Md. Health Occupations Code Ann. § 12-101.

¹⁴ Md. Health Occupations Code Ann. § 8-508.

¹⁵ Md. Health Occupations Code Ann. § 8-601; Certified Nurse Midwives may only prescribe substances commonly used in the practice of midwifery as defined by the Board of Nursing, in consultation with the Board of Pharmacy and the Board of Physicians.

¹⁶ Md. AGRICULTURE Code Ann. § 2-301 and Md. Health Occupations Code Ann. § 12-101.

Maryland Department of Health and Mental Hygiene (DHMH). The paragraphs below provide details on these requirements.

DEA Registration. Under the Controlled Substances Act (CSA), the DEA is responsible for preventing diversion and abuse of controlled substances while ensuring an adequate and uninterrupted supply is available to meet legitimate medical, scientific, and research needs. The DEA attempts to keep all controlled substance transactions within a “closed system” by requiring that all legitimate handlers (manufacturers, clinicians, etc.) of controlled substances register with the DEA and account for all distributions.

The CSA requires all practitioners who want to prescribe, administer, dispense, distribute, or perform research, analysis or teaching with any controlled substance to register with the DEA and renew their registration every three years, unless exempted.¹⁷ “Practitioners” can include physicians, dentists, veterinarians, scientific investigators, pharmacies, hospitals and other individuals or organizations licensed or permitted to use controlled substances in the course of their professional practice or research.¹⁸ The DEA registration grants practitioners the federal authority to handle controlled substances; however, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located.

Maryland Registration. Maryland law requires individuals and organizations to register with DHMH before manufacturing, distributing, dispensing, administering, conducting research with or prescribing controlled substances, termed “controlled dangerous substances” (CDS) in Maryland.¹⁹ By registering, providers receive a permit that lasts three years, and registrants and applicants for registration are subject to inspections by DHMH.²⁰ Practitioners must apply using a hard copy application.

In addition, in 2016 the law was amended to create a new requirement for all CDS prescribers and pharmacists to be registered with the Prescription Drug Monitoring Program (PDMP).²¹ Prescribers and dispensers must register by July 1, 2017. Additionally, in the future (subject to the DHMH Secretary’s determination), prescribers and dispensers will be required to register with the PDMP before obtaining a new or renewal CDS permit.²² Chapter 6 provides further details on the PDMP.

2. Rules for Prescribing

As both prescription drugs and controlled substances, prescription opioids are subject to laws and regulations that apply to each of these categories. The Federal Food, Drug, and Cosmetic Act establishes that prescription drugs may only be dispensed upon a written prescription from a licensed practitioner, or alternatively under an oral prescription that is then recorded in writing by the pharmacist. The law also establishes labeling requirements for prescription drugs.²³ However, controlled substances are subject to more stringent rules around prescribing.

¹⁷ Those who work in Public Health Service, Federal Bureau of Prisons, or military practitioners are exempt.

¹⁸ <https://www.law.cornell.edu/uscode/text/21/802>.

¹⁹ Md. Criminal Law Code Ann. § 5-301 and Md. Criminal Law Code Ann. § 5-101.

²⁰ Md. Criminal Law Code Ann. § 5-302 and § 5-305.

²¹ Md. Health-General Code Ann. § 21-2A-04.1 and Enrolled House Bill 437 (2016), Maryland General Assembly.

²² Md. Criminal Law Code Ann. § 5-304 and PDMP Legislation Fact Sheet, Version III, Maryland Department of Health and Mental Hygiene, < [http://bha.dhmh.maryland.gov/pdmp/Documents/Version%20III%20PDMP%20Fact%20Sheet%20FINAL%20\(1\).pdf](http://bha.dhmh.maryland.gov/pdmp/Documents/Version%20III%20PDMP%20Fact%20Sheet%20FINAL%20(1).pdf) > accessed 5/7/2017.

²³ 21 U.S.C. §353 (2017).

Federal regulations for controlled substances establish that a prescription for a controlled substance must be “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”²⁴ According to the regulations, the prescriber is responsible for proper prescribing and dispensing of controlled substances; however, the pharmacist also bears responsibility for ensuring the prescription is proper when filling it.²⁵ Some of the specific federal requirements of clinician prescribing are summarized in the table below.

Table 2-3. Federal Prescribing Rules and Requirements for Controlled Substances

Transmission of Prescription
<ul style="list-style-type: none"> • Clinicians must date and sign prescriptions on the issuance data and cannot pre-sign them • A prescription must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner, be written in ink or indelible pencil or typewritten, and must be signed manually by the practitioner • In emergency situations, a prescription for a Schedule II controlled substance may be telephoned to the pharmacy, and the prescriber must follow up with a written prescription sent to the pharmacy within seven days; prescriptions for Schedule III through V controlled substances may be written or transmitted orally or by fax • Prescriptions may be faxed under certain conditions: Schedule II prescriptions can be faxed to a pharmacist, but the original prescription is required for filling the prescription; Schedule III, IV and V prescriptions may be telephoned in or faxed to the pharmacist
Limits/Refills/Expiration of Prescription
<ul style="list-style-type: none"> • The prescription must include the patient’s full name and address, and the practitioner’s full name, address, and DEA registration number; the prescription must also include: drug name, strength, dosage form, quantity prescribed, directions for use, and number of refills (if any) authorized • There are no limits on the amount of controlled substances prescribed • There is no expiration of a prescription for Schedule II substances, while prescriptions for substances in Schedules III and IV expire six months after the date written and there is a limit of five refills within the six-month period • A pharmacist may partially fill a prescription for controlled substances – if the remainder is not dispensed within the following 72 hours for Schedule II substances or six months for substances in Schedules III through V, the prescription is void • Prescriptions for Schedule II controlled substances cannot be refilled and a new prescription must be issued (but multiple prescriptions may be prepared with instructions to fill on different dates) • Prescriptions for Schedule III through V controlled substances may be refilled up to five times in six months

In addition to the legal requirements of prescribing controlled substances, the Drug Enforcement Administration’s Office of Diversion Control released a Practitioner’s Manual that assists practitioners in

²⁴ 21 C.F.R. § 1306.04 (2017).

²⁵ Ibid.

understanding responsibilities under the CSA. In this manual, the DEA outlines several safeguards for prescribers in addition to the required security controls, including:²⁶

- Keep all prescription blanks in a safe place where they cannot be stolen;
- Minimize the number of prescription pads in use;
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order; and
- Use tamper-resistant prescription pads.

Prescribing in Maryland. State law and regulations also establish prescribing requirements, most of which mirror rules established in Federal law and regulations. However, Maryland law and regulations establish some additional prescribing requirements for controlled substances, as detailed below.

Expiration of Prescriptions. As noted earlier, Federal regulations establish that prescriptions for substances in Schedules III and IV expire six months after the date they were issued, while prescriptions for substances in Schedule II do not expire. However, State regulations establish that prescriptions for Schedule II substances must be filled within 120 days of issuance.²⁷ Additionally, prescriptions for substances in Schedules III, IV and V must also be filled within 120 of issuance unless the prescriber instructs that the prescription be filled more than 120 days after issuance (and in this case must be filled within six months of issuance).²⁸

Prescriber Requirements of the Prescription Drug Monitoring Program. Maryland law requires that prescribers and pharmacists register with the Prescription Drug Monitoring Program (PDMP) by July 1, 2017.²⁹ Additionally, beginning July 1, 2018, a prescriber must (1) request at least the prior four months of prescription monitoring data for a patient before initiating a course of treatment that includes prescribing or dispensing an opioid or a benzodiazepine; (2) request prescription monitoring data for the patient at least every 90 days until the course of treatment has ended; and (3) assess prescription monitoring data before deciding whether to prescribe or dispense – or continue prescribing or dispensing – an opioid or a benzodiazepine. More detail on the PDMP is available in Chapter 6.

Prescriber Limits Act (HB 1432) of 2017.³⁰ In 2017, the General Assembly passed legislation that states that the dosage, quantity, and duration of an opioid prescribed shall be based on an “evidence-based clinical guideline for prescribing controlled dangerous substances” and that a prescriber shall prescribe “the lowest effective dose of an opioid and a quantity no greater than the quantity needed for the expected duration of pain severe enough to require an opioid” unless the opioid is being used to treat cancer, terminal illness, or substance-related disorder. Previous versions of the legislation sought to limit the duration of an opioid prescription prescribed upon initial consultation or treatment to a seven-day supply except when for treatment of pain associated with cancer, terminal illness, or substance-related disorder.

²⁶ <https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>.

²⁷ COMAR 10.19.03.08.

²⁸ COMAR 10.19.03.09.

²⁹ Md. Health-General Code Ann. § 21-2A-04.1 and Enrolled House Bill 437 (2016), Maryland General Assembly.

³⁰ <http://mgaleg.maryland.gov/2017RS/bills/hb/hb1432T.pdf>.

Chapter 3. Best Practices in Prescriber Education

In recent years, the number of opioid prescriptions, the amount prescribed per prescription, the days' supply and the cumulative dose prescribed have all increased according to the United States Department of Health and Human Services.¹ However, most prescribers, including physicians, physician assistants, nurse practitioners, pharmacists, nurses, prescribing psychologists, and dentists, receive little training on the appropriate prescribing and dispensing of opioids. One U.S. Drug Control Strategy study found that students in medical school only receive on average eleven hours of training on pain education and most schools do not offer specific training on opioids or substance use disorders.² Additionally, changing formulations of opioids, revised clinical guidelines, and new information on the risks of opioids have recently emerged, making it difficult for prescribers to be aware of updated information.³

All stakeholders agree that there is a need for more prescriber education on the responsible and appropriate pain management and prescribing of opioids. Prescribers need to be knowledgeable about assessing patients' pain and function, methods of managing pain, and Federal and state requirements for prescribing. Education efforts should focus on addressing the risks of prescribing opioids while balancing the legitimate needs of patients for pain treatment.

This chapter summarizes the educational resources available through Federal agencies, medical schools, and medical associations on pain management and opioid prescribing. While each source has specific education recommendations, OLO found that the Federation of State Medical Board's "Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain"⁴ best reflects the general range of all established guidelines for opioid prescribing:

- Comprehensive evaluation and risk assessment of the patient;
- Informed consent and treatment agreement;
- Ongoing treatment review and patient monitoring;
- Individualized treatment and patient management plan;
- Maintaining a transparent medical record;
- Specialized consultations; and
- Adherence to controlled substances laws and regulations.

This chapter provides information on the available prescriber education resources, including:

- **Section A** summarizes specific prescriber education guidelines;
- **Section B** outlines resources and tools available to prescribers; and
- **Section C** summarizes prescriber education requirements in other jurisdictions.

¹ Addressing Prescription Drug Abuse in the United States Current Activities and Future, CDC. Opportunities https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf

² Mezei, L., Murinson, BB. "Pain Medication in North American Medical Schools." *The Journal of Pain*. 2011.

³ Prescription opioid abuse, pain and addiction: Clinical issues and implications <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4170948/>.

⁴ http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf.

The Comprehensive Addiction and Recovery Act 2016 (CARA)¹

As part of the Federal government effort to combat the opioid and heroin crisis, Congress passed CARA, a comprehensive law that address addiction support services through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal. The legislation authorizes over \$181 million each year and includes the following supports regarding prescriber education:

- Expansion of educational efforts to prevent abuse and promote treatment and recovery;
- Development of best practices for prescribing opioids by a task force composed of government representatives, treatment organizations, and other stakeholders; and
- Establishment of a national drug awareness campaign led by the Office of National Drug Control Policy to bring attention to the association between prescription opioid abuse and heroin use, as well as focus on the dangers of fentanyl.

A. Specific Prescriber Education Guidelines

The United States Department of Health and Human Services has taken the lead on addressing prescriber education. This section summarizes the efforts of various agencies within the Department to establish specific guidelines for prescribing opioids.

1. Centers for Disease Control

The Centers for Disease Control (CDC) is the nation’s leading public health institute. Located within the Department of Health and Human Services, the CDC is charged with “developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States.”⁵ The CDC has taken a three-pronged approach to combat the opioid epidemic:

- Improving data quality and timeliness to better track trends, identify communities at risk, and evaluate prevention strategies;
- Strengthening state efforts by scaling up effective interventions; and
- Improving patient safety by equipping health care providers with the data and tools needed to improve opioid prescribing.

In addition to linking users to educational resources offered by other federal agencies, the CDC has completed a comprehensive set of guidelines that address opioid prescribing and have been adopted by numerous state health departments throughout the country as best practices.

*Guidelines for Prescribing Opioids for Chronic Pain.*⁶ In March of 2016, the CDC developed a set of guidelines for treating adult patients with chronic pain (not including active cancer treatment, palliative care, or end-of-life care) in outpatient settings. The goals of the guidelines are to: (1) improve communication between clinicians

⁵ <https://www.cdc.gov/maso/pdf/cdcmiss.pdf>.

⁶ <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

and patients about the benefits and risks; (2) provide safer, more effective care for patients with chronic pain; and (3) help reduce opioid use disorder and overdose.

CDC Guideline for Prescribing Opioids for Chronic Pain

1. Use nonpharmacological therapy and nonopioid pharmacologic therapy as the first option for treatment of chronic pain and consider the use of opioids if the expected benefits outweigh the risks to the patient.
2. Establish realistic goals for pain and function and only continue opioid therapy if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
4. Prescribe immediate release opioids when starting use instead of extended-release/ long-acting (ER/LA) opioids.
5. Prescribe the lowest effective dosage; more specifically clinicians should reassess benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.
6. Prescribe short durations for acute pain, no greater than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation and should continue to evaluate benefits and harms at least every three months.
8. Evaluate risk factors for opioid-related harms prior to prescribing and throughout treatment.
9. Review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose, both prior to prescribing and throughout treatment.
10. Use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

2. Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA's 2014 Opioid Overdose Prevention Toolkit (Updated 2016) provides health care providers, community stakeholders, and local governments with information to develop practices and policies to prevent opioid-related overdoses. The Toolkit provides the following list of evidence-based clinical practices:

1. Assess the patient, including obtaining a history of drug use.
2. Take special precautions with new patients such as a more detailed assessment (medical history, previous substance use, and who has been caring for the patient in the past). In emergency situations, clinicians should prescribe the smallest possible dosage (not exceeding three days), schedule a return

visit the next day and consider prescribing naloxone. In non-emergency situations, clinicians should only prescribe enough to meet the need until the next appointment.

3. Check the state's PDMP database prior to prescribing to determine whether a patient is filling the prescriptions provided and/or obtaining prescriptions for the same or similar drugs from multiple physicians.
4. Select an appropriate medication based on the severity of symptoms in terms of the patient's ability to accommodate them, the patient's reliability in taking medications, and the dependence-producing potential of the medication.
5. Educate the patient about the risks and benefits of the proposed therapy and obtain informed consent.
6. Monitor the patient's response to treatment for drug efficacy and safety, compliance, and potential development of tolerance.
7. Evaluate whether and when to end opioid therapy, especially when behavior indicates that continued prescribing is unsafe or causing harm.

3. Food and Drug Administration (FDA)

In recent years, the FDA has made numerous efforts to combat the opioid epidemic in the country, including developing guidelines and educational tools for clinicians to use when prescribing opioids. In its *Blueprint for Prescriber Education (Blueprint) and Risk Evaluation and Mitigation Strategy (REMS) For Extended-Release and Long-Acting (ER-LA) Opioids (2012 Updated 2017)*⁷, the FDA developed guidelines for assessing patients for treatment with ER/LA opioid analgesic therapy.

ER/LA opioids are used for the management of persistent pain requiring around the clock opioids for an extended period. ER/LA tablets are designed to release the opioid analgesic over a longer period than standard tablets. The FDA has determined that extra attention should be paid to ER/LA opioids because there is a disproportionate safety problem, primarily due to the ER/LA opioid having more opioid analgesic contained in a single tablet. Improper use of any opioid can result in serious side effects, including overdose and death, and this risk is magnified with ER/LA opioids.⁸ The strategy includes guidelines on assessing patients for treatment, prescribing the appropriate amount of medication, and counseling patients on using ER/LA opioids. The full guidelines are extensive and can be found online.⁹

⁷ <https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM515636.pdf>.

⁸ <https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm309742.htm#Q1>.

⁹ Found at

<https://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm311290.pdf>.

Prescribing Guidelines from Other Stakeholders

In addition to Federal prescriber education guidelines and best practices, several medical societies and schools have released prescribing guidelines that have many overlapping themes with the Federal government resources. Some of these include:

- University of Massachusetts Medical School - *Minimizing the Misuse of Prescription Opioids in Patients with Chronic Nonmalignant Pain*;¹
- Association of Medical Colleges, Contemporary Issues in Medicine - *Education in Safe and Effective Prescribing Practice*;¹
- Federation of State Medical Boards - *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*;¹ and
- American Society of Addiction Medicine - *Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction*.¹

B. Prescriber Education Resources and Tools

Both the Federal Government and medical societies have created numerous educational guides and tools to provide clinicians and other stakeholders with comprehensive information to prescribe and/or dispense opioids in a responsible way. This section summarizes the information available.

Federal Government Resources. In recent years, the Federal government prioritized the nation's opioid epidemic. Numerous federal agencies, including the White House Office of National Drug Control Policy, the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, and the Department of Defense, meet regularly to coordinate federal efforts to address opioid abuse and misuse, including the education of prescribers.

The leading agency on efforts to improve prescriber education is the Department of Health and Human Services. As part of the Department's Opioid Initiative,¹⁰ the HHS Secretary established three priorities for prescriber education, including (1) providing training and educational resources such as updated prescriber guidelines, (2) assisting health professionals in making informed prescribing decisions and (3) addressing the over-prescribing of opioids.

The agency has created a website dedicated to the opioid epidemic, where clinicians can access extensive information on prescribing guidance in a centralized location.¹¹ The following table summarizes specific educational resources and tools available through several Department of Health and Human Services offices/agencies.

¹⁰ <https://www.hhs.gov/opioids/index.html>.

¹¹ <https://www.hhs.gov/opioids/index.html>.

