



MARYLAND
MMCC

Natalie M. LaPrade
Maryland Medical Cannabis Commission

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LEGISLATIVE REPORT

TREATMENT OF OPIOID USE DISORDER

WITH MEDICAL CANNABIS

Joy A. Strand, MHA
Executive Director
Maryland Medical Cannabis Commission

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I. BACKGROUND

Pursuant to Section 13 of House Bill 2/Chapter 598 of the Acts of 2018, the Natalie M. LaPrade Medical Cannabis Commission (the “Commission”) is mandated to submit this report on the treatment of opioid use disorder by using medical cannabis. This reporting requirement emerges as states grapple to find new ways to mitigate the increasingly grim and destructive consequences of the opioid epidemic.

The term “opioids” encompasses a wide range of drugs, including prescription pain relievers such as codeine, morphine, oxycodone, and hydrocodone, and illicit drugs heroin and fentanyl. The U.S. Centers for Disease Control and Prevention (CDC) warns that fentanyl is up to 50 times more potent than heroin and 50 to 100 times more potent than morphine.¹ In 2016, more than 42,000 Americans died from opioid-related overdoses, a 67% increase from 2014 (28,000). At least one-half of the total opioid-related deaths involve a prescription opioid. CDC data show that from 1999 to 2016, more than 200,000 individuals died in the U.S. from prescription opioid-related overdoses. Overdose deaths involving prescription opioids were five times higher in 2016 than in 1999.² In addition, data from the Substance Abuse and Mental Health Services Administration (SAMHSA) indicate that dependence on, or abuse of, prescription opioid pain relievers is the single greatest risk factor for heroin or fentanyl abuse or dependence.

Through the first six months of 2018, opioid-related overdoses in Maryland accounted for 1,185 deaths, which represents a 15% increase compared over the same period in 2017. (Attachment A) Maryland saw 153 more opioid-related deaths during the first six months of 2018 than the first six months of 2017. (Attachment B) Moreover, Maryland has experienced an alarming escalation in opioid-related deaths during the past five years – 888 (2014); 1,089 (2015); 1,856 (2016); 2,009 (2017); and 1,185 (YTD 2018 through June). (Attachment C) In 2018 alone, Maryland has seen 199 prescription opioid-related intoxication deaths, 469 heroin-related intoxication deaths, and 1,038 fentanyl-related intoxication deaths through June. There have been 133 more heroin-related deaths and 917 more fentanyl-related deaths when compared to death tolls from January through June of 2015. See the Maryland Department of Health data [here](#).

Overdose is not the only way in which opioid drugs are threatening public health. Misuse and opioid use disorder (OUD) are among the fastest growing and monumental problems facing our nation. The CDC estimates that prescription opioid sales nearly quadrupled from 1999 to 2010, without an overall change/increase in the amount of pain reported by Americans.³ Between 2007 and 2012, over 40% of all alcohol- and drug-related overdose deaths in Maryland involved one or more prescription opioids according to Maryland Department of Health data. In 2017, there was

¹ Algren D, Monteilh C, Rubin C, et al. *Fentanyl-associated Fatalities Among Illicit Drug Users in Wayne County, Michigan*. Journal of Medical Toxicology. March 2013; 9(1):106-115.

² Seth P, Rudd R, Noonana, R, Haegerich, T. *Quantifying the Epidemic of Prescription Opioid Overdose Deaths*. American Journal of Public Health, March 2018; 108(4), e1-e3.

³ Reiman, A, Welty, M, Solomon, P. *Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report*. Cannabis Cannabinoid Res. 2017. 2(1): 160-166. Published online Jun 1 doi: 10.1089/can.2017.0012.

an estimated 49,198 Maryland residents age 12 and older who were taking opioids or suffering from an opioid use disorder.

Increasingly states are looking to medical cannabis as a tool in the fight against the nation's opioid epidemic. These policy discussions stem largely from the growing evidence base that cannabis may be an effective and a safer alternative for pain treatment. Recent data also indicate that implementation of medical cannabis laws is associated with a reduction in opioid prescriptions among Medicaid and Medicare enrollees, and that states with medical cannabis programs experience fewer opioid overdose deaths.⁴⁵

Consequently, policymakers are considering cannabis not only as an alternative pain treatment to opioids, but as an opioid replacement therapy for OUD to help ease withdrawal symptoms and aid in relapse prevention. Continued high rates of opioid overdose deaths necessitate effective interventions, which may include cannabis use. Legislation authorizing cannabis-related OUD treatment has been introduced in at least seven states and passed in Hawaii, Maine, and New Mexico (before being struck down by Governor veto). A hurdle consistent among the states that have considered such legislation is the overriding concern that high-quality clinical research on the use of cannabis to combat OUD is first needed to better inform these important policy discussions.

II. MEDICAL CANNABIS IN THE TREATMENT OF OPIOID USE DISORDER

Opioid use disorder is a broad term used to describe opioid dependence and addiction. The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, (DSM-5) defines OUD by evaluating the number of diagnostic criteria an individual meets. Specifically, opioid use disorder applies to a person who (1) uses opioids (illicit or prescription) and (2) experiences two or more of the following symptoms in a 12 month period:

- Taking more opioids than intended
- Wanting or trying to control opioid use without success
- Spending a lot of time obtaining, taking, or recovering from the effects of opioids
- Craving opioids
- Failing to carry out important roles at home, work, or school because of opioid use
- Continuing to use opioids despite relationship or social problems
- Giving up or reducing other activities because of opioid use
- Using opioids even when it is unsafe
- Knowing that opioids are causing a physical or psychological problem, but using them anyway
- Tolerance to opioids
- Withdrawal symptoms when opioids are not taken

⁴ Wen H, Hockenberry JM, *Association of Medical and Adult-Use Marijuana Laws with Opioid Prescribing for Medicaid Enrollees*, JAMA Intern Med. 2018;178(5):673-679.doi: 10.1001/jamainternmed. 2018. 1007.

⁵ Bradford AC, Bradford WD, Abraham A, Bagwell Adams G. *Association Between US State Medical Cannabis Laws and Opioid Prescribing in Medicare Part D Population*. JAMA Intern. Med. 2018; 178(5):667-672. Doi:10.1001/jamainternalmed.2018.0266.

Support for Treatment of OUD with Medical Cannabis

There is mounting anecdotal evidence from patients and caregivers who have provided testimony in the states that have considered adding OUD for treatment with medical cannabis suggesting that medical cannabis may offer an effective tool for lowering opioid withdrawal cravings and addressing many withdrawal symptoms individuals in recovery experience, including nausea, diarrhea, muscle spasms, insomnia, and anxiety. Patients report that cannabis promotes restful sleep and helps reduce the intensity of cravings. It may also pose less of a risk than existing FDA-approved opioid-based treatments (methadone, buprenorphine, and naltrexone) since FDA-approved medications that are used in any manner other than prescribed can increase the risk of addiction and overdose.⁶ Further, there is anecdotal evidence that patients receiving medication for OUD have been shown to have better treatment outcomes when they are also able to access medical cannabis.⁷ Individual providers have testified to observing high-dose opiate patients eliminate or reduce use of opiates through the use of medical cannabis.

Recent animal models suggest that cannabinoids may have long-lasting therapeutic effects relevant to OUD.^{8,9,10} Cannabinoids are a class of active chemical compounds produced by the cannabis plant. A specific cannabinoid, cannabidiol, has been seen to reduce heroin cravings in animals and appears to restore some of the neurobiological damage induced by opioid use.¹¹ A small pilot, conducted by Dr. Yasmin L. Hurd, PhD, of the Friedman Brain Institute, Departments of Psychiatry and Neuroscience, Icahn School of Medicine at Mount Sinai Center for Addictive Disorders in New York City and her colleagues mirrored these findings. In the study, cannabidiol helped heroin users abstaining from use relieve anxiety related to cravings.¹² Proponents suggest cannabis extracts may reduce cravings and ease withdrawal symptoms in heroin users, but these claims are largely unproven in clinical trials.

Advocates also point to the substantial challenges many patients face in accessing medication-assisted treatment (MAT) (counseling combined with one of the three FDA-approved medications for OUD) for opioid use disorders as a reason to support allowing cannabis to treat OUD. Issues related to insurance coverage, provider availability, and access to treatment facilities remain considerable barriers to traditional OUD treatment options.

⁶ Lucas et al. *Substituting Cannabis for Prescription Drugs, Alcohol and Other Substances Among Medical Cannabis Patients: The Impact of Contextual Factors*. Drug and Alcohol Review, 2016; 35: 326-333.

⁷ Degenhardt L, Lintzeris N, Campbell G, et al. *Experience of Adjunctive Marijuana Use for Chronic Non-cancer Pain: Findings from the Pain and Opioids IN Treatment (POINT) Study*. Drug Alcohol Depend. 2015;147:44-150.

⁸ Ganage et al. *Differential Effects of Endocannabinoid Catabolic Inhibitors on Morphine Withdrawal in Mice*. Drug and Alcohol Dependence, 2015 January 1; 146: 7-16.

⁹ Manwell and Mallet. *Comparative Effects of Pulmonary and Parenteral Δ^9 -Tetrahydrocannabinol (THC) Exposure on Extinction of Opiate-induced Conditioned Aversion in Rats*. Psychopharmacology, 2015 May; 232(9):1655-65.

¹⁰ Ramesh et al. *Blockade of Endocannabinoid Hydrolytic Enzymes Attenuates Precipitated Opioid Withdrawal Symptoms in Mice*. The Journal of Pharmacology and Experimental Therapeutics, 2011; Vol. 339, No. 1.

¹¹ Hurd, et al. *Cannabidiol, a Nonpsychotropic Component of Cannabis, Inhibits Cue-induced Heroin Seeking and Normalizes Discrete Mesolimbic Neuronal Disturbances*, The Journal of Neuroscience, 2009, 14764-14769.

¹² Hurd, et al. *Early Phase in the Development of Cannabidiol as a Treatment for Addiction: Opioid Relapse Takes Initial Center Stage*, Neurotherapeutics, 2015 October; 12(4): 807-815.

Opposition to Treatment of OUD with Medical Cannabis

A comprehensive review of existing medical literature shows that there is no credible scientific evidence backing up the claims that cannabis is beneficial in treating addiction, and that there is some evidence suggesting that it may exacerbate substance use and dependency issues.¹³ Although there is limited human-subject research on the treatment of OUD with medical cannabis, the studies have not been widely accepted within the medical establishment and leading addictions organizations due to their limited scope and underlying methodology.¹⁴¹⁵¹⁶ In contrast, decades of high quality clinical research conclusively demonstrates that medication assisted treatment (MAT) combined with social support is an effective treatment for OUD.¹⁷¹⁸¹⁹²⁰²¹²²²³²⁴

Health care providers and health care organizations, particularly addiction specialists, maintain strong opposition to treating OUD with medical cannabis. During the committee hearings on Senate Bill 181 and House Bill 268 which were introduced during Maryland's 2018 legislative session and would have added OUD as a qualifying condition for treatment with medical cannabis, leading professional addiction societies in Maryland issued forceful statements opposing medical cannabis as an OUD treatment. Of primary concern is the absence of high-quality clinical research involving humans that demonstrates cannabis may be an effective treatment for OUD. Due to the lack of scientific evidence, the potential of medical cannabis to prevent opioid misuse, mitigate withdrawal symptoms, and reduce the likelihood of relapse is unknown. Rigorous human clinical trials that quantitatively measure the effectiveness of medical cannabis therapy for reducing opiate dependency are needed.

¹³ Olfson M, Wall mm, Liu S-M, Blanco C. *Cannabis Use and Risk of Prescription Opioid Use Disorder in the United States*. Am J Psychiatry. 2017; 175(1): 47-53. doi:10.1176/appi.ajp.2017.17040413.

¹⁴ Reiman, Amanda, Welty, Mark, Solomon, Perry. *Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report*. Cannabis and Cannabinoid Research, Volume 2.1. doi: 10.1089/can.2017.0012.

¹⁵ Degenhardt L, Lintzeris N, Campbell G, et al. *Experience of Adjunctive Marijuana Use for Chronic Non-cancer Pain: Findings from the Pain and Opioids MN Treatment (POINT) Study*. Drug Alcohol Depend. 2015; 147:44-150.