Summary of Federal Government Resources for Prescribers on Opioid Prescribing

Office/Agency	Prescriber Education Resources
Centers for Disease Control (CDC)	<ul style="list-style-type: none"> Created a seven part webinar series and fact sheet about the CDC prescribing guidelines Published <i>the Common Elements in Guidelines for Prescribing Opioids for Chronic Pain</i>¹² which is a review of eight sets of prescribing guidelines to identify common recommendations for pre-treatment, initial opioid treatment, follow-up, and discontinuation phases Maintain a website on the opioid epidemic with data, state information, and links to resources
Substance Abuse and Mental Health Services Administration (SAMHSA)¹³	<ul style="list-style-type: none"> Development of an in-person and video-based continuing medical education course, “Clinical Challenges in Prescribing Controlled Drugs: Prescribing Opioids for Chronic Pain” Creation of the Prescribers’ Clinical Support System for Opioid Therapies (PCSS-O) which provides support, training, and mentoring services to a variety of healthcare providers on the safe and appropriate prescribing of opioids Development of a series of free online courses at http://www.OpioidPrescribing.com Funding of CME courses on prescribing opioids developed by health organizations such as: The American Society for Pain Management; The American Society of Addiction Medicine; and The Prescription Drug Monitoring Program Training and Technical Assistance Center
National Institute of Health (NIH)/National Institute of Drug Abuse (NIDA)¹⁴	<ul style="list-style-type: none"> Establishment of four Centers of Excellence for Physician Information that target physicians-in-training, in partnership with the American Medical Association Designation of 11 health professional schools as Centers of Excellence in Pain Education, which develop, evaluate and distribute pain management curriculum resources Creation of two online continuing medical education courses on safe prescribing for pain and managing patients who abuse prescription opioids Development of several clinical resources on prescription opioids Development of the Opioid Risk Tool (ORT), which is a screening tool to assess risk for opioid abuse
Office of Disease Prevention and Health Promotion¹⁵	<ul style="list-style-type: none"> Development of Pathways to Safer Opioid Use, which is an interactive tool that provides information about preventing opioid-related adverse events to four stakeholders – the primary care physician, nurse, pharmacist, and patient – through case studies
United States Surgeon General¹⁶	<ul style="list-style-type: none"> Launch of the Turn the Tide Campaign to raise awareness about opioid addiction which provides clinicians with educational tools on pain management and safe prescribing of opioids including: Pain Treatment Toolbox; Checklist for Prescribing Opioids for Chronic Pain; and Calculating Total Daily Dose of Opioids for Safer Dosage
Federal Drug Administration (FDA)¹⁷	<ul style="list-style-type: none"> Mandated a Risk Evaluation and Mitigation Strategy (REMS) for extended-release and long-acting (ER-LA) opioids, which, among other things, requires drug manufacturers to develop and fund effective educational materials and initiatives to train practitioners on the appropriate use Funded the Partnership for Drug Free Kids SEARCH AND RESCUE Initiative which connects clinicians to resources that can assist in proactively identifying, addressing, and reducing prescription opioid abuse

¹² https://www.cdc.gov/drugoverdose/pdf/common_elements_in_guidelines_for_prescribing_opioids-20160125-a.pdf.

¹³ <https://www.samhsa.gov/atod/opioids>.

¹⁴ <https://www.drugabuse.gov/drugs-abuse/opioids>.

¹⁵ <https://health.gov/hcq/training-pathways.asp>.

¹⁶ <http://turnthetiderx.org/>.

¹⁷ <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>.

Other Resources Available. In addition to extensive government resources available that outline best practices in prescribing education, many relevant stakeholders in the medical community have created (or are planning to create) numerous resources and tools for prescribers to utilize. Some of these resources include:

- **American College of Physicians. *SAFE Opioid Prescribing Strategies – Assessment, Fundamentals, and Education.***¹⁸ In May 2016, the American College of Physicians created six online courses that provide information on: (1) the implementation of patient assessment strategies, including tools to assess risk of abuse, misuse, or addiction; (2) approaches to safely initiate therapy, modify dose, and discontinue ER/LA opioids; and (3) monitoring patients.
- **American Medical Association. *Task Force to Reduce Opioid Abuse.***¹⁹ In 2014, the AMA formed a task force to discuss ways to reduce the inappropriate prescribing of opioids and heroin overdoses and has compiled state, federal, academic and medical educational resources to promote appropriate prescribing for pain management. In addition, the AMA Task Force is developing statewide physician toolkits, a primer on the opioid epidemic, and an inventory of more than 100 online modules and webinars.

C. Prescriber Education Requirements in Other Jurisdictions

In April 2011, the Federal Government released a comprehensive Prescription Drug Abuse Prevention Plan²⁰ that created a national framework for reducing prescription drug diversion and abuse. One key strategy of the Plan is to educate health care providers about opioid painkiller prescribing. The plan further recommended that states require practitioners who request DEA registration to be trained on responsible opioid prescribing practices as a precondition of registration.

Per the National Alliance for Model State Drug Laws, as of January 2016, twenty-three states and Washington, D.C. have requirements, either in statute, regulation, or board guidelines for practitioners to obtain a certain number of opioid or pain management related continuing education credits as a condition of license application or renewal. The following table summarizes those requirements.

¹⁸ <https://www.acponline.org/meetings-courses/focused-topics/safe-opioid-prescribing-strategies-assessment-fundamentals-education>.

¹⁹ <https://www.ama-assn.org/delivering-care/task-force-reduce-opioid-abuse>.

²⁰ Website is no longer available. Information on Plan can be retrieved at <http://www.painmed.org/PatientCenter/PreventDrugAbuse/prescription-drug-abuse-prevention-plan/>.

Summary of Prescriber Education Requirements in States²¹

Alabama - State Board of Medical Examiners may order that a physician holding controlled substance registration certificate complete a course of CME related to prescribing, dispensing, or administering controlled substances
Arizona - Dentists are required to complete courses in pain management and chemical dependency, among others
California - Physicians must complete courses in pain management and treatment of terminally ill patients
Connecticut - Physicians must complete one contact hour every two years in courses including prescribing controlled substances and pain management
D.C. - Mayor may establish continuing education requirements
Florida - Practitioners must complete CME courses on uses/abuses controlled substances and Federal/state laws on prescribing controlled substances; must complete a course on the prevention of medical errors which includes inappropriate prescribing of opioids; physicians prescribing/dispensing CDS for pain management must complete 15 hours of pain management CME every year
Georgia - Physicians who do not hold certification in pain management or palliative medicine and whose opioid pain management patients comprise 50% or more of the patient population must complete 20 hours of CME in pain management every two years
Idaho - Optometrists who are certified to prescribe therapeutic pharmaceuticals must complete 12 hours of CME in ocular pharmacology and/or advanced ocular disease every year
Iowa - Physicians must complete CME on pain management every five years
Kentucky - Physicians who work at a pain management facility must complete ten hours of CME in pain management during each registration period throughout the physician’s employment agreement with the facility; physicians who are licensed to prescribe CDS must complete at least 4.5 hours of approved CME relating to the use of the PMP, pain management, addiction disorders, or a combination of two or more of those subjects
Massachusetts - Physicians who prescribe controlled substances must complete appropriate training regarding pain management; identification of patients at high risk for substance abuse; counseling patients about the side effects, addictive nature, proper storage and disposal of prescription medications; and opioid education
Michigan - Physicians must complete an appropriate number of hours or courses in pain and symptom management; pharmacists, optometrists and dentists must complete at least one continuing education hour in pain management
Mississippi - Physicians with an active DEA certificate must obtain five hours of continuing education related to the prescribing of medications with an emphasis on controlled substances; physicians practicing in a pain management medical practice must have 15 hours of CME in pain management annually

²¹ <http://www.namsdl.org/library/4475CD3E-1372-636C-DD2E5186156DFB6F/>.

Summary of Prescriber Education Requirements in States (Continued)

<p>Nevada - State medical boards may enact regulations requiring clinicians under their purview to complete CME relating specifically to the misuse and abuse of controlled substances during each period of licensure</p>
<p>New Mexico - Clinicians who have a DEA license to prescribe CDS must complete five hours of pain management continuing education</p>
<p>North Carolina - Medical boards must require continuing education on the abuse of controlled substances as a condition of license renewal for health care providers who prescribe controlled substances (including one hour on prescribing practices)</p>
<p>Ohio - Physicians providing care at a pain management clinic must complete at least 20 hours of CME in pain medicine every two years</p>
<p>Oregon - All medical board licensees must complete seven hours of pain management courses, including: 1) one-hour pain management course specific to Oregon; and 2) a minimum of six hours in the subjects of pain management and/or treatment of terminally ill and dying patients; licensed health care professionals must complete a pain management education program in order to improve the care and treatment of individuals with painful conditions, which includes: 1) six hours of continuing education in pain management, end of life care, or both; and 2) the web-based training offered by the commission; pharmacists have a one-time requirement to complete seven hours of continuing education in pain management, including: 1) a one-hour pain management course specific to Oregon; and 2) a minimum of six hours in pain management</p>
<p>Pennsylvania - Optometrists who are certified to prescribe and administer pharmaceutical agents must complete a minimum of 6 hours of continuing education in the prescription and administration of pharmaceutical agents for therapeutic purposes</p>
<p>South Carolina - Physicians must complete two hours of continuing education related to approved procedures of prescribing and monitoring controlled substances</p>
<p>Tennessee - Optometrists must complete two hours of CME related to controlled substance prescribing; all prescribers who have a DEA license must complete at least two hours of CME related to controlled substances prescribing; all health care providers providing pain management services at a clinic shall complete ten (10) hours in continuing education courses</p>
<p>Utah - Clinicians who prescribe CDS must complete at least 3.5 hours of CME in one or more controlled substance prescribing classes, except dentists who shall complete at least two such hours, including training on the scope of the controlled substance abuse problem in Utah and the US, all elements of the FDA Blueprint for Prescriber Education and the national and Utah-specific resources available to prescribers</p>
<p>Vermont - All medical licensees must complete at least one hour of CME in the topics of hospice, palliative care, or pain management; all medical licensees who prescribe controlled substances must obtain at least one hour of CME related to the topic of safe and effective prescribing</p>
<p>West Virginia - Physicians must complete a minimum of three hours of drug diversion training and best practice prescribing of controlled substances training upon license renewal unless he/she can prove he/she has not prescribed</p>

In addition to the states summarized by the National Alliance for Model State Drug Laws above, OLO identified nine states that require prescriber education on pain management/opioid prescribing in some form. OLO

further found several other states (Alaska²², Louisiana²³, and New Jersey²⁴) which have introduced legislation that would require prescriber education.

Additional State Prescriber Education Requirements

Delaware ²⁵ - Clinicians who have a CDS license must complete a one-time one-hour Delaware specific course in addition to two hours of general opioid education during each license renewal period
Maine ²⁶ - All providers licensed to prescribe CDS must complete three hours of CME relevant to prescribing opioids every two years
New Hampshire ²⁷ - Physicians who have a DEA license must complete three hours of Board-approved opioid-related CME each renewal cycle
New York ²⁸ – Prescribers with a DEA registration number must complete three hours of course work in pain management, palliative care, and addiction
Rhode Island ²⁹ - All practitioners prescribing long-acting opioids must complete a one-time educational program compliant with the ER/LA Opioid Analgesic REMS Educational requirements issued by the FDA. Any practitioner who prescribes a Schedule II opioid is required to complete eight hours of CME in any or all of the following topics: (1) Appropriate prescribing of opioids for pain; (2) Pharmacology; (3) Adverse events; (4) Potential for dependence; (5) Tolerance; (6) Addiction; (7) Alternatives to opioids for pain management
Texas ³⁰ - Dentists permitted to prescribe CDS must complete at least two hours of continuing education in controlled substances every three years, and all personnel in pain management clinics are required to complete 10 hours of continuing education related to pain management
Washington ³¹ - Physicians who prescribe long-acting opioids or methadone must complete four hours of CME specific to prescribing
Wisconsin ³² - Prescribers with a DEA license are required to complete two CME credits specifically related to prescribing controlled substances for at least the next two license renewals
Virginia ³³ - All licensees with the Board of Medicine with prescriptive authority must complete two hours of CME on pain management, the responsible prescribing of controlled substances, and the diagnosis and management of addiction every two years upon renewal

²² <https://gov.alaska.gov/newsroom/2017/03/governor-walker-introduces-legislation-to-combat-alaskas-growing-opioid-epidemic/>.

²³ http://www.nola.com/health/index.ssf/2017/04/opioids_bill_louisiana_senate.html.

²⁴ <http://www.aroc.org/TheJournal/Fall2016/capital-views.html>.

²⁵ <http://www.delawarepas.org/dapa/required-controlled-substance-education/>.

²⁶ http://legislature.maine.gov/legis/bills/bills_127th/chapters/PUBLIC488.asp.

²⁷ https://www.nhms.org/sites/default/files/Pdfs/NH_Opioid_Prescribing_Rules_FAQs_12-16.pdf.

²⁸ https://www.health.ny.gov/professionals/narcotic/docs/mandatory_education_guidance.pdf.

²⁹ <http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/8473.pdf>.

³⁰ <http://www.sos.state.tx.us/texreg/archive/September22016/Proposed%20Rules/22.EXAMINING%20BOARDS.html#44> and <http://www.tmb.state.tx.us/page/resources-cme-for-md-dos>.

³¹ <http://www.lanepowell.com/wp-content/uploads/2011/06/OpioidRuleComments1.pdf>.

³² http://dsps.wi.gov/Documents/MEB_CME%20Requirement.pdf.

³³ <https://cme.vcuhealth.org/perch/resources/va-bd-of-med-prescription-authority.pdf>.

Chapter 4. Prescriber Education on Opioids and Other Prevention Education Efforts in Maryland and Montgomery County

As discussed in Chapter 1, opioid-related overdose deaths have increased sharply since 2010, both within Montgomery County and across the State. In recent years, policymakers at both the State and County levels have used a variety of approaches to prevent opioid misuse. This chapter summarizes the policies and tools available to educate prescribers in Montgomery County on the safe use of opioids. This chapter also provides information on other local prevention education efforts. The chapter is organized as follows:

- **Section A** provides an overview of the State’s approach to opioid misuse prevention;
- **Section B** provides an overview of the County’s approach to opioid misuse prevention; and
- **Section C** describes prescriber education initiatives in Maryland

A. Opioid Misuse Prevention Approaches in Maryland

The Behavioral Health Administration (BHA) in the Maryland Department of Health and Mental Hygiene (DHMH) is responsible for developing an “integrated process for planning, policy, and services to ensure a coordinated quality system of care is available to individuals with behavioral health conditions.”¹ The BHA has engaged in comprehensive effort to reduce opioid overdoses and overdose deaths, including educating the public and implementing new medical practices. The Health Promotion and Prevention Division is responsible for providing services regarding the prevention of opioid misuse in the State. This section describes the State’s programs and initiatives that include opioid misuse prevention components.

1. Maryland Opioid Overdose Prevention Plan

The Maryland Opioid Overdose Prevention Plan is a Statewide strategy for reducing overdose deaths related to pharmaceutical opioids and heroin. The Plan was released in January 2013 and included strategies for:

- Enhancing overdose-related data sharing and analysis;
- Improving access to substance use disorder treatment and recovery services;
- Providing clinical education and training for healthcare providers;
- Implementing the Prescription Drug Monitoring Program (see Chapter 6); and
- Broadening access to naloxone.

Further, all Maryland counties (including Baltimore City) submitted local overdose prevention plans to DHMH. Important themes emerged from these plans:

- Promoting clinician education on opioid prescribing practices and use of the Prescription Drug Monitoring Program;
- Completing outreach to populations at high risk of overdose;
- Expanding access to medication-assisted treatment for individuals with opioid dependence;
- Encouraging naloxone distribution; and
- Increasing public awareness.

¹ DHMH also has a State Opioid Treatment Authority (SOTA), which regulates the establishment and operations of medication assisted treatment programs in the State.

2. Opioid Misuse Prevention Program

Through this program, the State provides funding to local jurisdictions to strengthen and enhance their local overdose prevention plans and to implement evidence-based opioid misuse prevention strategies. The BHA contracts with the Behavioral Health Research Team at the University of Maryland School of Pharmacy to provide evaluation and technical assistance to the 22 jurisdictions receiving OMPP funding.

Currently, all 18 jurisdictions (including one regional team: Caroline, Dorchester, Kent, Queen Anne's, and Talbot counties) have submitted OMPP strategic plans, which include the strategies listed below. OLO found that most counties included in their plans specific activities related to prescriber education, such as promulgating letters to increase awareness of prevention efforts and prescribing resources, outreach campaigns targeted at clinicians, and conducting training for clinicians.²

- Prescriber/dispenser education;
- Prescription Drug Monitoring Program awareness and enrollment;
- Media campaigns about sharing, storing and disposal of prescription medications;
- Youth education regarding the risks and harms of opioid misuse;
- Public awareness of naloxone and the Good Samaritan Law;
- Drug take back events and drop boxes;
- Dissemination of locked storage boxes for parents and senior citizens;
- Implementing Screening, Brief Intervention, and Referral to Treatment (SBIRT)³; and
- Training for law enforcement and first responders on referring users to treatment.

3. Overdose Fatality Review (OFR)

In 2014, the Maryland General Assembly passed legislation that allowed for local jurisdictions to create Overdose Fatality Review Teams, which are multi-agency/multi-disciplinary members that conduct confidential case reviews of overdose deaths with the goal of preventing future deaths. The team attempts to identify missed opportunities for prevention, gaps in the system and areas for increased collaboration. DHMH provides support and technical assistance to these teams.

4. Prescription Drug Monitoring Program (PDMP)

Established by Maryland statute in 2011, the State's PDMP is a secure database of all Schedule II-V controlled dangerous substances prescribed and dispensed in Maryland that aims to reduce prescription drug misuse and diversion. The PDMP provides access to data on prescription opioids and other CDS for healthcare providers, pharmacists, patients, researchers, health occupations licensing boards, and public health and safety agencies.

² For a summary of efforts in prescriber education in all OMPP reports in the state, see Appendix. For links to the plans of all Maryland Counties, go to https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Pages/Overdose-Prevention-Plans-by-County.aspx.

³ SBIRT (Screening, Brief Intervention, and Referral to Treatment) is an evidence-based comprehensive, integrated public health approach to the delivery of providing early intervention and treatment services to patients who have risky alcohol or drug use.

5. Public Awareness Campaign

In 2014, the BHA developed a public awareness campaign aimed at providing basic information to the public about opioid overdose prevention, including posters, pamphlets, and emergency cards to local jurisdictions. The campaign also includes online information dissemination through Facebook and YouTube. Additionally, in 2016, the BHA held the Integrative Overdose Prevention Conference, which provided numerous educational presentations on a variety of topics related to overdose prevention targeted at stakeholders in state and local government, along with medical community members.