¹⁶ Haroutounian S, Ratz Y, Ginosar Y, et al. *The Effect of Medicinal Marijuana on Pain and Quality of Life Outcomes in Chronic Pain: A Prospective Open-label Study*. Clin J Pain. 2016; 32:1036-1043.

¹⁷ Reed K, Day E, Keen J, et al. *Pharmacological Treatments for Drug Misuse and Dependence*. Expert Opin Pharmacother. 2015;16:325-333.

¹⁸ Kosten TR, O'Connor PG. *Management of Drug and Alcohol Withdrawal*. N Engl J Med. 2003;348:1786-1795.

¹⁹ Copenhaver MM, Bruce RD, Altice FL. *Behavioral Counseling Content for Optimizing the Use of Buprenorphine for Treatment of Opioid Dependence in Community-based Settings: a Review of the Empirical Evidence*. Am J Drug Alcohol Abuse. 2007;33:643-654.

²⁰ Montoya ID, Schroeder JR, Preston KL, et al. *Influence of Psychotherapy Attendance on Buprenorphine Treatment Outcome*. J Subst Abuse Treat. 2005;28:247-254.

²¹ Bart G. *Maintenance Medication for Opiate Addiction: the Foundation of Recovery*. J Addict Dis 2012; 31(5): 207-25.

²² 12 Volkow ND, Frieden TR, Hyde PS, Cha SS. *Medication-assisted Therapies—Tackling the Opioid-overdose Epidemic*. N Engl J Med 2014; 370: 2063-6

²³ Mattick RP, Breen C, Kimber J, Davoli M. *Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence*. Cochrane Database Syst Rev 2009;(3): CD002209.

²⁴ Weiss RD, Potter JS, Fiellin DA, et al. *Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial*. Arch Gen Psychiatry 2011; 68: 1238-46.

Opponents of treating OUD with medical cannabis include:

- American Society of Addiction Medicine (ASAM) (the oldest and largest medical specialty organization in the U.S., representing over 5,500 physicians and other providers who specialize in addiction treatment)
- Maryland-DC Society of Addiction Medicine (MDDCSAM)
- Maryland Affiliate of the National Council on Alcoholism and Drug Dependence (NCADD-Maryland)
- Maryland Association for the Treatment of Opioid Dependence (MATOD)
- National Council on Alcoholism and Drug Dependency (NCADD)
- National Institute on Drug Abuse (NIDA)

Further, there may be dangers to exposing individuals with substance use disorders or substance dependence to another intoxicating substance, which could create yet another drug dependency. Dr. Leah Bauer of the Maine Association of Psychiatric Physicians and the Addiction Resource Center at Mid Coast Hospital stated in a petition to the Maine State Legislature that using medical cannabis to treat OUD would encourage individuals with substance use disorders or substance dependence to use another toxic and habit-forming substance. The petition stated that adding OUD as a qualifying condition would be asking Maine to embark on an experiment the best medical science does not support.

III. LAWS IN OTHER STATES

The alarming and continued rise in the opioid overdose death rate, and the estimated 2.1 million Americans suffering from OUD underscores the need for effective OUD treatments. Policymakers in several states have identified medical cannabis as a potential alternative to FDA-approved medication assisted treatments in addressing OUD. Since 2016, at least nine states have considered legislation or regulations to allow medical cannabis as an opioid replacement therapy to help ease withdrawal symptoms and aid in relapse prevention. The following is a summary of the legislative and regulatory proposals considered in other states to allow medical cannabis in the treatment of OUD.

A. States Permitting Treatment of OUD with Medical Cannabis

In 2018, Pennsylvania, New Jersey, and New York became the first states to expressly allow medical cannabis for the treatment of OUD. Each state permits the use of medical cannabis to treat OUD, but with significant restrictions. A brief summary of the laws and programs is included below.

Pennsylvania

The Pennsylvania Department of Health promulgated temporary regulations to permit the use of medical cannabis to treat OUD on May 17, 2018, based on the recommendation of the State's Medical Marijuana Advisory Board. The regulations permit physicians to make medical cannabis available to patients only if all other traditional treatments are tried first and fail, or if the medical cannabis is used in conjunction with traditional therapies. Pennsylvania Secretary of Health Dr. Rachel Levine emphasized that "It's important to note that medical cannabis is not a

substitute for proven treatments for opioid use disorder.” Critical to the Department’s decision was that the state statute restricts clinical research to qualifying medical conditions. Therefore, only by adding OUD to the list of qualifying medical conditions could the Department authorize certified research centers in the State to initiate clinical trials on the use of cannabis to treat OUD.

The Pennsylvania Department of Health approved eight local universities as Certified Academic Clinical Research Centers to begin research on medical cannabis in May 2018. The universities include:

- Drexel University College of Medicine, Philadelphia
- Lewis Katz School of Medicine at Temple University, Philadelphia
- Penn State College of Medicine, Hershey
- Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia
- Perelman School of Medicine at the University of Pennsylvania, Philadelphia
- University of Pittsburgh School of Medicine, Pittsburgh
- Lake Erie College of Osteopathic Medicine (LECOM), Erie
- Philadelphia College of Osteopathic Medicine, Philadelphia

According to Pennsylvania Governor Tom Wolfe the “research component of Pennsylvania’s medical marijuana program sets it apart from the rest of the nation.” Due to federal restrictions on cannabis research, only a small number of physicians have access to cannabis for clinical trials. By adding OUD to the list of qualifying medical conditions the State’s medical schools are positioned to conduct critical clinical research on the effectiveness of cannabis to treat certain medical conditions, including OUD.

New Jersey

In March of 2018, New Jersey expanded the list of qualifying conditions under the State’s medical cannabis program. Included among the five new categories of conditions was “chronic pain related to musculoskeletal disorders.” The condition includes any petitions that fall within this category. Subsequently, the Department of Health granted a petition seeking to add OUD (Medical Marijuana Petition (MMP)-063) as a qualifying medical condition, if the disorder results from the treatment of chronic pain with opioids under the category titled “chronic pain related to musculoskeletal disorders.” The approved petition to add opioid use disorder may be viewed at <https://www.nj.gov/health/medicalmarijuana/documents/petitions/MMP-063.pdf>.

New York

On July 12, 2018, the New York State Department of Health filed emergency regulations adding “any condition for which an opioid could be prescribed” as a qualifying condition for medical cannabis. Effective immediately, registered practitioners may certify patients to use medical cannabis as a replacement for opioids, provided that the precise underlying condition for which an opioid would otherwise be prescribed is stated on the patient's certification. This allows patients with severe pain that does not meet the definition of chronic pain to use medical marijuana as a replacement for opioids. In addition, the regulation adds opioid use disorder as an associated

condition. However, the regulations only allow a patient with opioid use disorder to use medical cannabis as an opioid replacement if the patient is enrolled in a certified treatment program.

New York State Health Commissioner Dr. Howard Zucker noted that research indicates that marijuana can reduce opioid use and therefore has the potential to save countless lives. Opioid use disorder joins the list of 12 other qualifying conditions, including cancer, HIV, Parkinson's disease, multiple sclerosis, and epilepsy. In a press release following the emergency regulations the Department of Health indicated that "marijuana can be an effective treatment for pain, greatly reduces the chances of dependence, and eliminates the risk of fatal overdose compared to opioid-based medications." Moreover, the agency pointed to studies of states with medical cannabis programs that have found "notable associations of reductions in opioid deaths and opioid prescribing with the availability of cannabis products."

B. States Rejecting Treatment of OUD with Medical Cannabis

From 2016-2018, at least seven state legislatures considered bills that would expressly add OUD to the list of medical cannabis qualifying conditions. Of these, the majority rejected the legislation seeking to add OUD to the list of qualifying conditions. As previously stated, three states – Hawaii, Maine, and New Mexico – passed legislation authorizing the use of medical cannabis to treat OUD; however, the State's Governor vetoed the legislation in each instance following significant pressure from health care providers, health care organizations, and addiction specialists. A brief summary of each bill is included below.

Arizona

House Bill 2508 would have added opioid use disorder to the list of conditions for which medical cannabis may be prescribed in the State. The bill received a public hearing, but the overseeing committee did not hold a vote. The bill would have required at least a three-fourths majority in each house of the legislature to become law.

Hawaii

Hawaii has one of the lowest opioid prescribing rates in the country, according to National Institute on Drug Abuse. The State's opioid overdose death rate is less than half of the national average. Nonetheless, the number of opioid-related overdoses deaths has increased in recent years.

In July 2018, Hawaii Governor David Ige vetoed Senate Bill 2407, which would have allowed for the use of medical cannabis "to treat opioid use, substance use, and withdrawal symptoms resulting from the treatment of those conditions." SB 2407 moved through Hawaii's legislative process quickly with overwhelming support from lawmakers. Governor Ige vetoed the legislation on the grounds that the Department of Health in Hawaii already has the ability to add new qualifying conditions for medical cannabis treatments. Patients and physicians can initiate the formal petition process annually. The evidence-based process allows caregivers and patients to apply to add new conditions, including opioid use and withdrawal symptoms.

Maine

Maine has one of the highest opioid overdose death rates in the U.S. From 2012 to 2016, the number of opioid-related overdose deaths increased 400 percent, which is significantly higher than the national average. In April of 2016, Maine became the first state to formally consider medical cannabis in the treatment of OUD. In response to a petition submitted by caregivers in the State, health regulators convened to hear testimony on a proposal to make opioid use disorder a qualifying condition for the use of medical cannabis.

Four physicians, accompanied by medical cannabis patients and caregivers, testified in support of the proposal. The patients and caregivers presented personal experiences of using medical cannabis to prevent the development of a tolerance to opioids, and to eliminate the need for increased dosages of opioid medication. Patient testimony also suggested that the use of medical cannabis eased opioid-related withdrawal symptoms. Conversely, Maine's medical establishment, including representatives from the substance use disorder prevention community, expressed strong opposition to the proposal. The chief concern presented by opponents was the lack of scientific research indicating that cannabis is an effective OUD treatment. Some supporters of the petition acknowledged the lack of rigorous scientific evidence due to the continued Schedule I status of the drug under the federal Controlled Substances Act. After substantial deliberation, review of public testimony and written comments, and further consultation with physicians, the Department of Health rejected the petition to permit medical cannabis in the treatment of OUD.

In 2018, the Maine State Legislature passed a bill that would have permitted the use of medical cannabis for any medical reason. The bill, which had strong bipartisan support among state legislators, was originally introduced to permit the use of medical cannabis to treat OUD. In July 2018, Maine Governor Paul LePage vetoed the bill, largely for reasons unrelated to OUD. The bill will return to the Maine legislature for consideration of a veto override.

Maryland

As previously mentioned, during the 2018 legislative session, the Maryland General Assembly considered two bills – Senate Bill 181 and House Bill 268 – that would have added OUD as a qualifying condition for treatment with the use of medical cannabis. Both bills received an initial hearing, but only HB 268 was scheduled for a vote. The House and Government Operations Committee unanimously voted unfavorably on the bill. Representatives from numerous leading professional addictions organizations in Maryland strongly opposed the bills due to insufficient evidence of the efficacy of treating OUD with medical cannabis.

Massachusetts

In 2017, the State legislature in Massachusetts (the Massachusetts General Court) introduced H. 1050, which directed the Department of Public Health to establish a pilot program for veterans to use medical marijuana to treat medical conditions that are currently being treated with opioid-based medication and combat opioid use disorder. The bill was introduced through a public petition process. A hearing was held, but no vote was taken on the bill.

New Mexico

On September 7, 2018, New Mexico Department of Health Secretary Lynn Gallagher rejected (for the second time) a recommendation from the board of medical professionals to add opioid use disorder to the list of the State's 21 qualifying conditions. The measure was rejected due to lack of medical evidence on cannabis as a treatment for opioid addiction. The Department reasoned that clinical studies have not shown the use of medical cannabis to treat OUD to be safe or effective. It was noted, however, that in April 2017, two faculty members at University of New Mexico released findings from a study they conducted in which they observed that patients who used medical cannabis reduced their opioid use by 31%, while the control group saw a slight increase in overall opioid use.

In April 2017, New Mexico Governor Susana Martinez vetoed House Bill 527, which would have added 14 qualifying conditions to the medical cannabis program, including OUD. Governor Martinez vetoed the bill because the Department of Health and the Medical Cannabis Advisory Board were authorized to expand the qualifying conditions, and the legislative action circumvented this process and the expertise of the Department and the Board. Governor Martinez stressed that maintaining the integrity of New Mexico's medical marijuana program was vital.