6. Interagency Collaboration Initiatives

Maryland Governor Larry Hogan has made the opioid and heroin epidemic in the State a priority of his administration. In July 2016, the Governor signed the National Governors Association's Compact to Fight Opioid Addiction and in October of 2016 he signed the National Capital Region Compact to Combat Opioid Addiction. Each of these compacts pledges the jurisdictions to work collaboratively to stop the damaging effects of opioid addiction. Additionally, the Governor has implemented three major initiatives in the Department of Health and Mental Hygiene aimed at improving collaboration among stakeholders in Maryland.

Heroin and Opioid Emergency Task Force (Executive Order 01.01.2015.12). In 2015, this Task Force was formed with prevention and addictions treatment experts, law enforcement officials, and education representatives to make recommendations on:⁴

- Policy, regulations, or legislation to improve access to high quality heroin and opioid addiction treatment and recovery services;
- Improving Federal, State, and local law enforcement and public health coordination;
- Increasing awareness and reducing stigma associated with addiction while equipping parents and educators with tools to prevent youth and adolescent use of heroin and opioids; and
- Alternatives to incarceration for nonviolent offenders whose crimes are driven primarily by their drug addiction.

Inter-Agency Heroin and Opioid Coordinating Council (Executive Order 01.01.2015.13). The Inter-Agency Heroin and Opioid Coordinating Council, established in February of 2015, is charged with sharing data and information across agencies and with the Office of the Governor to support public health and public safety responses to the heroin and opioid epidemic. The Council also is tasked with developing recommendations to help meet this mission. The Council includes seven State health, public safety and education agencies as well as any additional agencies requested by the Chair.

Heroin and Opioid Prevention, Treatment and Enforcement Initiative. In January 2017, Governor Hogan and various state and county health and public safety officials announced the Heroin and Opioid Prevention, Treatment and Enforcement Initiative. The lynchpin of the new initiative is the Opioid Operational Command Center, which increases collaboration between State and local public health, human services, education, and public safety stakeholders, including 12 State agencies.

Declared State of Emergency. As a result of the initial findings of the Opioid Operational Command Center (OCCC), which stated that Maryland needed more flexibility to activate emergency teams across the State,

⁴ Available at <https://governor.maryland.gov/ltgovernor/wp-content/uploads/sites/2/2015/12/Heroin-Opioid-Emergency-Task-Force-Final-Report.pdf>.

Maryland Governor Hogan signed an executive order in February 2017 declaring a state of emergency regarding the heroin and opioid epidemic in the State. Overseen by the Executive Director of the Maryland Emergency Management Agency (MEMA), this declaration delegates emergency powers to state and local emergency management teams, which allows for rapid coordination across governments and with community organizations. The Governor also provided \$50 million over five years in new funding for prevention, recovery, and enforcement.

B. Opioid Misuse Prevention Approaches in Montgomery County

The Department of Health and Human Services (DHHS) is the primary department addressing the prevention of substance abuse in the County. The County has established a bi-annual Strategic Plan for Alcohol and Drug Abuse, which provides guidance on an overall approach to alcohol and drug abuse in the County. While it does not directly address prescriber education, the current Plan does list the following priorities for the County:

- Promotion of the prevention of substance misuse and its harmful consequences;
- Improvement of practices and demonstration of outcomes that sustain an accessible community-based system of intervention and treatment services at appropriate levels of care for youth and adults;
- Promotion of recovery, improvement of integration of the treatment continuum, and development of strategies to identify and meet emerging community needs; and
- Expansion of a Recovery Oriented System of Care model in the County.

Montgomery County Opioid Overdose Prevention Plan. In 2013, the State directed all counties which received funding under the OMPP grant to develop an overdose prevention plan. Montgomery County's Plan is divided into three levels of prevention, described in the next table.

Goals	Highlighted Strategies
Primary Prevention	
<ul style="list-style-type: none"> • Raise awareness of the overdose risk to both providers and the community • Promote safe practices in homes and primary care practice settings • Reduce exposure and associated risks in the home and community 	<ul style="list-style-type: none"> • Public forums by MCPS and the Collaboration Council's Drug Free Coalition • Targeted outreach to senior and other special populations • Continued participation in the annual drug take back program • Establishment of on-going drug take-back boxes
Secondary Prevention	
<ul style="list-style-type: none"> • Detect and treat pre-addiction/abuse thereby reducing the risk for overdose 	<ul style="list-style-type: none"> • Implementing Screening, Brief Intervention and Referral to Treatment (SBIRT) to create "no wrong door approach" • Implementing policy changes such as Good Samaritan laws, Marchman Act laws⁵, and prescription drug monitoring
Tertiary Prevention	
<ul style="list-style-type: none"> • Address the underlying risk factors for death and promote recovery and resiliency 	<ul style="list-style-type: none"> • Focus on emergency response to overdose events such as the use of Naloxone and targeted education of first responders • Expanding the number of physicians credentialed to use Buprenorphine and increasing alternatives for medication assisted treatment • Continuing the implementation of Recovery Oriented Systems of Care with peer based recovery programs and recovery coaches

The Overdose Prevention Plan further states, “Physicians, Nurses, and Pharmacists are not educated about the dangers of prescribing opioid medications to consumers,” and establishes goals specific to prescriber education. The goals include: educating and providing continuing CMUs/CEUs for prescribers, educating the medical community about opioid addiction, and increasing the collective knowledge of best practices. The Plan also states that DHHS will explore a partnership with the State to offer CME training to physicians on the risks and effective management of prescription opioids, including pain management.

Current Opioid Overdose Prevention Efforts. The County, in conjunction with the Collaboration Council, has created the website, “It’s Never Worth It,”⁶ which outlines opioid overdose prevention strategies, signs of overdose, what to do in cases of overdose, and information on the Good Samaritan law.⁷

In addition, DHHS receives State funding (Overdose Misuse Prevention grant), which helps to fund an overdose prevention coordinator within the department. This position is the contact point for the State’s DHMH opioid programming and is responsible for the creation of a community awareness campaign to provide opioid abuse prevention education and outreach along with working with law enforcement to implement a drug take back

⁵ Laws that provide an opportunity of involuntary commitment of persons whose addictive behaviors constitute a danger to self.

⁶ www.itsneverworthit.com.

⁷ The Maryland Good Samaritan Law provides protection from arrest as well as prosecution for certain specific crimes and expands the charges from which people assisting in an emergency overdose situation are immune.

program. DHHS staff report that, in the past, the Department has completed a prescriber education campaign but found that it was difficult to find methods to contact prescribers in the County.

Other Montgomery County Substance Use Prevention Efforts

Alcohol and Other Drug Abuse Advisory Council (AODAAC). The AODAAC is a community group that discusses and provides guidance to County officials on the formulation and administration of alcohol and other drug abuse prevention and treatment services in Montgomery County. AODAAC members include County Government staff, individuals in recovery, MCPS representatives, treatment representatives, and community groups.

Drug Awareness Working Group. In 2016, the Montgomery County Executive created the Drug Awareness Working Group (DAWG), which is a quarterly meeting of County department heads to discuss and make recommendations to address issues surrounding drug use, abuse, and distribution in the County.

Many Voices for Smart Choices (MVSC). Many Voices for Smart Choices is an organization funded by the County's DHHS that aims to prevent and reduce substance abuse by youth. The stated goals of MVSC include changing the social environment to decrease use of substances, build the capacity of prevention programs and services, and reduce risk factors among County youth through education and outreach. Members of the group include school representatives, County officials, medical representatives, and community groups.

Montgomery County Police Department. In addition to the enforcement of laws relating to the distribution of illegal drugs, the Montgomery County Police Department received State funding for a heroin coordinator position, which gathers and analyzes opioid use data and provides follow-up services to opioid users and their families.

Montgomery County Public Schools. MCPS provides education to students through its health curriculum on substance abuse. In addition, MCPS provides voluntary staff training on issues in mental health, which includes drug and alcohol education. MCPS staff report that they are working on expanding services and education for substance abuse.

State's Attorney Office. The Montgomery County State's Attorney's Office, working with the Bar Association, MCPD, and other County agencies, created the *Speak Up, Save a Life Program* to raise awareness of Maryland's growing overdose epidemic and how citizens (especially students) can utilize Maryland's Good Samaritan law to save lives. The program consists of videos, statistics, and a panel of speakers, which are provided on an as requested basis by schools, religious institutions, organizations, and community groups.

C. Prescriber Education Initiatives in Maryland

As noted earlier, both the Maryland Opioid Overdose Prevention Plan and the Opioid Misuse Prevention Program include prescriber education components. The Opioid Overdose Prevention Plan, released in 2013, described efforts that were in progress by the Maryland Board of Physicians and the Division of Drug Control (now the Office of Controlled Substances Administration) to provide clinical guidelines to physicians and pharmacists on appropriate opioid prescribing and dispensing. This section describes the clinical guidelines, education requirements, and other resources related to opioid prescribing in Maryland.

1. Opioid Prescribing Guidelines

The Behavioral Health Administration (BHA) and Maryland Board of Physicians websites include links to the CDC’s opioid prescribing guidelines, which were released in 2016 and are designed to provide guidance to primary care providers on pain treatment for adults, particularly for chronic pain. Additionally, over the past five years, the BHA, the Board of Physicians and other stakeholders have promulgated clinical guidelines related to opioid prescribing, as described below.

Board of Physicians: Assuring a Safe Environment for CDS Prescribing. The Winter 2012 newsletter of the Maryland Board of Physicians included guidelines for prescribing of controlled dangerous substances (CDS). The guidelines consist of “frequently cited prescribing standards”, and are offered as a tool for prescribers to show due diligence in providing a safe prescribing environment.⁸ The guidelines include recommended actions for prescribers to complete before prescribing CDS as well as after prescribing and throughout treatment with CDS, as summarized in the table below.

The guidelines highlight *medication reconciliation* as an important element of safe CDS prescribing. This process is recommended by the Joint Commission, a national independent health accreditation organization, as part of its National Patient Safety Goals. Medication reconciliation consists of comparing a patient’s current medications with newly ordered medications in order to identify duplications, omissions and interactions and to assess the need to continue current medications.⁹

Table 4-1. Board of Physicians CDS Prescribing Guidance, 2012

Prior to prescribing	<ul style="list-style-type: none"> • Establish physician-patient relationship • Consider potential serious harm from abuse when prescribing opioid medications • Obtain consent from patient to communicate with other providers and pharmacists • Collect and review medical records to confirm prior diagnoses and medical regimens • Perform medication reconciliation • Screen patient for history of mental health or substance use disorders • Perform a medical history and physical
After and throughout prescribing	<ul style="list-style-type: none"> • Document patient interactions and expectations for CDS use and outcomes • Keep a signed contract with patients with expectations of CDS use • Use urine drug screening to track adherence to prescribed regimen • Conduct other laboratory tests as appropriate • Consider alternative treatment modalities and provide referrals as appropriate

Source: Maryland Board of Physicians Newsletter, Winter 2012, <http://www.mbp.state.md.us/forms/winter2012a.pdf>

Information on Lethal Mixtures – Benzodiazepines and Opioids, Including Buprenorphine. Individuals who use opioid medications in combination with benzodiazepines, a class of drugs that includes alprazolam (Xanax®), are at a higher risk of experiencing a fatal overdose. Buprenorphine, an opioid that is often used to treat opioid use disorders, is typically not associated with overdose deaths. However, in combination with benzodiazepines, the risk of overdose from buprenorphine is increased. In 2014, DHMH promulgated information to prescribers on the lethal combination of benzodiazepines and opioids compiled by the University of Maryland School of

⁸ “Assuring a Safe Environment for CDS Prescribing,” Maryland Board of Physicians Newsletter, Winter 2012, pp. 2-3, < <http://www.mbp.state.md.us/forms/winter2012a.pdf> >, accessed 4/24/2017.

⁹ National Patient Safety Goals Effective January 2017, Hospital Accreditation Program, The Joint Commission, < https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2017.pdf > accessed 4/24/2017.

Pharmacy.¹⁰ Specifically, this document included the following recommendations for physicians that prescribe opioids to patients on a chronic basis:

1. Avoid benzodiazepines in patients who are prescribed opioids on a chronic basis, or if necessary use benzodiazepines only on a short-term basis;
2. Conduct regular urine screens to assess whether patients are using opioids;
3. Review Prescription Drug Monitoring Program (PDMP) data for patients being prescribed controlled dangerous substances and notify other prescribers of any discrepancies; and
4. Establish written treatment agreements with patients to clarify expectations and educate patients about the risk of overdose when opioids and benzodiazepines are combined.

Zohydro ER Letter. In 2014, DHMH promulgated a letter to clinicians regarding a prescription opioid called Zohydro ER that had been recently approved by the FDA. Zohydro ER is an extended-release tablet of hydrocodone. In the letter, DHMH cautioned clinicians that the tablets lack characteristics used in other prescription opioids to prevent tampering and abuse. For example, if the Zohydro ER tablets are crushed or chewed, the opioid may be released immediately into the patient's body, not in an extended timeframe as intended. The letter also included general guidelines for prescribing Zohydro ER and other prescription opioids:¹¹

- Review the patient's medications with the patient and pharmacy for drug interactions;
- Use the lowest effective dose;
- Obtain signed consent for communication with all other providers/prescribers and pharmacies;
- Collect and review medical records from the original source to confirm prior diagnoses, medications and treatments;
- Document patient interactions, expectations and outcome goals;
- Keep a signed contract which explains expectations of opiate use;
- Use random or scheduled urine drug screening;
- Consider ancillary therapies and referrals for specialty care such as physical therapy and referral to orthopedics and pain management clinics; and
- Screen the patient for mental health or addiction issues.

Maryland Emergency Department Opioid Prescribing Guidelines. In 2015, the Maryland Hospital Association Executive Committee charged its Council on Clinical and Quality Issues with developing guidelines for providers

¹⁰ Love, R., and DiPaula, B., "Lethal Mixtures: Benzodiazepines and Opioids, Including Buprenorphine," University of Maryland School of Pharmacy, June 11, 2014, < http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Documents/2014.06.11%20-%20Letter%20to%20Boards%20re%20Benzos%20and%20Opioids.pdf > accessed 4/25/2017.

¹¹ "Zohydro Informational Letter," Maryland Department of Health and Mental Hygiene, May 14, 2014, < http://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/2014.05.14%20-%20Zohydro%20Letter%20to%20Clinicians.pdf > accessed 5/16/2017.

to address the misuse of prescription opioids.¹² Maryland's 47 acute care hospitals have committed to adopt the following guidelines, which are focused on prescribing in emergency departments:

1. Hospitals should develop a process to screen for substance misuse;
2. When possible, personnel should consult the Maryland PDMP before writing an opioid prescription;
3. Hospitals should develop a process to share the emergency department visit history of patients with other providers and hospitals that are treating the patients by using the Chesapeake Regional Information System for our Patients (CRISP), Maryland's health information exchange;
4. Emergency department personnel should attempt to notify the patient's primary opioid prescriber or primary care provider of the visit and medication prescribed;
5. Providers should not write prescriptions for controlled substances that were lost, destroyed or stolen;
6. Emergency department providers should not prescribe long-acting or controlled release opioids unless necessary;
7. Emergency room personnel should counsel the patient on: storage and disposal of the medications; proper use of medication; and the avoidance of using opioids and concomitant sedating substances due to the risk of overdose; and
8. Emergency department providers should prescribe no more than a short course and minimal amount of opioid analgesics for serious acute pain, lasting no more than three days.

2. Prescriber Education Requirements

DHMH oversees several professional licensing boards that are responsible for licensure and discipline of health professionals that can prescribe controlled dangerous substances (CDS) such as opioids. These classes of health professionals include physicians¹³, advance practice nurses, dentists, and podiatrists. Additionally, the Department of Agriculture oversees the Board of Veterinary Medical Examiners, which is responsible for the licensure and discipline of veterinarians, who can also prescribe opioids.

The Governor's Heroin and Opioid Emergency Task Force, established in 2015, recommended that the relevant professional licensing boards require licensees to complete continuing education related to opioids. While all boards require licensees to complete continuing education, most boards do not require licensees to complete specific education regarding opioid prescribing. One of the boards – the Board of Dental Examiners - currently imposes a specific continuing education requirement related to opioid prescribing as a condition for license

¹² "Maryland Emergency Department Opioid Prescribing Guidelines," Maryland Hospital Association, 2015, < <http://www.mhaonline.org/docs/default-source/Resources/Opioid-Resources-for-Hospitals/maryland-emergency-department-opioid-prescribing-guidelines.pdf?sfvrsn=2> > accessed 4/25/2017.

¹³ A physician can delegate prescriptive authority to physician assistants (PA) if the PA has:

- Passed the National Commission on Certification of Physician Assistants exam within the previous 2 years of submitting the delegation agreement; or
- Provided documentation of successful completion of 8 Category I hours of pharmacology education within the previous 2 years of submitting the delegation agreement; and a Bachelor's Degree or its equivalent or two years of work experience as a physician assistant.

In order to prescribe controlled dangerous substances, the PA must also have a valid state controlled dangerous substance registration and Drug Enforcement Agency (DEA) registration.

renewal. Additionally, the Board of Podiatric Medical Examiners will begin imposing a prescribing education requirement for the 2018-2019 renewal cycle.

The table below summarizes the opioid prescribing requirements imposed by each board. Of note, in 2015 the Maryland Board of Physicians imposed a requirement for physicians to complete a one-hour course on opioid prescribing at every renewal cycle. However, this requirement was discontinued due to legislation passed by the General Assembly in 2016 that now prohibits the Board of Physicians from requiring licensees to complete a specific course or program as a condition of license renewal.¹⁴

Table 4-2. Opioid Prescribing Education Requirements Imposed by Professional Licensing Boards

Board	Requirement
Board of Physicians	Previous opioid prescribing education requirement is no longer in effect as of October, 2016
Board of Nursing	No requirement
Board of Dental Examiners	Dentists must complete a two-hour Board-approved course on proper prescribing and disposal of prescription drugs every other renewal cycle
Board of Podiatric Medical Examiners	One required continuing medical education credit per renewal cycle must address prescribing practices for controlled substance medications for pain management starting with the 2018-2019 renewal cycle
Board of Veterinary Medical Examiners	No requirement

The Board of Dental Examiners provides a free online course in collaboration with the University of Maryland School of Dentistry to fulfill the requirement: *Proper Pharmacologic Prescribing and Disposal for the Dental Practitioner by the University of Maryland School of Dentistry*. The learning objectives of this course are as follows:

- To articulate and inform licensees about the new Maryland Dental Regulation on Continuing Education;
- To describe the Prescription Drug Monitoring Program of the State of Maryland;
- To identify proper prescription writing practices;
- To describe opioid drug prescribing and the prescription drug abuse crisis;
- To identify best practices for appropriate handling and disposal of medications and controlled substances;
- To review the use of the non-narcotic pain relievers to reduce the number of opioids needed for post-operative pain; and
- To identify pain relievers and blood thinners, herbals and other drug interactions.¹⁵

¹⁴ Md. Health Occupations Code Ann. § 14-316(d)(5)

¹⁵ “Proper Pharmacologic Prescribing and Disposal for Dental Practitioners,” Course Learning Objectives document, downloaded from the Blackboard online learning platform, < https://openeducation.blackboard.com/webapps/blackboard/content/listContent.jsp?course_id= 66_1&content_id= 3025_1&mode=reset > accessed 4/25/2017.