New York

During the 2018 legislative session, the New York State Assembly introduced two cross-filed (identical) bills, Assembly Bill 9016 and Senate Bill 7564, which sought to add OUD to the list of conditions covered for lawful use of medical cannabis. Neither bill was passed. AB 9016 passed the Assembly but was referred to the Rules Committee in the Senate, and SB 7564 did not receive a hearing.

C. Need for Clinical Research

A review of the legislative and regulatory proposals in other states, and SB 181 and HB 268 in Maryland, underscore the need for high-quality clinical research on the effectiveness of medical cannabis to treat OUD. Adding OUD as a qualifying condition absent substantial clinical research on the effectiveness and safety of medical cannabis as a treatment presents significant public health and safety concerns. As such, the U.S. Centers for Disease Control and Prevention (CDC), the National Institute on Drug Abuse (NIDA), the American Society of Addiction Medicine (ASAM), the National Council on Alcoholism and Drug Dependency (NCADD), and many other medical and addiction organizations oppose adding OUD as a qualifying condition without objective data.

The continued federal prohibition on cannabis hinders clinical research on cannabis. Due to its Schedule I status cannabis products are not tested for safety and effectiveness like FDA-approved medications; measured and dosed like food products; subjected to agricultural-safety and pesticide standards like crops; and held to labeling standards like alcohol. In August 2016, the U.S. Drug Enforcement Administration (DEA) denied two petitions to re-schedule cannabis as a less dangerous drug under the Controlled Substances Act. Cannabis remains a Schedule I controlled substance because there is no accepted medical use, and it has a high potential for abuse. Schedule I is the most restrictive category for law enforcement purposes and includes heroin and LSD. Other

highly addictive substances such as oxycodone and methamphetamine are classified as Schedule II drugs, and therefore may be prescribed in limited circumstances.

Nonetheless, the DEA and FDA acknowledge that more research is needed on the medical effectiveness of cannabis, and each has begun to loosen the restrictions on cannabis research. Previously, the University of Mississippi, operating under a contract with the National Institute on Drug Abuse (NIDA), was the only entity authorized to cultivate cannabis for research purposes in the United States. In the future, additional entities may apply to grow and distribute cannabis for FDA-authorized research purposes. DEA currently has 350 individuals registered to conduct research on cannabis and its components. Notably, DEA has approved every application for registration submitted by researchers seeking to use NIDA-supplied marijuana to conduct research that the U.S. Department of Health and Human Services (HHS) determined to be scientifically meritorious.

IV. EFFORTS TO REDUCE NUMBER OF OPIOID PRESCRIPTIONS

Over-prescribing is a key factor in the opioid epidemic in Maryland and across the country. Prescription drug sales nearly quadrupled from 1999 to 2010, while the percent of Americans reporting acute and chronic pain was constant. Concurrently, heroin-related deaths more than tripled between 2010 and 2014. The opioid epidemic has fueled a spike in fatal and non-fatal drug overdoses, and claimed the lives of 2,009 Marylanders last year, up from 888 in 2014 and 529 in 2011.

Opioid use disorder or opioid dependence often begins with treatment of acute pain. To address this danger, the CDC Guidelines for Prescribing Opioids for Chronic Pain issued in March of 2016, suggest that “when opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity 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.” CDC experts noted that each day of unnecessary opioid use increases the likelihood of physical dependence without adding any benefit.

Based on this growing body of evidence, legislators in Maryland have sought to modify provider prescribing habits. In 2017, the Maryland General Assembly enacted legislation limiting the initial length of opioid prescriptions. Health Occupations Article, §1-223, Annotated Code of Maryland requires that for the treatment of pain, a health care provider shall prescribe the lowest effective dose of an opioid and in a quantity that is no greater than the quantity needed for the expected duration of pain severe enough to require an opioid. In addition, when a patient is prescribed an opioid, the patient must be advised of the benefits and risks associated with the drug.

Local hospitals and health care providers have also taken steps to curb opioid prescriptions. Johns Hopkins Hospital established opioid prescribing guidelines for patients following 20 common surgeries, which reduce the length of opioid prescriptions in most cases. The guidelines were published in the Journal of the American College of Surgeons on August 14, 2018. (See [https://www.journalacs.org/article/S1072-7515\(18\)31129-3/pdf](https://www.journalacs.org/article/S1072-7515(18)31129-3/pdf)) The guidelines recommend one to 15 oxycodone 5-mg tablets for 11 of the 20 procedures, 16 to 20 for six of the procedures, and no opioids for the remaining three procedures. In implementing the guidelines the hospital noted

that reducing the amount of opioids prescribed is critical because surgery is a common way in which individuals are initially exposed to opioids and 1 in 16 surgical patients eventually become long-term users after surgery.²⁵

V. THE ROLE OF MEDICAL CANNABIS IN THE OPIOID EPIDEMIC

Chronic pain is among the most widespread and costly medical conditions, impacting over 100 million Americans and with total direct and individual costs of up to \$635 billion per year.²⁶ Data suggest that cannabis legalization reduces prescription opioid use by serving as an alternative pain treatment. Medical cannabis laws may also have downstream policy effects on reducing opioid-related hospitalizations, overdose deaths, and traffic fatalities. The following section examines existing literature on the association between medical cannabis and opioid use, including as a treatment for opioid use disorder.

A. Medical Cannabis as an Alternative Pain Treatment

Identifying alternative pain treatment options is critical to reducing the number of opioid-related overdose deaths and the prevalence of opioid use disorder and dependence. In 2016, the U.S. Surgeon General issued a first-ever report on drug addiction, which concluded that evidence-based harm reduction approaches are cost effective and successful at reducing opioid-related hospitalizations, deaths, and traffic fatalities. Recent data indicate that cannabis is an effective and safer alternative for pain treatment. The National Academies of Sciences, Engineering, and Medicine (NAM) found “conclusive or substantial evidence” from randomized controlled trials to support its findings that cannabis is effective for the treatment of chronic pain in adults. The implementation of medical cannabis laws is also associated with significant decreases in opioid prescriptions among Medicaid and Medicare enrollees. These findings are briefly summarized below.

- **States with laws legalizing medical cannabis experienced 24.8% fewer opioid-related overdose deaths between 1999 and 2010.** The study compared the mean annual opioid overdose mortality rate between states with medical cannabis laws and states without medical cannabis laws. From 1999-2010, 13 states enacted medical cannabis laws (California, Oregon, Washington, Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont). Analyzing the opioid-related overdose deaths in each state following implementation of the medical cannabis laws showed that medical cannabis laws were associated with a lower rate of overdose-deaths. *See* M.A. Bachhuber, et al., *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010*, JAMA Intern Med. 2014;174(10):1668–1673. doi:10.1001/jamainternmed.2014.4005.

²⁵ Brummett CM, Waljee JF, Goesling J, et al. *New persistent opioid use after minor and major surgical procedures in US adults*. JAMA Surg 2017; 152:e170504.

²⁶ Pergolizzi J, Boger RH, Budd K, et al. Opioids and the management of chronic severe pain in the elderly: consensus statement of an International Expert Panel with focus on the six clinically most often used World Health Organization Step II opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone). Pain Pract. 2008;8(4):287-313.

- **Strong evidence exists to support the conclusion that cannabis effectively treats chronic pain in adults.** The 2017 report issued by NAM reviewed observational and clinical studies conducted since 1999. The comprehensive literature review concluded that cannabis is effective at treating chronic pain in adults. See The National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*, National Academies Press, 2017, available at <http://www.nap.edu/24625>.
- **Medical cannabis patients report using medical cannabis as a substitute for prescription drugs.** A self-selected convenience sample of 2,774 individuals who have used cannabis at least once in the past 90 days were surveyed for responses on effectiveness of medical cannabis to treat pain. Nearly 1 in 2 (46%) reported using cannabis as a substitute for prescription drugs, with opioids being the most common class of drugs substituted (35.8%). The patient-reported outcomes support prior research that individuals are using cannabis as an opioid substitute. See J.M Corroon et al., *Cannabis as Substitute for Prescription Drugs – A Cross-Sectional Study*, Journal of Pain Research, 2017. <https://doi.org/10.2147/JPR.S134330>.
- **Evidence suggests cannabis may be an effective alternative to opioid analgesics for cancer-associated chronic and neuropathic pain.** A review of clinical studies from 1975-2014 indicates that medical cannabis reduces chronic and neuropathic pain in advanced cancer patients do not respond well to opioid analgesics. See A. Blake et al., *A Selective Review of Medical Cannabis in Cancer Pain Management*, Ann Palliat Med., 2017:

B. Association Between Cannabis Legalization and Opioid Prescribing Among Medicaid and Medicare Enrollees

Implementation of medical cannabis laws is associated with a reduction in the number of opioid prescriptions among Medicaid and Medicare enrollees. In 2018, two highly-publicized cross-sectional studies concluded that implementation of state medical cannabis programs was associated with a significant decrease in the rate of opioid prescribing among each population. The findings of each study are summarized below.

Medicaid

States with medical cannabis and adult-use cannabis laws have lower opioid prescribing rates. From 2011-2016, state implementation of medical cannabis laws was associated with a 5.88% lower rate of opioid prescribing (95% CI, -11.55% to -.21%). A cross-sectional study compared opioid prescribing rates among Medicaid enrollees between states that started to implement medical and adult-use cannabis laws between 2011 (the first year of the mandatory data reporting requirements under the Affordable Care Act) and 2016, and the rest of the country.²⁷

During this period, an estimated one-third of opioid prescriptions were misused or abused, of which Medicaid had a disproportionately large share. Medicaid/low-income adults included in the Medicaid expansion are shown to have disproportionately high risks for chronic pain, as well

²⁷ Wen H, Hockenberry JM. Association of Medical and Adult-Use Marijuana Laws with Opioid Prescribing for Medicaid Enrollees. JAMA Intern Med. 2018;178(5):673–679. doi:10.1001/jamainternmed.2018.1007.

as opioid use disorder and overdose. Implementation of medical and adult-use marijuana laws was associated with a lower Medicaid-covered opioid prescribing rate.

Among the eight states that implemented medical cannabis laws during the study period (2011-2016), one-half (Delaware, Massachusetts, Minnesota and New Hampshire) had significantly lower opioid prescribing rates. Maryland was among the states that did not have statistically significant changes in opioid prescribing rates. However, the medical cannabis program did not become operational in Maryland until December 1, 2017. This means that implementation of the State law was outside the scope of the data analyzed in this study.

Medicare

In August 2018, a cross-sectional study published in *JAMA Internal Medicine* found that the use of all pain medications, including opioids, decreased among Medicare Part D enrollees following implementation of state medical cannabis laws.²⁸ Medicare Part D is an optional prescription drug benefit plan that covers more than 42 million Americans age 65 years or older. This population uses prescription drugs at significantly higher rates than the overall adult population, and is among the fastest growing populations using medical cannabis.

The study reviewed the total number of daily opioid doses in each state from 2010 to 2015. During this period there were on average more than 23 million daily doses of any opioid dispensed per year in each U.S. state. Utilizing multiple regression analyses found that Medicare enrollees in states with medical cannabis laws filled significantly fewer daily doses of opioids than Medicare enrollees in other states. States with medical cannabis dispensaries experienced 3.742 million fewer daily doses (95% CI, -6.289 to -1.194). This represents a 14.4% decrease in the use of prescription opioids in states with medical cannabis dispensaries.

Summary

Each study suggests that implementation of medical cannabis laws may reduce opioid prescribing and daily use. However, neither study evaluated whether individuals were switching from prescription opioids to medical cannabis or whether any individuals used medical cannabis to treat OUD. Additional research is needed to determine whether there is a causal relationship between medical cannabis laws and reductions in prescription opioid use.

To this end, a study was published in the “To the Editor” section of *JAMA Internal Medicine* in September 2018, which found that the opioid-related overdose death rate was accelerating in states where medical and/or adult use cannabis laws had been implemented.²⁹ Moreover, the death rate surpassed that of nonlegalizing states. The study reviewed opioid-related overdose death data from 2010 to 2016, and determined that the age-adjusted death rate was higher in states with cannabis legalization and that the age-adjusted death rate was increasing at a faster rate than in non-legalizing states. While several researchers have challenged the methodology of

²⁸ Bradford AC, Bradford WD, Abraham A, Bagwell Adams G. *Association Between US State Medical Cannabis Laws and Opioid Prescribing in the Medicare Part D Population*. *JAMA Intern Med*. 2018;178(5):667–672. doi:10.1001/jamainternmed.2018.0266.