3. Additional Clinical Education Resources

Additional sources of clinical education resources on prescription opioids include the Maryland Office of Controlled Substances Administration (OCSA) and the various professional associations that serve licensees in the State. Additionally, the BHA is currently working to develop a targeted outreach and education program for prescribers of controlled substances.

Maryland Office of Controlled Substances Administration (OCSA). The Office of Controlled Substances Administration is responsible for the administration of the regulation and licensing of controlled substance dispensing in the State. One of the primary responsibilities of OCSA is the inspection of dispensing locations (mostly pharmacies). OCSA inspects all establishments on a rotating basis and will also investigate any establishment about which it has received a complaint.

During an inspection, the Office will review dispensing records and storage of controlled substances. The Office has created a “red flag” inspection, which includes the review of past filled prescriptions for a series of fourteen red flags such as cash prescriptions, out of state prescribers, and more than one family member receiving the same CDS. If the Office finds that there are potential issues with dispensing within an establishment, the Office can subpoena PDMP records from DHMH to investigate further. While OCSA does not complete any formal prescriber education, staff report that during these inspections, OCSA staff speak with pharmacists about the recent CDC guidelines on prescribing and stress that there are alternative options for pain management in addition to opioids.

Professional Associations. As noted above, all professional licensing boards require licensees to complete continuing education to renew their licenses, and one board currently imposes a specific continuing education requirement on opioid prescribing. Licensees that are not required to complete specific coursework related to opioid prescribing may nonetheless have the option to complete coursework on opioid prescribing in order to fulfill the general continuing education requirements.

Professional associations that serve licensees in the State, such as MedChi (the Maryland State Medical Society), the Maryland State Dental Association, and the Maryland Podiatric Association, often provide or connect licensees with accredited courses that fulfill the continuing education requirements imposed by the relevant Board. Licensees may need to pay a fee to access the courses. MedChi offers an online education catalog, which connects physicians with affordable online courses in a variety of topics, including pain management and drug abuse, offered by accredited education providers across the country. In 2015, the Montgomery County Medical Society (the local office of MedChi) offered several in-person courses to assist physicians in meeting the now-discontinued requirement to complete one hour of continuing education on opioid prescribing.

Targeted Outreach and Education. BHA staff report that the State provides training and education to prescribers as requested, including providing training to the various medical boards. BHA staff also report that they have conducted extensive training to prescribers and dispensers of opioids on the implementation of the PDMP program.

In addition, BHA is working with the University of Maryland, School of Pharmacy (UMSP) to develop a process for identifying and conducting targeted outreach and education to aberrant opioid and other controlled substance prescribers. The first step will include development of clinical guidelines for primary care practitioners that address when opioid prescribing is appropriate and, if it is, how to mitigate the risks of opioid prescribing.

Chapter 5. Prescription Drug Monitoring Programs in the United States

As noted in Chapter 1, the public health impacts of prescription opioids represent a growing cause for concern locally and nationwide. As of September 2015, 49 states and the District of Columbia had enacted prescription drug monitoring programs (PDMPs) in an effort to prevent harmful use of prescription drugs, including prescription opioids and others.¹ PDMPs collect electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners and make them available to authorized stakeholders including prescribers, professional licensing boards and law enforcement agencies.

PDMPs aim to both prevent diversion of prescription drugs (the channeling of drugs for illegal purposes and abuse) and improve medical care and public health efforts by improving prescribing decisions, identifying individuals who require treatment, and informing public health initiatives. This chapter describes how PDMPs work and reviews recommended policies and practices for maximizing PDMP effectiveness. OLO found that experts recommend a variety of strategies for ensuring that PDMP data are accurate and complete and for increasing utilization among prescribers and other user groups. The chapter is organized as follows:

- **Section A** describes typical program features of PDMPs in the United States; and
- **Section B** examines recommended policies and practices for PDMPs.

A. Overview of Prescription Drug Monitoring Programs in the United States

Prescription drug monitoring programs (PDMPs) are state-level programs intended to prevent harmful use of prescription drugs. PDMPs collect prescribing and dispensing data from pharmacists and store the data in an electronic database. The government, healthcare providers and other authorized entities can access the data to help prevent prescription drug misuse, support education and research about use and misuse, and aid law enforcement. Prescribers (physicians and others) represent key target users of PDMP data, since they can use it to learn about their patients' prescription history and thereby make more informed prescribing decisions.

The first PDMP was established by New York State in 1918, with a majority of existing PDMPs established after the year 2000. The early PDMPs were paper-based, focused on law enforcement objectives, and only monitored prescription drugs with the highest potential for abuse. In the 1990s, PDMPs began to use computer-based systems, and the focus of the programs shifted from law enforcement objectives to improving medical care and supporting public health efforts. Currently, all PDMPs use electronic databases.²

¹ *2015 Annual Review of Prescription Monitoring Programs*, National Alliance for Model State Drug Laws, September, 2015, < <http://www.namsdl.org/IssuesandEvents/2015%20Annual%20Review%20of%20Prescription%20Monitoring%20Programs.pdf> > accessed 11/3/2016.

² "History of Prescription Drug Monitoring Programs," PDMP Training and Technical Assistance Center, Brandeis University, < http://www.pdmpassist.org/pdf/PPTs/LE2012/1_Giglio_HistoryofPDMPs.pdf > accessed 1/26/2017.

Prescription Drug Diversion

Many PDMPs seek to prevent prescription drug diversion – the redirection of prescription drugs for illegitimate purposes through theft or other illegal practices. Drug diversion occurs in several ways, including:³

- **“Doctor Shopping.”** An individual posing as a legitimate patient visits multiple physicians to obtain multiple prescriptions, either to obtain drugs for themselves, friends/family, or to sell for a profit. Individuals may lie about current medications and/or use fake names to obtain prescriptions.
- **Indiscriminate Prescribing and Dispensing.** Physicians write medically unnecessary prescriptions, often operating out of “pill mills” – clinics that provide no legitimate care and may conspire with a pharmacy that fills the prescriptions. Often working in cash only, clinicians can make a profit operating pill mills.
- **Health Care Fraud.** Physicians and pharmacies bill third parties, such as Medicare, for medically unnecessary prescriptions and drugs that are never dispensed to patients. Some pharmacies have been caught bribing patients for their Medicare ID numbers to bill for unneeded prescriptions.
- **Criminal Enterprises.** Organized crime groups engage in trafficking of genuine and counterfeit prescription drugs obtained through theft or purchased from providers.

1. PDMP Operations

All existing PDMPs are administered at the state level. Because PDMPs can serve multiple purposes, states vary with respect to the entities that administer the programs and can include the states’ boards of pharmacy, health departments, professional licensing boards, and law enforcement agencies. All PDMPs include the basic components described below.

Monitored Drugs. States establish which prescription drugs to monitor through their PDMP programs. Monitored drugs can include those categorized as “controlled substances” under Federal and state laws as well as non-controlled substances. At a minimum, PDMPs collect data on prescription drugs in Federal Schedules II through IV for controlled substances, which include many prescription opioids as well as other prescription drugs such as tranquilizers and stimulants.⁴ Many states also collect data on substances in Federal Schedule V, which are substances less likely to be abused than those in other schedules, and some states collect data on prescriptions of certain non-controlled substances that may be abused in combination with other drugs or that are otherwise indicative of abuse.

Drug Dispensing Reporting Requirements. PDMPs obtain prescribing and dispensing data primarily from pharmacists, who are typically required to electronically submit data to a PDMP database within a specified timeframe after dispensing monitored drugs. Many states also require that nonresident pharmacies that

³ “Spotlight on Drug Diversion,” Office of Inspector General, U.S. Department of Health and Human Services Website, < <https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp> > accessed 11/8/2016; and “Pharmaceutical Crime and Organized Criminal Groups: An Analysis of the Involvement of Organized Criminal Groups in Pharmaceutical Crime Since 2008,” Interpol, Pharmaceutical Crime Sub-Directorate, July 17, 2014 < <https://www.interpol.int/Media/Files/Crime-areas/Pharmaceutical-crime/Pharmaceutical-Crime-and-Organized-Criminal-Groups> > accessed 11/8/2016.

⁴ Ibid. and “Prescription Drug Monitoring Frequently Asked Questions,” Prescription Drug Monitoring Program Training and Technical Assistance Center, < http://www.pdmpassist.org/pdf/PDMP_FAQ_2015_FinalForPrint.pdf > accessed 11/3/2016.

dispense monitored drugs to the state’s residents submit data to the PDMP. Additionally, physicians and other practitioners who dispense drugs directly to their patients, as well as veterinarians, are often required to submit data.⁵ States often exempt pharmacies located in hospitals and other institutional facilities that dispense drugs that are directly administered to patients on the premises from reporting requirements.

Access to PDMP Data. PDMPs authorize certain entities and individuals to access data for specified purposes, including preventing diversion and improving medical care. PDMPs can only achieve their goals if authorized stakeholders utilize the data. Examples of stakeholders who typically have access to PDMP data are summarized in the next table.

Table 5-1. Examples of Entities Authorized to Access PDMP Data

Entity	Purpose
Prescribers and Pharmacists	To obtain information about patients under their care
Law Enforcement	To assist with drug investigations (court order may be required)
Licensing and Regulatory Boards	To investigate health professionals who prescribe or dispense controlled substances inappropriately
Third-Party Insurers and State Medicaid Programs	For reviews of patients and providers, for example to identify patients that should be limited to one physician and one pharmacy for controlled substance prescriptions
State Medical Examiners or Coroners	For cause of death investigations
Research Organizations	For analysis and research of identified PDMP data

Source: “Prescription Drug Monitoring Frequently Asked Questions,” Prescription Drug Monitoring Program Training and Technical Assistance Center

B. PDMP Recommended Policies and Practices

The evidence on the effectiveness of PDMPs in preventing prescription drug misuse is mixed. Some studies show that PDMPs are associated with lower rates of prescription drug misuse and changes to prescribing practices, but others do not show an association. Assessing the impact of PDMPs is challenging because every state’s PDMP program is different, and many PDMPs experience low levels of utilization.⁶

Researchers have identified numerous policies and practices that are believed to maximize the effectiveness of PDMP programs by (1) promoting data completeness, accuracy and interoperability, and increasing PDMP utilization among (2) prescribers and (3) other authorized parties. In some cases, significant evidence demonstrating the impact of the policy or practice is available, while in others the policy or practice is recommended based on expert opinion alone. This section summarizes recommended policies and practices.

1. Ensuring Data are Complete and Accurate

Several recommended PDMP policies and practices are intended to ensure that data in the PDMP database are accurate and include all of the information necessary to achieve desired goals. These include data collection and management practices, along with requirements to collect specific information.

⁵ Ibid., and Lee, Christine Sh-Teng, "Prescription Drug Monitoring Programs: A Policy Review and Recommendations for States," Thesis, Georgia State University, 2015, < http://scholarworks.gsu.edu/iph_theses/363 > accessed 11/9/2016.

⁶ *Facing Addiction in America: the Surgeon General’s Report on Alcohol, Drugs and Health*, U.S. Department of Health and Human Services, 2016, p. 3-25 < <https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf> > accessed 2/13/2017

Promotion of PDMP Compliance and Data Integrity. PDMP data can be incomplete and/or inaccurate if pharmacists do not comply with reporting requirements and if errors occur when entering data into the PDMP database. A work group convened in 2014 by the PDMP Training and Technical Assistance Center (TTAC) identified numerous recommendations for PDMPs to promote pharmacy compliance and data integrity, including:⁷

- For PDMPs that exempt certain pharmacists from registering for the PDMP, pharmacists' eligibility for the exemption should be independently confirmed, and the PDMP should place a time limit on the exemption so that pharmacists must reapply for the exemption periodically;
- PDMPs should provide training materials, technical specifications for data transmissions, and detailed information on any policy changes to assist pharmacists in complying with PDMP rules;
- Where possible, PDMPs should conduct data analysis to flag possible cases of noncompliance, for example by comparing data on drugs ordered from distributors to a pharmacist's reported dispensing history in the PDMP database; and
- PDMPs should use an automated quality check system that flags identifiable errors, such as blank fields, and sends error notifications to pharmacists for correction, and the system should allow the PDMP to track errors and corrections for each pharmacist.

Collection of Specified Information to Identify Potential Misuse. Stakeholders, policy experts and case study evidence suggest that requiring collection of the types of data listed below can assist in identifying questionable behavior that may not otherwise be apparent:

- Data on prescriptions of drugs in all schedules of controlled substances;
- Data on prescriptions of certain drugs that are not controlled substances, but that may be misused in combination with other drugs or are otherwise indicative of misuse;⁸
- Positive identification data for the person who picks up the prescription to determine whether someone other than the patient had possession of the prescribed drugs; and
- Payment method data to show which transactions were made in cash, a potential indicator of questionable activity.⁹

24-Hour Prescription Reporting Interval or Real-Time Reporting. PDMPs vary with respect to how often pharmacists and other dispensers must submit data to the PDMP, from real-time to monthly. Experts recommend requiring pharmacists to submit prescription data within a maximum of seven days of dispensing

⁷ "PDMP Suggested Practices to Ensure Pharmacy Compliance and Improve Data Integrity," Prescription Drug Monitoring Program Training and Technical Assistance Center, Technical Assistance Guide, April 13, 2015, < http://www.pdmpassist.org/pdf/Pharmacy_compliance_data_quality_TAG_FINAL_20150615.pdf > accessed 12/29/2016.

⁸ Examples of nonscheduled drugs monitored by PDMPs include gabapentin and cyclobenzaprine (two drugs, used to treat pain, that have been misused in some cases), human growth hormone (often used illegally "off-label" for anti-aging), ephedrine and prescribed pseudoephedrine (decongestants that can be used to illegally manufacture methamphetamine), and opioid antagonists (drugs like naloxone, or Narcan®, that are used to reverse the toxic effects of opioid overdoses). See < <http://www.pdmpassist.org/content/drug-schedules-monitored> >.

⁹ Clark, T., Eadie, J., Knue, P., Kreiner, P., and Strickler, G., "Prescription Drug Monitoring Programs: Assessment of the Evidence for Best Practices," Prepared for the Pew Charitable Trusts by the Prescription Drug Monitoring Program Center of Excellence, September 20, 2012, pp. 12-20.

the drug and ideally within 24 hours or in real-time to ensure PDMP data are complete.¹⁰ As of 2015, 26 out of 49 state PDMP programs required daily reporting and two states required real-time or near real-time reporting.¹¹

Interstate PDMP Data Sharing. By sharing PDMP data with one another, states can more effectively identify cases of interstate prescription drug diversion. For example, data from Kentucky indicate that a small but significant portion (nearly 7% in Kentucky) of prescriptions are filled in a different state than the one in which they were prescribed, most commonly in a neighboring state.¹² Nearly 40 states, including Maryland, share PDMP data with other states through a platform developed by the National Association of Boards of Pharmacy.¹³

It is important to note that the implementation of the items recommended above is often dependent on the technological capabilities and structure of the PDMP database. Advanced information systems are necessary to allow for real-time prescription reporting and for integration with other sources of data such as electronic prescription systems. Furthermore, most PDMPs adhere to data formatting standards established by the American Society for Automation in Pharmacy (ASAP), but many PDMPs use older versions of the standards. Only more recent standards allow for the collection of certain types of information listed above, such as payment method data.

2. Promoting Prescriber Utilization

Many PDMPs experience low levels of prescriber utilization. In a 2014 national survey, primary care physicians reported prescribing opioids to about 35 patients per month, but only reported accessing PDMP data for eight patients during the month preceding the survey. A growing body of research indicates that increasing PDMP utilization among prescribers in particular can reduce opioid prescribing and “doctor shopping”.¹⁴ As a result, increasing prescriber utilization is a key goal of many PDMPs.

Several factors influence prescriber utilization rates, including the presence of certain policies.¹⁵ A 2016 report from Brandeis University and the Pew Charitable Trusts describes the following eight approaches for increasing prescriber utilization of PDMP databases and the evidence in support of them, summarized below:

- Prescriber Registration & Use Mandates;
- Streamlined Enrollment;
- Delegation of Access to PDMP;
- Educational and Promotional Initiatives;
- Unsolicited Reporting to Flag Misuse;
- Health IT Integration; and
- Data Timeliness;
- Enhanced User Interfaces.

¹⁰ Clark, T., Eadie, J., Knue, P., Kreiner, P., and Strickler, G., “Prescription Drug Monitoring Programs: Assessment of the Evidence for Best Practices,” p. 16.

¹¹ *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, The Pew Charitable Trusts, December 2016, < http://www.pewtrusts.org/~media/assets/2016/12/prescription_drug_monitoring_programs.pdf > accessed 12/29/2016, p. 30.

¹² Clark, T., Eadie, J., Knue, P., Kreiner, P., and Strickler, G., “Prescription Drug Monitoring Programs: Assessment of the Evidence for Best Practices,” p. 49.

¹³ “Physicians and PDMPs: Improving the Use of Prescription Drug Monitoring Programs,” The Network for Excellence in Health Innovation, Issue Brief, November 2015, p. 9 and <https://nabp.pharmacy/initiatives/pmp-interconnect/>.

¹⁴ *Facing Addiction in America: the Surgeon General’s Report on Alcohol, Drugs and Health*, U.S. Department of Health and Human Services, 2016, p. 3-25 < <https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf> > accessed 2/13/2017.

¹⁵ *Prescription Drug Monitoring Programs: Evidence-Based Practices to Optimize Prescriber Use*, The Pew Charitable Trusts, December 2016, < http://www.pewtrusts.org/~media/assets/2016/12/prescription_drug_monitoring_programs.pdf > accessed 12/29/2016.

Prescriber Registration and Use Mandates. Originally, PDMPs did not require prescribers to access the PDMP database. In recent years, some states have begun to enact prescriber mandates that typically require prescribers to both register in the PDMP system and access PDMP data for all initial controlled substances prescriptions and other specified prescriptions. The first state to enact a comprehensive mandate for all initial prescriptions of any controlled substance was Kentucky in 2012. Several states, including Maryland, have since enacted similar mandates, though many, including Maryland's, are not yet in effect.

Because existing comprehensive prescriber use mandates have only been operational for a few years, limited data are available on their effectiveness. Available data show that prescriber use mandates may significantly increase use of PDMP data and reduce doctor shopping. For example, in New York, the PDMP program experienced a sharp increase in requests for PDMP reports from 11,000 requests per month to 1.2 million after the mandate went into effect. In Kentucky, instances of patients receiving controlled substances prescriptions from multiple providers (a sign of doctor shopping) decreased from over 14,000 to under 7,000 after the implementation of the mandate. However, because prescriber use mandates are often enacted with additional reforms, it is not possible to definitively determine whether the mandates caused the observed outcomes.¹⁶

The experiences of states that have implemented prescriber use mandates highlight two important considerations. First, to successfully implement a mandate, the PDMP must have infrastructure in place that allows prescribers to easily and efficiently register and access data. Second, stakeholders have expressed concerns that such mandates might result in a "chilling effect" on prescribing, meaning that prescribers will avoid prescribing monitored substances either to avoid the burden of accessing the PDMP or out of fear of being accused of improper prescribing. Both Kentucky and New York monitored prescribing trends to assess whether their mandates resulted in a "chilling effect", and the data did not show that this occurred.¹⁷

Delegation of Access to PDMP. Currently, the majority of PDMPs allow prescribers to authorize other members of their healthcare teams to access the PDMP on their behalf, in order to reduce the time that prescribers must spend to access data. Typically, those PDMPs that permit delegation allow prescribers who are registered with the PDMP to establish subaccounts for certain staff members. Some states limit the number of subaccounts allowed per prescriber, and some states limit delegation to licensed professionals such as nurses.

Many states adopted delegation while concurrently implementing prescriber use mandates, making it difficult to isolate the impact of delegation on prescriber utilization. However, data show that, where allowed, delegates use PDMPs frequently, sometimes more frequently than prescribers do. In Kentucky, for example, delegates requested 64% of PDMP reports in 2015. Additionally, survey data suggest that many prescribers consider that the most effective way to use PDMP data is to have delegates include PDMP data in patient charts in advance of the prescriber's appointments.¹⁸

Delegation has raised concerns about patient privacy and confidentiality, though the extent to which delegation increases the risks of improper PDMP data uses is unclear. States that have implemented delegation have not seen high levels of delegate misuse of data, though such activity may go unreported. Researchers note that many prescribers already delegate patient record keeping tasks to their staff, and that prescribers can integrate monitoring of PDMP use by staff with their existing processes for monitoring use of patient data.¹⁹

¹⁶ Ibid., pp. 8-18.

¹⁷ Ibid., pp. 13 and 15.

¹⁸ Ibid., pp. 18-23.

¹⁹ Ibid., pp. 19-20.

Unsolicited Reporting to Flag Potential Misuse. As of 2015, 32 states provided unsolicited reports to prescribers, which proactively alert prescribers when their patients meet specified criteria for possible questionable behavior, including evidence of doctor shopping or filling prescriptions for commonly misused combinations of drugs. Examples of the types of criteria used to flag a patient for an unsolicited report include:

- Meeting a specified threshold for multiple provider episodes, which are cases of a patient visiting numerous prescribers or pharmacies to obtain similar drugs;
- Meeting a specified threshold for a certain quantity of opioids obtained over a specified period of time;
- Multiple overlapping prescriptions for medications containing opioids; or
- Receiving prescriptions for certain combinations of drugs that are indicative of misuse.

Some states allow prescribers, at their discretion, to send their patients' reports to other prescribers treating the same patient, a practice referred to as "user-led" unsolicited reporting. Some states also send unsolicited reports to additional recipient groups, such as dispensers, professional licensing boards or law enforcement agencies. Unsolicited reports typically consist of a letter or e-mail that advises prescribers to query the PDMP for the patient's history. A state may choose to mail letters rather than use e-mail if it does not have access to all prescribers' e-mail addresses.

Data indicate that unsolicited reports increase prescriber utilization by (1) informing unregistered prescribers of the presence of the PDMP and motivating them to register in order to access PDMP data; and (2) prompting registered prescribers to access PDMP data. A study of Maine's PDMP showed that prescribers who received unsolicited reports were significantly more likely to register with the PDMP compared with prescribers that did not. In Nevada, an increase in the number of unsolicited reports was accompanied by prescribers querying the PDMP database more often, indicating that unsolicited reporting increases utilization of PDMPs. Data from Indiana's PDMP also show that both registrations and prescriber queries of the PDMP increased after implementation of unsolicited reporting.²⁰

Data Timeliness. As noted earlier, experts recommend requiring pharmacists to report prescription data at least daily and at best in real-time. Researchers suggest that short reporting intervals not only improve data quality, but they can also increase prescriber utilization by increasing confidence in the accuracy and utility of PDMP data. In Oklahoma, the only state with real-time reporting, prescriber queries of the PDMP database increased by 63% in the year after implementation of real-time reporting and continued to increase after that. However, implementation of real-time reporting has been found to require significant cost and time investments.²¹

Streamlined Enrollment. Prescriber enrollment is a key process for PDMPs. PDMPs must be able to enroll prescribers efficiently while ensuring that only legitimate prescribers and authorized delegates can access PDMP data. Some programs require hard copies of notarized applications to be mailed, faxed or scanned and sent electronically. However, as of 2015, 39 states had established streamlined PDMP enrollment systems that allow prescribers to register online by using licensing data held by the government to verify their identity and licensing status. Additionally, some states automatically enroll prescribers with the PDMP as part of their license renewal.²²

²⁰ Ibid. pp. 23-29.

²¹ Ibid. pp. 29-34.

Limited data are available on the impact of streamlined prescriber enrollment. Case studies from Tennessee and Minnesota show that streamlined enrollment can save significant amounts of time for PDMP staff and allow for faster processing of applications. No security problems have been reported as a result of eliminating notarization requirements.

Educational and Promotional Initiatives. Prescribers should be educated on PDMPs, including how to register and use the system, along with how PDMP data can inform prescribing decisions. States use a variety of educational approaches, including websites, written materials and presentations. Case studies show that a lack of information often prevents prescribers from using the PDMP, suggesting that educational and promotional initiatives can increase utilization. As of 2015, 40 state PDMPs conducted education and outreach activities to provide prescribers with information and instruction on the features of the PDMP and how to use it. Of those, 13 PDMPs mandate prescriber training on the use of the PDMP. No data exist on the specific impact of such initiatives on prescriber utilization due to the difficulties of isolating the impact of this practice.²³

Health Information Technology Integration. In recent years, 14 states, including Maryland, have worked to include PDMP data within electronic health records (EHRs). An EHR is a digital collection of a patient's health information used by providers to manage health information. In order to facilitate PDMP integration with providers' EHR systems, some states have integrated their PDMPs with health information exchanges (HIE), which are electronic systems often supported by states that are designed to help health providers share patients' medical information with other providers.

When PDMPs are integrated with EHRs, the EHR automatically queries the PDMP, so that a patient's record contains controlled substances prescription history data as well as other patient information. As a result, PDMP data are made available to prescribers without the need to access an additional account. States that have integrated their PDMPs with health information technologies have received positive feedback from prescribers on the integration, and in some cases have experienced sharp increases in prescriber utilization following integration. For example, when Indiana made PDMP data available to hospitals via the Indiana HIE, queries of the PDMP increased by 59% over the prior month.²⁴

Enhanced User Interfaces. Traditionally, PDMPs allow prescribers to view comprehensive data on their patients' controlled substances prescription history. Prescribers must then interpret the data to determine whether the patient is at risk of misusing prescription drugs. In order to assist prescribers in more efficiently interpreting and using PDMP data, 18 states have implemented or begun to implement enhanced user interfaces that make the data easier to use, such as a flagging system, dashboard, or summary information.

For example, Kentucky's interface calculates the "morphine milligram equivalents" (MME) for each prescription to more easily show prescribers the quantity of opioids that were prescribed and flags patients whose controlled substances prescription history exceeds a threshold established by a state advisory group. Other states have implemented mobile apps, which provide a user-friendly interface for accessing PDMP data on mobile devices, and dashboards, which provide easy-to-read data summaries. Some states use NARxCHECK, a commercial product that calculates a risk score for each patient and produces a graphical analysis of patients' controlled substance prescription history. Because enhanced user interfaces are relatively new, limited data are available on their impact on prescriber utilization.²⁵

²³ Ibid. pp. 39-45.

²⁴ Ibid. pp. 45-50.

²⁵ Ibid. pp. 51-56.

3. Facilitating Utilization of PDMP Data By Other Authorized Parties

In addition to prescribers, entities including professional licensing boards, law enforcement, dispensers and third-party insurers can use PDMP data to prevent or halt the diversion of prescription drugs and improve medical care and public health efforts. In its 2015 report on approaches for combating the prescription opioid epidemic, the Johns Hopkins School of Public Health offers two recommendations for facilitating PDMP utilization by parties other than prescribers, summarized below.²⁶

Providing Proactive Analysis to All Appropriate Recipient Groups. As noted earlier, 32 states provided unsolicited reports in 2015, in which recipients are alerted to questionable activity that may be indicative of prescription drug diversion or misuse. Most states provide unsolicited reports primarily to prescribers, but other recipient groups can benefit from them as well:

- Pharmacists can be made aware of questionable activity among patients or prescribers;
- Licensing boards and law enforcement can use the data to identify and stop inappropriate and illegal activities; and
- State and community prevention programs can use the data to identify “hot spots” to guide targeted and informed prevention and treatment efforts.

Allowing Third-Party Payers to Access PDMP Data. PDMP data offers third-party payers more complete information regarding prescribing and dispensing to their enrollees, which can then be used to inform their decision-making and assist in fraud prevention. For example, some payers have implemented “Lock-in” programs that restrict high-risk patients to one prescriber and one pharmacy. However, if patients pay for medications in cash or use a different third-party payer, a payer may not become aware of potential misuse or improper prescribing or dispensing without access to PDMP data.

According to the PDMP Training and Technical Assistance Center, 33 PDMPs had the authority to share data with Medicaid programs, seven have the authority to share data with Medicare, nine can share data with state workers’ compensation programs, and four can share data with private third-party payers.²⁷ Some stakeholders have expressed concerns that third-party payers could use the data to deny coverage or legitimate care. The PDMP Training and Technical Assistance Center notes that some protections against such actions already exist in Federal law and through insurance regulatory boards. States can also explicitly prohibit third-party payers from denying coverage based on PDMP data unless the payer has identified fraud, diversion or a legitimate health issue in investigating a claim.²⁸

²⁶ Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015, pp. 30-31 < <http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf> > accessed 1/24/2017.

²⁷ “PDMPs Authorized and Engaged in Sending Solicited and Unsolicited Reports to Public and Private Insurance Entities,” Prescription Drug Monitoring Program Training and Technical Assistance Center, November 25, 2016, < http://www.pdmpassist.org/pdf/Insurance_Entity_Table.pdf > accessed 4/10/2017.

²⁸ “PDMPs and Third Party Payers Meeting: Report of Findings,” PDMP Center of Excellence, December 2012, < http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Brandeis_COE_PDMP_3rd_pty_payer_mtg_rpt.pdf > accessed 4/10/2017.

Chapter 6. Maryland's Prescription Drug Monitoring Program

As described in Chapter 5, prescription drug monitoring programs are state-run programs intended to prevent harmful use of prescription drugs. These programs store data on the prescribing and dispensing of specified drugs in an electronic database, which is used to inform prescribing and dispensing decisions, support the investigative efforts of law enforcement, professional licensing boards and other bodies, and inform public health efforts.

Located in the Maryland Department of Health and Mental Hygiene (DHMH), Maryland's Prescription Drug Monitoring Program (PDMP) was established in 2011 by Maryland statute and became fully operational in December of 2013.¹ This chapter describes Maryland's PDMP, examines data on its performance, and assesses the extent to which it employs recommended practices. OLO found that, three years after the PDMP became operational, the State continues to improve and refine the PDMP, and it has implemented or is in the process of implementing the majority of recommended practices described in Chapter 5. The chapter is organized as follows:

- **Section A** describes Maryland's Prescription Drug Monitoring Program (PDMP);
- **Section B** reviews PDMP performance data; and
- **Section C** examines the PDMP's alignment with recommended practices described in Chapter 5.

A. Features of Maryland's Prescription Drug Monitoring Program

The mission of the Maryland PDMP is to assist health providers and public health professionals in identifying and preventing abuse of prescription drugs that contain controlled dangerous substances (CDS), to assist law enforcement agencies and professional licensing boards in identifying and investigating unlawful drug diversion, and to promote a balanced use of prescription data that supports law enforcement while preserving access to medical care.² To this end, the PDMP's responsibilities include:

- Creating an electronic database of CDS prescription information;
- Monitoring the prescribing and dispensing of prescriptions that contain CDS; and
- Making prescription data available to the authorized individuals and entities defined in State law.³

1. PDMP Advisory Board and Technical Advisory Committee

State law requires DHMH to establish an advisory board and a technical advisory committee to advise the Department regarding the PDMP and to provide assistance and guidance regarding specific requests and cases.

Advisory Board. The Advisory Board consists of representatives from DHMH, professional licensing boards, prescribers, pharmacists, law enforcement, and patients. The Board must meet at least three times annually and is charged with:

¹ As of July, 2013, Maryland was one of three states, along with the District of Columbia, that did not yet have an operational PDMP. See "Compilation of State Prescription Monitoring Program Maps," National Alliance for Model State Drug Laws, July, 2013, <http://www.namsdl.org/library/13D46B1B-1372-636C-DD8A80A2928024DF/>.

² Md. Health-General Code Ann. § 21-2A-02.

³ 2016 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program (under § Health – General Article §21-2A-05(f)(3(ii)), January 24, 2017, p.2.

- Making recommendations regarding legislation, regulations and funding for the PDMP;
- Providing the Governor with an annual report on the PDMP that provides information on the usage and impact of the program;
- Providing ongoing guidance regarding the implementation and operation of the program; and
- Consulting with stakeholders and experts as appropriate.⁴

Technical Advisory Committee. The technical advisory committee consists of nine health professionals from a variety of specialties appointed by the Secretary of DHMH. The purpose of the committee is to:

- Review requests for PDMP information from law enforcement agencies, professional licensing boards, rehabilitation programs, other states, and other units of DHMH; and
- Provide guidance with respect to specific cases of possible drug abuse or misuse and of possible violations of professional standards by a prescriber or dispenser.⁵

2. PDMP Operations

The PDMP is located in the Behavioral Health Administration (BHA) of the Maryland Department of Health and Mental Hygiene (DHMH). DHMH has partnered with Chesapeake Regional Information System for our Patients (CRISP)⁶, the statewide health information exchange (HIE), to design, implement, and operate core PDMP information technology services. DHMH and CRISP contracted with Health Information Designs (HID) to develop the PDMP database and RxSentry, which is a web-based program that has the capability to collect, analyze, and report PDMP data.

Monitored Drugs. The PDMP monitors drugs in Schedules II through V of controlled dangerous substances (CDS) as established in State law, or all schedules except Schedule I (which have no accepted medical use). As such, the PDMP monitors all prescription drugs that are CDS. Drugs not listed in State schedules for controlled dangerous substances are not monitored.⁷

Drug Dispensing Reporting Requirements. State law establishes that pharmacists and other professionals that are licensed to dispense CDS (“dispensers”) must report data electronically to the State for each monitored prescription drug that they dispense to patients in the State.⁸ Pharmacists located outside of the State are also required to report if they dispense drugs to patients in the State. Regulations require that for each dispensed drug pursuant to a prescription, dispensers must report the following data to the PDMP:

- Prescription number;
- Date of prescription issuance;
- Date prescription was filled;

⁴ Md. Health-General Code Ann. § 21-2A-05.

⁵ Md. Health-General Code Ann. § 21-2A-07.

⁶ CRISP is the nonprofit corporation that serves as Maryland’s designated Health Information Exchange (HIE), a system for health care professionals and patients to access and share medical information electronically. CRISP connects 46 acute care hospitals in Maryland.

⁷ Md. Health-General Code Ann. § 21-2A-02.

⁸ Md. Health-General Code Ann. § 21-2A-03(c).

- If the prescription is new or a refill;
- Number of refills ordered;
- Source of payment;
- National Drug Code;
- Metric quantity;
- Days' supply;
- Patient name, date of birth, sex, telephone number, address and identification number from a driver's license or other identification; and
- Prescriber name and Drug Enforcement Administration identification number.⁹

Current regulations require dispensers to report data within three days of dispensing the drug; however, the State is in the process of amending the regulations to reduce this timeframe to 24 hours.¹⁰ DHMH reports that many dispensers already report daily. If a dispenser does not dispense CDS during a given reporting period, they are not required to report to the PDMP, but the system allows for "zero reporting" if dispensers choose to do so.

Health Information Designs provides a guide for dispensers on reporting data to the PDMP.¹¹ The data submitted by dispensers must conform to the American Society for Automation in Pharmacy (ASAP) data standard specified by DHMH (currently version 4.2).¹² The system automatically rejects records that contain certain types of serious errors (such as missing data for a critical field), and the dispenser must re-submit the corrected data within three business days.¹³

The following dispensers are exempted the reporting requirement: hospital pharmacies that only dispense drugs for direct administration to hospital inpatients, opioid treatment services programs, veterinarians that dispense controlled substances for animals, and pharmacies that receive waivers because they exclusively serve persons living in a facility such as an assisted living or hospice care facility. Waivers are valid for two years, and pharmacies that receive waivers are subject to onsite unannounced inspections.¹⁴

PDMP Data Users and Access. State law establishes which individuals and entities can receive PDMP data. Table 6-1 lists each user group that can access or request PDMP data, divided into three categories - clinical users, investigative users and other users:

- Clinical users access data in connection with the care of their patients;
- Investigative users request data regarding specific investigations into illegal activity, breaches of professional standards, or fatality case reviews; and
- Other users, such as patients that wish to access their data and organizations conducting research.

⁹ COMAR 10.47.07.03(A).

¹⁰ COMAR 10.47.07.03(B) and Md. Health-General Code Ann. § 21-2A-04(b)(3).

¹¹ "Dispenser's Implementation Guide," Maryland Department of Health and Mental Hygiene, Prescription Drug Monitoring Program, June 2015, < http://www.hidesigns.com/assets/files/mdpdmp/MD_PDMP_Dispensers_Implementation_Guide.pdf > accessed 3/1/2017.