²⁹ A. Bleyer and B. Barnes, *Opioid Death Rate Acceleration in Jurisdictions Legalizing Marijuana Use*, *JAMA Internal Med*. 2018;178(9):1280-1281.

this study – including the inaccurate assessment of states that have legalized medical and adult-use cannabis – the results call attention to the need for further investigation of the association between cannabis legalization and opioid-related overdose deaths.

VI. CONCLUSION

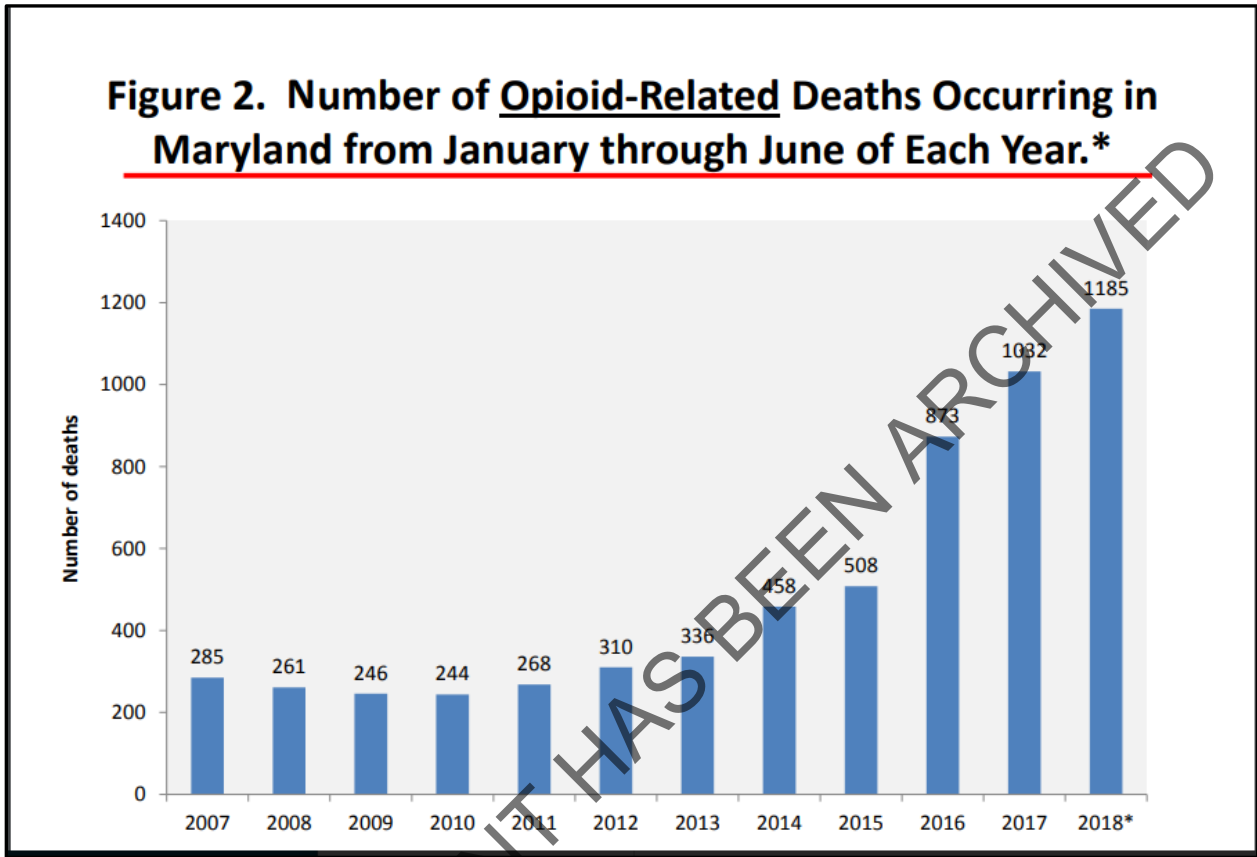
Maryland Health-General Article §13-3304 establishes certain qualifying medical conditions for which the Maryland Medical Cannabis Commission (“the Commission”) may authorize medical providers to certify patients to obtain medical cannabis. The list of qualifying medical conditions includes: cachexia, anorexia, wasting syndrome, severe or chronic pain, severe nausea, seizures, and severe or persistent muscle spasms. In addition, the statute authorizes the Commission to approve applications for “any other condition that is severe and for which other medical treatment have been ineffective if the symptoms reasonably can be expected to be relieved by the medical use of cannabis.”

Pursuant to this statutory authority, the Commission added glaucoma and post-traumatic stress disorder (PTSD) to the list of qualifying medical conditions through its regulations under COMAR 10.62.03.01. The Commission also allows each provider who registers with the Commission to treat other severe conditions for which traditional treatments have proven ineffective. In order to certify for a medical condition outside the list of expressly authorized conditions, the provider must include the medical condition as part of the provider’s registration with the Commission. Subsequently, certifying providers may certify patients to obtain medical cannabis to treat OUD under the current regulatory system. While it is not listed among the qualifying medical conditions, a certifying provider may treat OUD with medical cannabis if in their professional judgment the condition is (1) severe, (2) other treatments such as FDA-approved MAT has been ineffective, and (3) the symptoms reasonably can be expected to be relieved by the use of medical cannabis.

The Commission’s regulations establish that any person may submit a petition to add a medical condition or disease to the list of qualifying conditions codified in COMAR 10.62.01. In December 2018, the Commission received two petitions requesting the addition of OUD to the list of medical cannabis qualifying conditions. If the Commission determines that either or both of these petitions are “facially substantial” then it must conduct a public hearing within the next 12 months to evaluate whether the medical condition or disease should be included in the list of qualifying conditions. The Commission’s Research Committee, which includes two physicians, a scientist, addiction specialist, and horticulturist, is currently evaluating the petitions to determine whether they are facially substantial and require a public hearing. The Commission will provide the General Assembly with updates on the status of the OUD petitions, including information on any public hearings to consider adding OUD as a qualifying medical condition.