¹² The ASAP format standard organizes prescription data into "segments" (such as dispensing record or prescriber information) and is transmitted as a single file. PDMP Technical and Assistance and Training Center, Technical Assistance Guide No. 01-14. <http://www.pdmpassist.org/pdf/TAG_Additional_Data_Fields_FINAL.pdf> Accessed 5/4/17.

¹³ "Dispenser's Implementation Guide," Maryland Department of Health and Mental Hygiene, Prescription Drug Monitoring Program, June 2015, < http://www.hidesigns.com/assets/files/mdpdmp/MD_PDMP_Dispensers_Implementation_Guide.pdf > accessed 3/1/2017.

¹⁴ Md. Health-General Code Ann. § 21-2A-01(d) and Md. Health-General Code Ann. § 21-2A-03(f).

Table 6-1. PDMP Data Users Authorized by Law

User Group	Permitted Use
Clinical Users	
Prescribers and their delegates	In connection with the medical care of the prescriber's patient
Dispensers and their delegates	In connection with the dispensing of a monitored drug
Investigative Users	
Law enforcement agencies	On issuance of a subpoena
Professional licensing boards	On issuance of an administrative subpoena
Rehabilitation programs	On issuance of an administrative subpoena
State and local fatality review teams	Upon request for furthering a bona fide individual case review
Office of the Chief Medical Examiner	On request with approval of the DHMH Secretary
Maryland Medical Assistance Program (Medicaid)	On request with approval of the DHMH Secretary
Office of the Inspector General	On request with approval of the DHMH Secretary
Office of Health Care Quality	On request with approval of the DHMH Secretary
Division of Drug Control	On request with approval of the DHMH Secretary
Other User Groups	
Patients and their authorized representatives	Upon request for PDMP data about the patient
Other state's prescription drug monitoring program	Upon request
Other organizations and individuals	On request, for research, education and public reporting, with identifying information redacted
PDMP Technical Advisory Committee	To review data for indications of questionable activity and to review data requests

Source: Md. Health-General Code Ann. § 21-2A-06

As noted above, the Chesapeake Information System for our Patients (CRISP) is Maryland’s State-designated health information exchange (HIE). CRISP provides an online portal for clinical users (prescribers, dispensers and their delegates) to access PDMP and other health data on their patients. Investigative users (law enforcement, professional licensing boards and other public entities) can request PDMP data via a separate online system called RxSentry®, managed by Health Information Designs. In many cases, investigators must provide a subpoena to access the data. Other users, such as patients seeking data on themselves and organizations conducting research, must contact DHMH directly to request data.

Additionally, the PDMP works with other states to share data. In 2015, the PDMP began to share data with Virginia through PMP Interconnect (PMPi), a platform established by the National Association of Boards of Pharmacy. Since then, the PDMP has also begun sharing data with West Virginia, Connecticut and Arkansas through the same platform. PMPi makes data from these states available to clinical users in Maryland via CRISP. The PDMP is currently exploring ways to share data with other states, which has not yet occurred due to a provision in Maryland law that prevents redisclosure of data to unlicensed professionals.¹⁵

¹⁵ 2016 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program, January 24, 2017, p. 20 < [https://bha.health.maryland.gov/Documents/HG%2021-2A-05%20-%20BHA%20-%20PDMPFinal%20SignedBHA_01-24-17OGA1767%20\(2\).pdf](https://bha.health.maryland.gov/Documents/HG%2021-2A-05%20-%20BHA%20-%20PDMPFinal%20SignedBHA_01-24-17OGA1767%20(2).pdf) > accessed 5/9/2017

3. Approaches to Maximize PDMP Utilization

Since the creation of the PDMP in 2011, changes to the law and program improvements have been made with the intent of maximizing utilization of the PDMP, particularly among prescribers. Because the PDMP has only been operational for three years, some planned changes and improvements have not yet been fully implemented, and additional changes are under consideration. The following summarizes how the State is implementing legislative and policy changes to maximize the utilization of the PDMP.

Registration and Use Mandates for Prescribers and Dispensers. In 2016, the PDMP law was amended to establish new registration and data access rules for prescribers and dispensers, as detailed below:

- By July 1, 2017, prescribers authorized to prescribe controlled dangerous substances and all dispensers must be registered with the PDMP; and
- Starting July 1, 2018, prescribers must query the system for at least the prior four months of prescription monitoring data for every initial prescription of an opioid or benzodiazepine and for every 90 days thereafter as long as the patient is being prescribed the drug.¹⁶

Delegation of Access to PDMP. Amendments to the law in 2016 expanded the definition of “delegates” – the individuals to which prescribers and dispensers can delegate their access to the PDMP. Prescribers and dispensers can now delegate their authority to access PDMP data to any individual who is employed by or under contract with them. Previously, prescribers could only delegate access to licensed health professionals such as nurses. Prescribers and dispensers are responsible for ensuring that delegates only access the PDMP for the purposes authorized by law and that they protect the confidentiality of the data.¹⁷

Unsolicited Reporting for Prescribers and Dispensers. As noted earlier, unsolicited reports proactively alert PDMP users of potential misuse or abuse of monitored substances by individuals. The 2016 amendments to the law authorized DHMH to implement unsolicited reporting for prescribers and dispensers. Currently, the PDMP identifies patients that exceed thresholds for “multiple provider episodes” (visiting a certain number of prescribers and pharmacies over a three-month period to obtain and fill prescriptions for monitored substances). The PDMP Technical Advisory Committee reviews each report generated by the PDMP to determine whether it should be sent to the patient’s prescriber and if so, a hard copy of the unsolicited report is sent to the prescriber in the mail. Unsolicited reports are not currently being sent to dispensers.

DHMH staff have also considered using the unsolicited reporting authority to notify prescribers if they have a history of prescribing to individuals that experience an overdose or if the prescriber/dispenser of a possible violation of the law or breach of professional standards. DHMH would not only notify the prescriber or dispenser, but would also provide education on proper dispensing and/or prescribing. DHMH is currently working with the University of Maryland School of Pharmacy to develop guidelines and determine how to target providers for outreach and education.¹⁸

¹⁶ Chapter 147, 2016 (House Bill 437), Approved by the Governor on April 26, 2016; and “PDMP Legislation Fact Sheet: Version III Information Regarding Maryland Prescription Drug Monitoring Program,” Maryland Department of Health and Mental Hygiene, September 30, 2016, < https://www.crisphealth.org/wp-content/uploads/2016/12/UPDATED-PDMP-Legislation-Fact-Sheet_v3.0_13Dec2016.pdf > accessed 3/14/2017.

¹⁷ Ibid.

¹⁸ 2016 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program, January 24, 2017, pp. 18-19 and Report on the Capacity of the Maryland Prescription Drug Monitoring Program to Identify & Report Possible Illegal or Inappropriate Prescribing & Dispensing, January 13, 2017, <

Unsolicited Reporting for Investigative Users. Current law permits investigative users to request data from the PDMP only in connection with existing individual investigations. The law does not permit DHMH to proactively report possible violations of the law or breaches of professional standards to investigative users. The 2016 amendments to the PDMP law required DHMH to report on the technical capacity of the PDMP to identify possible violations of the law and breaches of professional standards and to analyze the possibility of reporting these to law enforcement, licensing entities, or units of DHMH.

The report, submitted to the legislature in January of 2017, states that DHMH currently has the capacity to identify certain possible violations and breaches by analyzing data on high-volume prescribing or dispensing of CDS, prescribing or dispensing to multiple patients that are themselves receiving prescriptions from multiple providers, and prescribing or dispensing to multiple individuals living in the same residence. However, DHMH is currently working with experts to develop more sophisticated approaches for using PDMP data for this purpose; for example, the system could identify clinicians who maintain patients on high doses of opioids or who co-prescribe opioids with drugs, like benzodiazepines, that together are indicative of misuse. DHMH is also exploring methods to identify “pill mill” activity and self-prescribing.¹⁹

Auto Registration. In advance of the implementation of the registration mandate that takes effect in 2017, DHMH has implemented an auto registration process for prescribers. Both prescribers and dispensers can register online with no requirement to send hard copy applications or documents. However, prescribers with a Maryland license, or who have a DEA, CDS, or NPI²⁰ number can use the auto registration process, which uses licensing records from the professional licensing boards to pre-populate fields in the online application for PDMP registration, reducing the amount of time prescribers must spend manually entering information.²¹

Outreach and Education. DHMH staff conduct outreach and provide education on the PDMP for clinicians, investigative users, licensing boards, and professional associations. These efforts include a 20-minute training video that all PDMP registrants must view,²² distribution of fact sheets and conducting group presentations. Furthermore, DHMH provides small-group or one-on-one training to investigative users on request. The State has provided funding to CRISP for staff to field technical questions, and DHMH staff are also available to answer technical questions from users.

DHMH staff report that the PDMP currently does not have the capacity to respond to clinical inquiries from PDMP users. In particular, program staff are not able to answer questions from prescribers or dispensers about how to interpret PDMP data on a patient’s CDS medications or how to address suspected misuse of CDS. To better support users with clinical decision-making based on PDMP data, DHMH staff report that they are exploring ways to link a method called Screening, Brief Intervention, and Referral to Treatment (SBIRT) to the PDMP. SBIRT is an evidence-based practice intended to identify, reduce and prevent the misuse of drugs and alcohol and substance use disorders. This tool can provide a framework to assist clinical users of the PDMP to identify and respond to suspected misuse of prescription drugs.

<https://bha.health.maryland.gov/Documents/HB0437%20-%20BHA%20-%20PDMP%20-%20Final%20Signed011317OGA1755.pdf> > accessed 5/9/2017

¹⁹ Ibid.

²⁰ A National Provider Identifier or NPI is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). < <https://aspe.hhs.gov/report/frequently-asked-questions-about-national-provider-identifier-npi> > Accessed 5/5/17.

²¹ Report on the Capacity of the Maryland Prescription Drug Monitoring Program to Identify & Report Possible Illegal or Inappropriate Prescribing & Dispensing, p. 11

²² See: <https://www.crisphealth.org/services/prescription-drug-monitoring-program-pdmp/pdmp-registration/>

Health Information Systems Integration. As part of its work as the HIE, CRISP works with health providers to integrate their electronic health record (EHR) systems with CRISP. Integration of CRISP with EHRs allows clinical users to access PDMP data while viewing other patient information in the EHR, without having to sign into a separate system. In 2016, CRISP introduced the following tools for EHR integration, and has worked with health care providers to implement the tools for their EHR systems:²³

- **Single sign-on (SSO)**, which allows users to access a patient’s record in CRISP by clicking a button in their EHR system, without the need to sign into CRISP separately; and
- **In-context notifications**, which display relevant data from CRISP, such as PDMP data, within the provider’s EHR.

Exploring Options for Enhancing the User Interface. The existing CRISP interface shows clinical users PDMP data on CDS prescriptions along with other patient information available in CRISP. Users are responsible for determining whether the patient is at risk of misusing prescription drugs. DHMH is currently exploring ways to improve the interface to better assist clinical users with interpreting and using PDMP data. For example, the interface could include data visualization or analytics or could provide users with morphine milligram equivalent data, which could help users to better understand the quantity of opioids prescribed to patients.

Expanded Data Analysis and Reporting for Research Purposes. As the PDMP matures, DHMH is working to enhance its capacity to facilitate the use of PDMP data for research, education and public health efforts. Funding from the Governor’s Emergency Heroin and Opioid Task Force includes two positions to assist with PDMP data management and analysis. Additionally, three federal grants awarded in 2015 and 2016 are supporting expanded data analysis and reporting efforts, as described below:²⁴

- Data Reports for Local Health Departments. With a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA), DHMH is working with the University of Maryland School of Pharmacy to develop data reports to assist local health departments and other entities in reducing overdoses, impacting opioid prescribing, increasing access to treatment, and improving patient care.
- Predictive Risk Model Tool. A Department of Justice grant is supporting DHMH’s work with Johns Hopkins University to develop a tool that will predict risk for opioid-related health problems and deaths among individuals.
- Surveillance Reporting and Overdose Prevention Epidemiologist. Funding from the CDC supports DHMH’s work to develop surveillance reporting capabilities using PDMP data, as well as an Overdose Prevention Epidemiologist who will examine PDMP data alongside overdose fatality data.

B. PDMP Performance

At the time of writing, Maryland’s PDMP had been operational for approximately three years. In accordance with State law, the PDMP Advisory Board submits an annual report to the Governor on the impact of the PDMP.²⁵ These reports contain trend data on numbers of controlled substances prescriptions dispensed and on utilization of the PDMP. Most of the data reported are State-level data. OLO requested additional county-level data from DHMH, but OLO had not received the data at the time of writing.

²³ 2016 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program, January 24, 2017, pp. 3-4

²⁴ Ibid., pp. 21-22

²⁵ The annual reports can be accessed at: <https://bha.health.maryland.gov/pdmp/Pages/PDMP-Advisory-Board.aspx>

1. Data on Dispensed Prescriptions

The annual reports of the PDMP Advisory Board present data on the numbers of prescriptions of controlled substances that were filled, as reported by dispensers to the PDMP. Table 6-2 displays Statewide data for 2014 to 2016 on prescribing of controlled substances and prescribing of opioids by drug and by patient age. Of note:

- The number of opioid prescriptions increased from 3.3 million in 2014 to 3.6 million in 2015 (likely due to the designation of tramadol as a controlled substance), then decreased slightly in 2016 to 3.4 million;
- From 2014 to 2016, prescriptions of oxycodone HCL (e.g. Oxycontin®) increased by 60,000 prescriptions, while prescriptions of oxycodone/acetaminophen (e.g. Percocet®) decreased by over 100,000 and hydrocodone/acetaminophen (e.g. Vicodin®) decreased by over 200,000 prescriptions;
- Patients aged 50-59 accounted for the most opioid prescriptions, followed by patients aged 40-49.

Table 6-2. Numbers of Controlled Substances and Opioid Prescriptions Filled in Maryland, 2014-2016

	2014	2015	2016
Total Controlled Substances Prescriptions	7,213,572	7,486,710	7,374,883
Total Opioid Prescriptions	3,308,072	3,579,481	3,441,427
Opioid Prescriptions by Drug (Top Ten)			
Oxycodone HCL	726,438	778,730	789,323
Oxycodone HCL/Acetaminophen	711,067	662,779	598,420
Tramadol HCL*	169,674	574,379	565,117
Hydrocodone/Acetaminophen	741,557	593,635	523,092
Acetaminophen with Codeine	218,605	222,504	219,184
Buprenorphine HCL/Naloxone HCL	190,358	194,629	205,503
Morphine Sulfate	170,247	181,706	187,374
Hydromorphone HCL	101,417	95,971	84,618
Fentanyl	80,796	78,424	75,020
Methadone	70,549	64,550	61,042
Opioid Prescriptions by Patient Age			
0 – 9	12,641	14,343	15,225
10 – 19	74,592	75,559	68,615
20 – 29	322,319	310,731	271,634
30 – 39	479,636	490,648	466,453
40 – 49	662,133	658,385	603,664
50 – 59	859,023	937,194	910,186
60 – 69	522,310	616,391	633,673
70 – 79	244,248	299,589	299,980
80 – 89	108,149	141,925	137,748
90 – 99	22,170	32,115	31,628
100+	649	2,199	2,340

*Tramadol, which was previously not included on schedules of controlled substances, became a Schedule IV drug effective August 18, 2014; therefore, only tramadol prescriptions filled after this date were reported to the PDMP. Sources: 2014, 2015 and 2016 reports of the PDMP Advisory Board on the Impact of the PDMP

Data Limitations. The annual report for 2016 identifies several limitations of these data. First, the number of prescriptions is an imperfect measure because it does not quantify the numbers of patients who are using the drugs, nor does it distinguish between prescriptions of different quantities of medication. Furthermore, prescription data are not currently subject to data audits or validation by the PDMP, so the data may contain errors and inaccuracies. The PDMP is working to address these issues in the future. For example, a new Data Quality Specialist position has been funded to examine the completeness and accuracy of PDMP data.

Additionally, the total number of prescriptions includes tramadol, a drug which was added to Schedule IV for controlled substances in August of 2014 and was previously not scheduled. Therefore, the increase in opioid prescriptions from 2014 to 2015 is largely reflective of the fact that 2015 is the first year where the data include a full year of tramadol prescriptions. Similarly, the data on prescriptions containing buprenorphine can be misleading, because buprenorphine is an opioid that is frequently used to treat substance use disorders. Increases in prescriptions of this drug may reflect increased support from the State in recent years to provide buprenorphine treatment for individuals suffering from substance use disorders.

2. PDMP Utilization

A key indicator of PDMP performance is the extent to which authorized users access and utilize PDMP data. Table 6-3 provides Statewide data on clinical and investigative user accounts and queries. The data show that numbers of registered users and utilization of the PDMP among both clinical and investigative users have increased significantly each year since the program became operational in December of 2013, and particularly during 2016. As shown in Table 6-3, as of October of 2016, the number of active clinical users had increased to 18,000 from 8,700 (a 110% increase) in the previous year, with the largest increases occurring among prescribers. The PDMP annual report for 2016 suggests two drivers behind the Statewide registration and utilization increases in 2016:

- The passage of the 2016 amendments to the PDMP law that will require prescribers of CDS and all dispensers to register for the PDMP by July 1, 2017 and to query the system in specified circumstances beginning July 1, 2018; and
- The implementation of new tools for integration of CRISP and health providers' electronic health records (EHR) systems.

Table 6-3. Maryland PDMP Clinical and Investigative Users, Queries and Requests, 2014-2016

	2014	2015	2016
Clinical Users			
# of Registered Clinical Users	7,320	14,258	26,524
# of Active Clinical Users (as of October)*	6,124	8,675	18,261
Prescribers	3,686	6,203	14,366
Dispensers	1,586	1,236	2,439
Delegates	852	1,236	1,456
% of Prescribers Subject to Mandate Registered			60%
% of Dispensers Subject to Mandate Registered			32%
Monthly Clinical Queries in PDMP** (as of October)	58,500	86,667	195,000
Investigative Users			
# of Registered Investigative Users (as of October)	NA***	137	170
Federal, State and Local Law Enforcement		72	90
Licensing Boards		37	40
DHMH Agencies		28	29
Fatality Review Teams		0	11
Average Monthly Investigative Requests	10	34	57
Fatality Review Teams	0	0	9
DHMH	1	2	2
Licensing Boards	1	1	3
Law Enforcement	9	31	43

*"Active users" are defined as those who accessed the system within the last 90 days

** Monthly clinical queries based weekly queries at the end of each year

*** Data on numbers of investigative users were not available for 2014

Sources: 2014, 2015 and 2016 reports of the PDMP Advisory Board on the Impact of the PDMP

The annual report notes that the number of prescriber accounts increased sharply immediately following the passage of the PDMP legislation in 2016. As of October 23, 2016, 60% of Statewide prescribers that will be subject to the new registration mandate were registered, and 32% of Statewide dispensers that will be subject to the mandate were registered.

Data in the annual report suggest that the health care information systems integration has driven increased PDMP utilization. Data on clinical queries in 2016 broken down by query type show that the numbers of "standard patient queries," meaning those queries made via the CRISP portal, did not increase substantially during 2016 compared with 2015. Rather, the increase in monthly clinical queries between 2015 and 2016 shown in Table 6-3 consists almost entirely of "in-context notification queries." This functionality, introduced in May of 2016, displays PDMP data within providers' electronic health records (EHR) systems.

County-Level Data. The limited county-level data provided in the 2016 annual report show that most counties experienced significant increases in the numbers of clinical registrants between October of 2015 and October 2016. However, as shown in Table 6-4, more than half of the total increase in registrants occurred in Baltimore City, where the number of registrants increased from 3,500 to 10,000. Baltimore City accounted for nearly 40% of total registrants. In Montgomery County, clinical registrants increased from 2,200 to 4,000, the second largest increase in the State.

Table 6-4. PDMP Clinical Registrants in October 2015 and October 2016 By Maryland County

County	2015	2016	Change
Montgomery	2,244	4,088	+1,844
Baltimore City	3,524	10,272	+6,748
Baltimore County	1,744	2,377	+633
Unknown / Outside Maryland	1,719	2,417	+698
Prince George's	1,250	1,818	+568
Anne Arundel	741	1,120	+379
Harford	495	641	+146
Frederick	394	620	+226
Howard	294	439	+145
St. Mary's	237	236	-1
Wicomico	222	415	+193
Carroll	185	286	+101
Cecil	184	257	+73
Washington	158	309	+151
Charles	137	190	+53
Worcester	101	220	+119
Calvert	97	138	+41
Allegany	88	205	+117
Talbot	83	113	+30
Queen Anne's	62	79	+17
Garrett	56	73	+17
Dorchester	46	59	+13
Kent	30	33	+3
Caroline	21	23	+2
Somerset	19	20	+1

Source: 2016 report of the PDMP Advisory Board on the Impact of the PDMP, pp. 5-6

3. Data on Unsolicited Reporting Based on Multiple Provider Episodes

As noted on earlier, the PDMP began to implement unsolicited reporting in 2016 to alert prescribers of “multiple provider episodes,” which refers to cases of patients that obtained and/or filled prescriptions from multiple prescribers or through multiple pharmacists. The PDMP selects thresholds based on program capacity to process the volume of unsolicited reports, which are mailed to recipients. The PDMP started with a threshold of at least 15 prescribers and/or 15 pharmacists in three months, and then lowered the threshold to 10 prescribers and/or 8 pharmacies (to capture more patients). Table 6-5 displays the numbers of unsolicited reports generated by the system for four three-month periods in 2016 and the relevant thresholds that were applied.

Table 6-5. Statewide Unsolicited Reporting Prescriber Notifications, 2016

Applicable Threshold	Date Range of Notifications	# of Notifications
15 prescribers/15 pharmacies	April-June	41
	May-July	16
10 prescribers/8 pharmacies	June-August	144
	July-September	165

Source: 2016 report of the PDMP Advisory Board on the Impact of the PDMP, pp. 18-19

Given the limited amount of data available at this early stage of implementation of unsolicited reporting, no conclusions about its impact can be drawn. In the future, the PDMP intends to conduct additional analysis to ascertain whether unsolicited reporting impacts prescriber behavior for those patients identified as having multiple provider episodes.

C. Alignment with Recommended Practices

Chapter 5 describes recommended practices to maximize the effectiveness of PDMPs. These practices are intended to promote data completeness, accuracy and interoperability, and increase PDMP utilization. OLO found that the Maryland PDMP has implemented several of the recommended practices described in Chapter 5. To summarize, Table 6-6 lists the status of each recommended practice in Maryland’s PDMP.

Table 6-6. Maryland PDMP Adherence to Recommended Practices

Practice	Status	Notes
Data quality		
<u>Promotion of pharmacy compliance</u>		
Automated data quality check system	Implemented	
Data audit to check compliance	In progress	Data quality specialist position funded
Waivers independently verified and time-limited	Implemented	
Training materials for dispensers	Implemented	
<u>Collection of specific data</u>		
Data on all schedules of controlled substances	Implemented	
Data on unscheduled drugs linked to misuse	Not in progress	Not authorized by law
Positive identification data for person picking up	Not in progress	Not required by regulations
Payment method data	Implemented	
<u>Other</u>		
24-hour interval/real-time reporting	In progress	24-hour interval being implemented
Updated data standards	Implemented	PDMP uses ASAP standard 4.2 (2011)
Interstate data sharing	Partially implemented	
Promoting Prescriber Utilization		
Prescriber registration and use mandates	In progress	Mandates take effect in 2017 and 2018
Delegation	Implemented	
Unsolicited reporting	Implemented	
Streamlined enrollment	Implemented	
Educational and promotional initiatives	Implemented	
Health information technology integration	Implemented	
Enhanced user interface	Under study	
Facilitating Utilization by Other Authorized Parties		
Proactive analysis for all recipient groups	Under study	Being explored for investigative users
Allowing third-party payer access to PDMP data	Limited	Only Medicaid permitted

The table shows that Maryland's PDMP has implemented or is in the process of implementing the majority of the recommended practices described in Chapter 5. Of those practices that are not currently in the process of being implemented, two are currently being studied to determine whether and how to implement them:

- **Enhanced User Interface** - DHMH is currently exploring ways to enhance the user interface for clinical PDMP users to assist them in interpreting PDMP data, including data visualization or analytics; and
- **Proactive Analysis for All Recipient Groups** - unsolicited reporting is currently allowed for prescribers and dispensers, and DHMH is currently studying whether to permit unsolicited reporting for investigative purposes.

The implementation of other identified recommended practices are currently limited by State law or regulation:

- **Collection of Data on Unscheduled Drugs with Risk of Abuse** - State law does not authorize the PDMP to monitor unscheduled substances;
- **Collection of Positive Identification Data for the Person Picking Up a Prescription** - State regulations do not currently require dispensers to report positive identification data for the individual who picks up a prescription, who may be different from the patient;²⁶
- **Interstate Data Sharing** - Maryland regulations only allow redisclosure of PDMP data to licensed health professionals, but regulations in other states are less restrictive, preventing Maryland from sharing data with some states;²⁷ and
- **Allowing Third-Party Payer Access to PDMP Data** - State law permits the PDMP to share data with the State Medicaid program but not with other third-party payers such as private insurers, Medicare or workers' compensation programs, or pharmacy benefit managers.

²⁶ COMAR 10.47.07.03(A).

²⁷ COMAR 10.47.07.05(K)(2).

Chapter 7. Findings and Discussion Issues

This chapter summarizes the major findings of this report and presents recommended discussion issues developed by the Office of Legislative Oversight based on the findings.

FINDINGS

Background and Legal Framework

Finding #1. Nationally, just under one in 100 individuals experienced a prescription opioid use disorder in 2015. Nearly 19,000 individuals died as a result of drug overdoses involving prescription opioids in 2014.

Opioids are a class of chemically-related drugs that include both legal and illegal drugs. The use of the opioids can relieve pain and cause feelings of euphoria and pleasure, but can also lead to changes in the brain that result in physical dependence on the drugs. As such, all opioids, including prescription opioids, carry significant risks:

- According to a 2015 survey, one in 20 individuals in the United States are estimated to have “misused” prescription opioids in the last year, meaning that they used them in ways not intended by a doctor. Individuals who misuse prescription opioids are more likely to use heroin.
- Just under one in 100 individuals experienced a prescription opioid use disorder, meaning they were physically dependent on the drugs and experienced significant impairments as a result of using them.
- Nationally, the CDC reports that nearly 19,000 individuals died from drug overdoses involving prescription opioids in 2014, the most recent year for which data were available.

Finding #2. Montgomery County has experienced significantly lower numbers of opioid overdose deaths relative to its population compared with the State, but deaths in the County related to heroin and fentanyl have increased very sharply in recent years, similar to Statewide trends.

The Maryland Department of Health and Mental Hygiene (DHMH) tracks trends in unintentional drug- and alcohol-related intoxication deaths occurring in the State. In 2016, there were 1,856 total deaths involving licit and illicit opioids in the State, which is more than quadruple the number of deaths in 2010. Sharp increases in heroin and fentanyl-related deaths are responsible for most of the rise in opioid-related deaths, but prescription opioid related deaths, often involving combinations of prescription opioids and heroin and/or fentanyl, have also increased. Statewide data for 2016 show seven prescription opioid-related deaths per 100,000 population, 20 heroin-related deaths per 100,000 population, and 19 fentanyl-related deaths per 100,000 population.

Overall, Montgomery County has experienced lower rates of fatal overdoses involving opioids compared with the rest of the State. In 2016, 26 overdose deaths related to prescription opioids occurred in the County, or about over 2.5 deaths per 100,000 population. However, County trends are similar to Statewide trends in that heroin-related and fentanyl-related deaths have shown significant increases in the past five years – total deaths involving heroin increased from 11 in 2011 to 48 in 2016, and total deaths involving fentanyl increased from zero to 43 during the same time period.

Finding #3. Federal and Maryland State law provide detailed directives on how practitioners can prescribe and administer opioids.

Opioids that have accepted medical uses are classified as prescription drugs. Federal law establishes that these drugs may only be dispensed upon written prescription of a practitioner who has been licensed by law to administer the drug. State law outlines the categories of licensed professionals in Maryland that are authorized by law to prescribe prescription drugs: physicians, physician assistants, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, and veterinarians.

In addition, most prescription opioids are also classified as “controlled substances” and are subject to special regulations under the United States Controlled Substances Act (CSA). Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules (summarized below) based on medicinal value, harmfulness, and potential for abuse/addiction.

Federal Schedules for Controlled Substances

Schedule	Characteristics of Substances	Examples (<i>Opioids in Italics</i>)
I	No currently accepted medical use in the United States and have a high potential for abuse	<i>heroin</i> , cannabis, LSD, and MDMA ("Ecstasy")
II	Currently accepted medical use but a high potential for abuse	<i>oxycodone</i> , <i>fentanyl</i> , cocaine, methamphetamine
III	Currently accepted medical use with potential for moderate or low physical dependence or high psychological dependence	<i>buprenorphine</i> , ketamine, anabolic steroids
IV	Currently accepted medical use in treatment and lower potential for abuse compared with drugs in Schedule III	alprazolam (Xanax®), diazepam (Valium®)
V	Currently accepted medical use in treatment and lower potential for abuse compared with drugs in Schedule IV	<i>Codeine and hydrocodone cough suppressants</i>

Federal regulations and State law establish specific rules for prescriptions of controlled substances, including required information, method of transmission, limits on the amount prescribed, refills, and expiration of prescriptions. Prescribers of controlled substances must also be registered with the U.S. Drug Enforcement Administration (DEA), the Maryland Department of Health and Mental Hygiene (DHMH), and the State’s Prescription Drug Monitoring Program (PDMP).

Prescriber Education

Finding #4. Many prescribers have not received significant training on the appropriate prescribing of opioids. The Federal government and other organizations offer a significant number of educational resources to practitioners on the responsible prescribing of opioids.

In recent years, the number of opioid prescriptions, the amount prescribed per prescription, the days’ supply and the cumulative dose prescribed have all increased according to the United States Department of Health and Human Services.¹ However, most prescribers, including physicians, physician assistants, nurse practitioners, pharmacists, nurses, prescribing psychologists, and dentists, receive little training on the appropriate prescribing and dispensing of opioids. One U.S. Drug Control Strategy study found that students in medical school only

¹ Addressing Prescription Drug Abuse in the United States Current Activities and Future, CDC. Opportunities https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf

receive on average eleven hours of training on pain education and most schools do not offer specific training on opioids or substance use disorders.

In recent years, the Federal government has made efforts to make the nation’s opioid epidemic a priority. One cornerstone of the Federal government’s efforts to provide prescriber education on opioids is the Centers for Disease Control *Guidelines for Prescribing Opioids for Chronic Pain*, which are a set of twelve recommendations for opioid prescription practices for treating adult patients with chronic pain. The recommendations cover three categories: (1) assessing when opioid treatment should be used or continued; (2) opioid selection, dosage, duration, follow-up, and discontinuation; and (3) identifying risks and addressing harms of opioid abuse. Many state governments have adopted the CDC Guidelines.

The Federal Government has also created numerous resources, toolkits, and guidelines to provide clinicians and other stakeholders with comprehensive information to prescribe and/or dispense opioids in a responsible way. In addition, many other medical stakeholders have established guidelines and provide prescribers with resources/assessment tools for proper opioid prescribing, including: the Federation of State Medical Boards; the American Medical Association; and the Association of Medical Colleges.

Finding #5. OLO identified thirty-two states and Washington, D.C. that have requirements, either in statute, regulation, or board guidelines, for practitioners to obtain a certain number of opioid or pain management related continuing medical education (CME) credits as a condition of license application or renewal.

OLO found that thirty-two states and Washington, D.C., have implemented a requirement for clinicians in the state to complete a certain number of opioid or pain management related CME credits to receive or renew their medical license. Prescriber education requirements can be found in statute, regulation, or board guidelines and vary by number of credits required, topic, and which practitioners must complete them. For example, only practitioners with CDS licenses must complete CME in opioid-prescribing in Alabama, Kentucky, and Utah, but all physicians in California, Florida and Oregon must complete the required CME. For the specific requirements in all states, see Chapter 3.

CME Required for Practitioners with CDS License	Alabama, Delaware, Kentucky, Maine, Massachusetts, Mississippi, New Hampshire, New Mexico, New York, North Carolina, Rhode Island, Tennessee, Utah, Vermont, Washington
CME Required for All Physicians	California, Connecticut, Florida, Iowa, Michigan, Oregon, South Carolina, West Virginia
CME Required by Other Practitioners	Arizona, Georgia, Idaho, Nevada, Ohio, Pennsylvania, Texas, Washington D.C.

Finding #6. Two out of the five Maryland State medical boards that license prescribers recently established requirements that licensees complete continuing medical education (CME) specific to proper prescribing as a condition for license renewal. However, State law expressly prohibits the Board of Physicians from requiring completion of a specific course for license renewal.

The Department of Mental Health and Hygiene oversees several professional licensing boards that are responsible for licensure and discipline of health professionals that can prescribe controlled dangerous

substances (CDS), such as opioids. While all boards require licensees to complete continuing education, most boards do not require licensees to complete specific education regarding opioid prescribing. The Governor’s 2015 Heroin and Opioid Emergency Task Force recommended the relevant professional licensing boards require licensees to complete continuing education related to opioids as a part of license renewal.

The table below summarizes the current requirements for medical license holders in the State. The Board of Dental Examiners has implemented a CME requirement relating to opioid prescribing, with the Board of Podiatric Medical Examiners planning to implement a similar requirement in the 2018-2019 renewal cycle. Further, the Maryland Board of Physicians imposed a requirement in 2015 for physicians to complete a one-hour course on opioid prescribing at every renewal cycle, but this requirement was discontinued due to legislation passed by the General Assembly in 2016, which stated that the Board of Physicians could not require any specific CME.

Board	Requirement
Board of Physicians	Previous opioid prescribing education requirement is no longer in effect as of October, 2016
Board of Nursing	No requirement
Board of Dental Examiners	Dentists must complete a two-hour Board-approved course on proper prescribing and disposal of prescription drugs every other renewal cycle
Board of Podiatric Medical Examiners	One required continuing medical education credit per renewal cycle must address prescribing practices for controlled substance medications for pain management starting with the 2018-2019 renewal cycle
Board of Veterinary Medical Examiners	No requirement

Finding #7. The State of Maryland and Montgomery County have made significant efforts to address the opioid epidemic through prevention efforts in recent years. However, prescriber education is not a current focus of those efforts.

Maryland Governor Larry Hogan has made the opioid and heroin epidemic in the State a priority of his administration, including the formation of the Heroin and Opioid Emergency Task Force and Inter-Agency Heroin and Opioid Coordinating Council, along with the declaration of a state of emergency regarding the heroin and opioid epidemic in the State. The State has also undertaken the following prevention-related efforts to address opioid use/misuse:

- Creation of the Maryland Opioid Overdose Prevention Plan, which is a statewide strategy for reducing overdose deaths with increased data sharing, access to treatment, and education;
- Establishment of the Opioid Misuse Prevention Program, which provides funding and technical assistance to counties for prevention activities including prescriber education;
- Implementation of the Prescription Drug Monitoring Program (PDMP), which monitors the prescribing and dispensing of controlled dangerous substances;
- Launch of the Heroin and Opioid Prevention, Treatment and Enforcement Initiative, which includes the formation of the Opioid Operational Command Center.

The Behavioral Health Administration (BHA) is the State agency responsible for addressing substance use issues. The BHA’s primary strategy on opioid prescribing education has been to disseminate prescribing resources and

guidelines, including the CDC opioid prescribing guidelines. In addition, the BHA is working with the University of Maryland, School of Pharmacy (UMSP) to develop a process for identifying and conducting targeted outreach and education to aberrant opioid and other controlled substance prescribers.

Montgomery County. Located in the Department of Health and Human Services, the County’s overdose prevention coordinator serves as the central position for addressing drug overdoses in the County. The position was responsible for creating the County’s Opioid Overdose Prevention Plan and works with other County departments on joint efforts to address the problem. The County’s efforts specific to opioid misuse prevention have been focused on outreach and education efforts that target the public. Executive Branch staff report that DHHS completed a prescriber education campaign in the past but found that it was difficult to find methods to contact prescribers in the County.

Prescription Drug Monitoring Program

Finding #8. The evidence is mixed on whether prescription drug monitoring programs (PDMPs) prevent prescription opioid misuse, and experts recommend a variety of strategies for maximizing their effectiveness.

Forty-nine states (including Maryland) and the District of Columbia have created prescription drug monitoring programs (PDMPs) in an effort to prevent harmful use of prescription drugs, including prescription opioids. PDMPs collect and store data on the prescribing and dispensing of specified drugs in an electronic database, which is used to inform prescribing and dispensing decisions, support the investigative efforts of law enforcement, professional licensing boards and other bodies, and inform public health efforts. For example, a prescriber can use PDMP data to check whether a patient is “doctor shopping” for prescription opioids.

Assessing the impact of PDMPs is challenging because every state’s PDMP program is different, and many PDMPs experience low levels of utilization among authorized stakeholders. Some studies show that PDMPs are associated with lower rates of prescription drug misuse and changes to prescribing practices, but others do not show an association. Researchers have identified numerous policies and practices that are believed to maximize the effectiveness of PDMP programs by (1) promoting data completeness, accuracy and interoperability; and (2) increasing PDMP utilization among prescribers and other authorized parties. The table below summarizes these recommended practices.

Recommended Practices for Maximizing PDMP Effectiveness

Data Quality	Promotion of pharmacy compliance Collection of specific information that can indicate misuse Data timeliness and standards Interstate data sharing
Promoting Prescriber Utilization	Prescriber registration and use mandates Delegation of access to PDMP Unsolicited reporting to flag misuse Streamlined enrollment processes Educational and promotional initiatives Health information technology integration Enhanced user interfaces
Promoting Utilization Among Other User Groups	Proactive analysis for all recipient groups Allowing third-party payer access to PDMP data

Finding #9. Maryland’s PDMP became fully operational in 2013, and the State continues to improve and refine the program. The State has implemented or is in the process of implementing the majority of recommended practices for PDMPs.

Located in the Maryland Department of Health and Mental Hygiene (DHMH), Maryland’s Prescription Drug Monitoring Program (PDMP) was established in 2011 by Maryland statute and became fully operational in December of 2013. Since the creation of the PDMP, changes to the law and program improvements have been made with the intent of maximizing utilization of the PDMP, particularly among prescribers. Maryland has implemented or is in the process of implementing the majority of the PDMP recommended practices summarized in Finding 8. Of note, prescriber registration and use mandates enacted in 2016 will take effect in 2017 and 2018, respectively, that will require all prescribers to register for the PDMP and access prescription monitoring data before initially prescribing certain drugs, including opioids.

Finding #10. Statewide data show that PDMP utilization among prescribers and other user groups has grown since the program’s creation. As of October 2016, 60% of the prescribers that will be subject to the registration mandate were registered with the PDMP.

A key indicator of PDMP performance is the extent to which authorized users access and utilize PDMP data. The data in the table below show that numbers of registered users and utilization of the PDMP among both clinical and investigative users have increased significantly each year since the program became operational in December of 2013, and particularly during 2016. DHMH reports indicate two drivers behind the Statewide registration and utilization increases:

- The enactment of the mandates that will require prescribers and dispensers to register for the PDMP by July 1, 2017 and to query the system in specified circumstances beginning July 1, 2018; and
- The implementation of new tools for accessing PDMP data via medical providers’ existing electronic health records (EHR) systems.

Maryland PDMP Clinical and Investigative Users, Queries and Requests, 2014-2016

	2014	2015	2016
Clinical Users (prescribers, dispensers and their delegates)			
# of Registered Clinical Users	7,320	14,258	26,524
# of Active Clinical Users (as of October)	6,124	8,675	18,261
% of Prescribers Registered			60%
% of Dispensers Registered			32%
Monthly Clinical Queries in PDMP (as of October)	58,500	86,667	195,000
Investigative Users (law enforcement, licensing boards, and others)			
# of Registered Investigative Users (as of October)	NA	137	170
Average Monthly Investigative Requests	10	34	57

Available county-level data show that Baltimore City, where 10,000 clinicians had registered for the PDMP as of October of 2016, accounted for nearly 40% of total clinical registrants in the State. Approximately 4,000 clinicians located in Montgomery County were registered with the PDMP at that time, accounting for 15% of total registrants. OLO requested additional county-level data on PDMP registration and opioid prescriptions, but had not yet received the data as of the writing of this report.

DISCUSSION ISSUES

Discussion Issue #1: County Role in Prescriber Outreach and Education

Most prescribers receive little training on the appropriate prescribing and dispensing of opioids. The County's Overdose Prevention Plan established goals specific to prescriber education, including: educating and providing continuing education for prescribers, educating the medical community about opioid addiction, and increasing the collective knowledge of best practices. DHHS staff report that the Department completed a prescriber education campaign but found that it was difficult to find methods to contact prescribers.

Additionally, new mandates will take effect in 2017 and 2018 regarding the State's Prescription Drug Monitoring Program (PDMP). Prescribers in the State will be required to register with the PDMP by July of 2017, and to query the system for their patients' prescription monitoring data when initially prescribing certain controlled dangerous substances, including opioids. As of October of 2016, 60% of prescribers in the State were already registered with the PDMP, but nearly 40% of those were located in Baltimore City.

Currently, the County's opioid misuse prevention efforts do not include a prescriber outreach or education component. The Council may wish to discuss with Executive Branch representatives whether opportunities exist to work with State agencies or local chapters of professional associations to link prescribers with educational resources on opioids and provide information on registering with and accessing the State's PDMP.

Discussion Issue #2: State Law on Prescriber Education

Currently, there are seven types of practitioners in Maryland that can legally prescribe drugs: physicians, physician assistants, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, and veterinarians, all of whom must complete some continuing medical education (CME) for license renewal.

The Governor's Heroin and Opioid Emergency Task Force, established in 2015, recommended that the relevant professional licensing boards require licensees to complete continuing education related to opioids. Of the seven professional groups, two (podiatrists and dentists) are required by their respective licensing boards to complete opioid-specific CME as part of their license renewals. The Board of Physicians previously required CME on opioid-prescribing until State legislation was passed in 2016 that expressly prohibits the Board from requiring that physicians complete a specific course or program as a condition for license renewal.

Prescriber education can enable practitioners to make appropriate, well-informed decisions about whether to initiate, modify, or discontinue opioid treatment for each individual patient based on the benefits and risks of the specific treatment. OLO found that thirty-two states and Washington, D.C. have implemented a requirement for clinicians in the state to complete a certain number of opioid or pain management related CME credits to receive or renew their medical license. The requirements vary, with some states requiring all physicians to have opioid-specific training and others requiring only that those with a DEA license to prescribe controlled substances complete the CME.

The Council may wish to discuss with relevant stakeholders in the County the benefits and drawbacks of requiring mandatory prescriber education, including which groups of practitioners should be included. If the Council determines that prescriber education should be mandatory, it could work with State legislators and other stakeholders to establish requirements within State law.

Chapter 8. Agency Comments

The Office of Legislative Oversight shared final drafts of this report with Montgomery County Government staff for technical comment. OLO appreciates the time taken by County Government staff to review the draft report and to provide technical feedback. This final report incorporates technical corrections and feedback received by MCG personnel.

Written comments from the Chief Administrative Officer (CAO) are attached. In the letter, the CAO stated that the State of Maryland released the 2016 report on the Drug and Alcohol-Related Deaths in Maryland during their review of this report. For the final draft, OLO has updated this report with the new data.



OFFICES OF THE COUNTY EXECUTIVE

Isiah Leggett
County Executive

Timothy L. Firestine
Chief Administrative Officer

MEMORANDUM

June 14, 2017

To: Chris Cihlar, Director, Office of Legislative Oversight

From: Timothy L. Firestine, Chief Administrative Officer *Timothy L. Firestine*

Subject: Draft OLO Report 2017-11: Prescription Opioids: Prescriber Education and the Maryland Prescription Drug Monitoring Program

Thank you for the opportunity to review and comment on the Office of Legislative Oversight's (OLO) Draft Report 2017-11: Prescription Opioids: Prescriber Education and the Maryland Prescription Drug Monitoring Program. We appreciate your thorough report on this significant national, state, and local crisis, and posed discussion items regarding the County role in prescriber outreach and education and the State law on prescriber education.

Since the draft report was completed, the State has released the 2016 report on Drug and Alcohol-Related Intoxication Deaths in Maryland. Although you may have received this information and may update the final report to include it, there are some findings on which we would like to comment.

We are particularly concerned with both the dramatic increase in overdose deaths and by the drugs used in those deaths. In reviewing prescription opioids, the number of deaths has increased by 3 percent between 2014 and 2016 (from 23 to 26); however, within that number, deaths from oxycodone overdose doubled from 8 to 16 in the past year in Montgomery County alone. Still more alarming is the fact that overdose deaths due to fentanyl rose from 8 in 2014 to 43 in 2016, an increase of more than 500 percent, while in the same period heroin related deaths rose by 45 percent.

In 2016, we lost 102 residents to overdoses from multiple drugs. The State's annual report notes deaths from alcohol, cocaine, and benzodiazepines have all been on the rise in recent years. For example, the number of alcohol related deaths doubled between 2015 and 2016. While collectively these deaths account for only 11 percent of all State-wide overdose deaths, these drugs, including alcohol, are often found in combination with each other and with opiates. It appears that, while opiates are currently the deadliest of abused drugs, we are also

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seeing a rise in the numbers of individuals who are suffering from addiction and are using multiple drugs to feed their addictions.

As stated in the draft report, Montgomery County Government, our providers, concerned citizens, and families who have lost loved ones to addiction have not been idle in attacking opiates as the deadliest drug of choice or as the underlying addiction that drives drug abuse. For example, as part of the County's prevention plan in past years, we provided education and information to prescribing physicians in the County. Though efforts did not have the level of impact we desired on prescribing practices, we have continued our efforts to include education and public awareness, interdiction and law enforcement, drug take-back programs, and treatment. We have trained police officers and school health nurses, and have equipped them with naloxone. The use of naloxone by emergency medical services and law enforcement has saved hundreds of lives in 2016.

Additionally, family members who have lost loved ones to addiction, have formed support groups to help others cope, and are offering education to other family members. Individuals who are successfully in recovery are being trained as peer recovery coaches and are reaching out to help support others in their efforts to recover.

While the draft report makes note of our local collaborations, the County is now also working in closer partnership with the State since Governor Hogan declared a state of emergency around overdose deaths. That collaboration was strengthened and supported this past legislative session through several laws and policy changes that will strengthen the State's capacity to treat addiction and to better understand and attack the misuse of opiates and reduce the number of deaths. The State is also in the process of developing standards and guidance for the use of prescription opioids. We are especially supportive of the mandate for medical prescribers and pharmacists to make full use of the Prescription Drug Monitoring Program (PDMP). Once implemented, the PDMP will have a dramatic effect on the illegal access to and abuse of prescription opiates. We believe though, in addition to the PDMP, State licensing boards will need to more directly address prescriber education through continuing education and other requirements.

We would like the draft report to note, that while the number of deaths related to prescription opioids is low relative to overdose deaths related to heroin and fentanyl, we remain concerned about the role that prescribed opioid medications may play as a starting point on the road to addiction. Through the work of the County's Overdose Fatality Review Team, we are studying, among other things, the prescription opiate histories of individuals who died from overdoses on opiates. Our goal is to examine the role of prescription opiates in greater detail in the coming months. As we learn more, this information will be used to help educate physicians and inform the public about the safe usage and risks of prescription opiates.

The lives of many of our County residents have been tragically affected by addiction. It is not only the individual who has overdosed, but also parents, spouses, children, friends, extended family, and the community who all suffer with each death. While the County's

Chris Cihlar, Director, Office of Legislative Oversight
June 14, 2017
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overdose death rate is one of the lowest in the State, our sense of urgency remains steadfast. We will continue our work to prevent the loss of any life to addiction and to strengthen individual and family resiliency. Our partners in public safety, the treatment community, and our advocates remain deeply committed to doing everything possible to reduce the number of lives we lose to opiates, to help our residents find treatment and recover from addictions, and to ensure that our youth do not fall prey to addiction.

We concur with the findings of this draft report. Although several of the findings will need to be addressed at the State level, we look forward to continuing our collaboration with the State on this issue and to actively work to implement the State-wide strategy with County-based prescribers.

If you have any questions or need additional information, please contact Uma S. Ahluwalia, Director, Department of Health and Human Services at (240) 777-1266 or uma.ahluwalia@montgomerycountymd.gov.

TLF:lp

c: Fariba Kassiri, Assistant Chief Administrative Officer
Bonnie Kirkland, Assistant Chief Administrative Officer
Uma S. Ahluwalia, Director, Department of Health and Human Services
Raymond L. Crowel, Chief, Behavioral Health and Crisis Services

APPENDIX

Summary of Prescriber Education Efforts in Maryland Counties from Opioid Misuse Prevention Program Strategic Plans

Allegany	<ul style="list-style-type: none"> • Conduct training, “The Prescribing of Opioids, Finding the Right Balance” • Develop a video to address synthetic drug abuse • Present at Western Maryland Health Systems during Grand Rounds www.prescribechangeallegany.org
Anne Arundel	<ul style="list-style-type: none"> • Send email/letter to all clinical providers, hospitals, and pharmacies that included: overview of state and county-level overdose prevention efforts and links to online resources • Conduct provider education through grand rounds http://denialisdeadly.org
Baltimore City	<ul style="list-style-type: none"> • Conduct campaigns to increase clinician awareness of PDMP • Develop and distribute opiate prescribing clinical practice guideline recommendations for emergency room clinicians • Develop education materials for all pain management specialists on the identification and treatment of patients with substance use disorders • Conduct training on brief interventions and referral to treatment resources www.bmoreincontrol.org
Baltimore	<ul style="list-style-type: none"> • Send letter to be sent to all prescribers in that informs them of increase in deaths associated with prescription opiates along with safe prescribing practices, the use of SBIRT, information on the PDMP, and contact number for additional information • Provide Grand Rounds to hospitals • Provide training to relevant staff of Baltimore County Department of Health and Human Services • Offer training for substance use disorder treatment providers about overdose prevention and effective interventions
Calvert	<ul style="list-style-type: none"> • Present to the medical staff of Calvert Memorial Hospital • Send letters to community prescribers on prevention efforts • Distribute educational brochures to all local pharmacies for counter display • Educate provides about the PDMP www.facebook.com/ActNowCalvert
Carroll	<ul style="list-style-type: none"> • Conduct REMS training • Partner with CHC to provide CME availability for physicians • Sponsor and/or support trainings that will provide prescribers with the information necessary to treat those with chronic pain • Identify what the jurisdiction believes to be best practices and work with local providers to establish and implement those practices at local agencies www.itsneverworthit.com

<p>Cecil</p>	<ul style="list-style-type: none"> • Conduct presentations on "Prescription Overdose" and "Risk Evaluation and Mitigation Strategies for Prescribing Opioids in Patients with Chronic Pain" to Union Hospital medical staff • Hosted presentations by a Delaware Public Health Program Administrator on "Delaware efforts to Reduce Addiction, and Doctor Shopping," and by a Deputy Attorney General from the Delaware Department of Justice on "Delaware Prescription Drug Diversion." <p>www.rewriteyourscript.org</p>
<p>Frederick</p>	<ul style="list-style-type: none"> • Conduct outreach on pain management programs • Offer support, education, and information about prevention and access to available resources • Provide clinical toolkits to aid professionals in various methods of intervening with substance use that can lead to overdose • Present to various medical and other practices in the County <p>www.takebackmylife.org</p>
<p>Garrett</p>	<ul style="list-style-type: none"> • Conduct a mini-series of Grand Rounds at the hospital on the treatment of pain and addiction • Outreach to group and solo practices in the use of SBIRT • Provide educational materials for offices on risks of overdose and lifesaving procedures in case of overdose <p>www.addictionhappens.org</p>
<p>Harford</p>	<ul style="list-style-type: none"> • Facilitate prescriber education/trainings on pain management and the prescription drug monitoring program • Assist in identifying and recruiting prescribers to participate in REMS training • Modify the drug take-back message to include a broader public health/education message • Work with University of MD Upper Chesapeake Health System to explore developing a policy about opioid prescribing limitations for Hospital emergency department <p>www.facebook.com/HCODCP</p>
<p>Howard</p>	<ul style="list-style-type: none"> • Conduct community training program for health care providers to present the overdose prevention strategies • Provide "train the trainers" approach for health care providers that will offer the consumer training on substance use disorder treatment programs, mental health treatment programs, urgent care centers, etc. <p>http://intheknowhc.gov</p>

<p>Mid-Shore*</p>	<ul style="list-style-type: none"> • Generate mailing list of all direct medical providers and e-mail letter re: Prescription Drug Monitoring Program (PDMP), MD Prevention initiatives/alerts and resources • Generate a mailing list of all health care gate keepers (front desk, nurses, therapists, referral sources, navigators) and engage in information awareness campaign • Create a survey or script for use by Chesapeake Helps! to collect information or inform physicians • Conduct a special outreach to dentists and physical therapists about the plan, PDMP, and prevention strategies • Utilize Shore Health and the Eastern Shore Area Health Education Center to educate physicians and other health care professionals about prevention and treatment options • Engage in a well-organized, highly effective (best practices) opiate prevention marketing campaign targeted for physicians and gatekeepers – utilizing professional marketing consultation and materials. <p style="text-align: right;">http://iwishiknewmidshore.org</p>
<p>St. Mary's</p>	<ul style="list-style-type: none"> • Create a collaborative network for disseminating education • Send a letter to practitioners that will use local data to define the problem in the county and provide an overview of state initiatives and local plans • Conduct a forum for the clinical community to discuss the problem in the county, as well as strengths and needs of the clinical community • Distribute toolkits and educational materials to the clinical community <p style="text-align: right;">http://healthystmarys.com/smartrx</p>
<p>Somerset</p>	<ul style="list-style-type: none"> • Educate providers on Prescription Drug Monitoring Programs • Assist with recruitment of prescribers to participate and provide logistical support and facilities <p style="text-align: right;">www.unmaskaddiction.org</p>
<p>Washington</p>	<ul style="list-style-type: none"> • Develop and implement outreach on provider/prescriber education by the County's Opioid Overdose Prevention Plan Workgroup • Provide education on the utilization of evidence based therapies to reduce and/or eliminate overdose <p style="text-align: right;">www.projectactnow.gov</p>
<p>Wicomico</p>	<ul style="list-style-type: none"> • Contact Local/National CME, Purdue Pharma in relation to potential training on prescription drugs • Conduct a survey of physicians on education interests through Survey Monkey • Develop a plan, research potential resources/proper use of resources, and educate physicians • Develop and implement a policy for writing prescriptions for opioids for those who doctor/pharmacy shop
<p>Worcester</p>	<ul style="list-style-type: none"> • Provide education for provider recognition of drug overdose risks to be distributed in all Addictions related programs • Educate and train the Worcester County employed psychiatrists to offer medication assisted opioid addiction treatment • Education to Health Care providers to follow guidelines for responsible prescribing • Circulate information about available Addictions Treatment programs • CMEs partnership opportunities including MedChi and Reach Health Services

*Caroline, Dorchester, Kent, Queen Anne's, and Talbot