ATTACHMENT A

Note: Maryland saw 1,185 opioid-related deaths during the first six months of 2018.



ATTACHMENT B

Note: Maryland saw 153 more opioid-related deaths during the first six months of 2018 compared to the first six months of 2017.

Table 2. Comparison of Opioid-Related Intoxication Deaths^{1,2} by Place of Occurrence, Maryland, January – June, 2018³ and 2017.			
Jurisdiction	Opioid Intoxication Deaths		2018 vs 2017
	Jan. - Jun. 2018	Jan. - Jun. 2017	# DIFFERENCE
Maryland Total	1185	1032	153
Allegany	16	26	-10
Anne Arundel	129	102	27
Baltimore City	442	358	84
Baltimore County	194	163	31
Calvert	11	9	2
Caroline	3	4	-1
Carroll	46	26	20
Cecil	32	23	9
Charles	8	16	-8
Dorchester	4	6	-2
Frederick	44	34	10
Garrett	2	2	0
Harford	46	50	-4
Howard	21	28	-7
Kent	1	1	0
Montgomery	41	44	-3
Prince George's	51	63	-12
Queen Anne's	4	4	0
Somerset	5	1	4
St. Mary's	16	16	0
Talbot	3	7	-4
Washington	44	25	19
Wicomico	14	15	-1
Worcester	8	9	-1

¹Includes deaths that were the result of recent ingestion or exposure to any opioid, prescribed or illicit.

²Includes only deaths for which the manner of death was classified as accidental or undetermined.

³Counts for 2018 are not complete.

ATTACHMENT C

Table 6. Number of Opioid-Related Intoxication Deaths^{1,2} by Place of Occurrence, Maryland, 2007-2017 and YTD 2018 Through June.³

Jurisdiction	Opioid Intoxication Deaths											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 YTD
Maryland Total	628	523	570	504	529	648	729	888	1,089	1,856	2,009	1,185
Allegany	12	7	6	11	8	10	11	11	20	55	36	16
Anne Arundel	54	57	45	44	53	68	67	85	89	169	198	129
Baltimore City	256	154	199	139	142	189	212	275	354	628	692	442
Baltimore County	95	92	83	95	93	104	125	146	195	305	323	194
Calvert	12	6	11	4	10	11	5	16	19	25	25	11
Caroline	0	2	1	2	8	4	2	7	3	9	8	3
Carroll	12	15	16	12	7	27	21	29	34	44	51	46
Cecil	23	9	21	21	24	22	22	25	26	28	57	32
Charles	8	9	10	9	10	12	9	16	17	16	34	8
Dorchester	2	3	1	6	2	5	5	0	1	5	10	4
Frederick	12	7	18	12	28	23	33	34	37	80	66	44
Garrett	0	2	3	1	1	0	4	2	4	0	4	2
Harford	24	31	28	38	28	32	34	38	45	76	93	46
Howard	14	13	11	9	18	17	26	18	25	40	47	21
Kent	2	4	2	3	1	0	4	2	3	4	4	1
Montgomery	35	29	31	25	28	36	40	53	59	84	91	41
Prince George's	27	33	38	27	24	30	38	48	45	106	124	51
Queen Anne's	4	2	3	4	4	2	7	9	4	6	6	4
Somerset	5	3	2	1	3	2	4	2	4	6	3	5
St. Mary's	3	9	7	10	6	9	10	8	12	13	33	16
Talbot	3	3	2	2	1	3	6	4	5	10	8	3
Washington	11	21	14	13	16	20	26	34	57	63	51	44
Wicomico	6	7	10	10	10	17	14	15	17	44	28	14
Worcester	8	5	8	6	4	5	4	10	14	20	15	8

¹Includes deaths that were the result of recent ingestion or exposure to prescription and illicit opioids.

²Includes only deaths for which the manner of death was classified as accidental or undetermined.

³Counts for 2018 are not complete.

THIS DOCUMENT HAS BEEN ARCHIVED

ATTACHMENT D

Table 8. Number of Fentanyl-Related Intoxication Deaths^{1,2} by Place of Occurrence, Maryland, 2007-2017 and YTD 2018 Through June.³

Jurisdiction	Fentanyl Intoxication Deaths											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 YTD
Maryland Total	26	25	27	39	26	29	58	186	340	1,119	1,594	1,038
Allegany	3	0	1	2	1	1	1	1	5	29	29	13
Anne Arundel	3	5	3	5	2	3	6	23	29	98	152	108
Baltimore City	3	2	4	4	2	4	12	72	120	419	573	414
Baltimore County	6	9	9	6	4	5	11	36	65	182	244	168
Calvert	0	1	1	0	1	0	0	5	2	11	22	10
Caroline	0	0	0	1	4	0	0	0	1	3	7	3
Carrroll	0	2	0	2	0	1	2	4	11	20	40	35
Cecil	2	1	0	2	2	0	0	1	7	9	44	27
Charles	0	0	0	0	1	1	3	1	4	17	26	7
Dorchester	0	0	0	2	0	0	2	0	1	3	7	3
Frederick	0	0	0	2	3	1	2	6	11	49	49	42
Garrett	0	1	0	0	1	0	0	0	2	0	2	1
Harford	1	1	0	3	2	1	1	2	16	46	73	38
Howard	1	0	0	0	0	2	3	5	7	27	36	19
Kent	0	0	0	0	0	0	0	1	0	3	3	1
Montgomery	2	0	1	1	0	2	0	8	17	43	72	26
Prince George's	1	0	2	2	0	1	6	7	15	58	103	41
Queen Anne's	1	0	0	0	0	0	1	1	0	4	5	4
Somerset	1	1	0	1	0	0	2	0	1	6	3	5
St. Mary's	0	0	1	1	1	0	1	3	3	4	26	14
Talbot	1	1	0	1	0	0	0	2	2	7	3	3
Washington	0	0	0	2	0	1	4	1	14	31	39	37
Wicomico	1	1	3	1	1	4	1	7	1	34	24	11
Worcester	0	0	2	1	0	1	0	0	6	16	12	8

¹Includes deaths that were the result of recent ingestion or exposure to prescription or illicit fentanyl.

²Includes only deaths for which the manner of death was classified as accidental or undetermined.

³Counts for 2018 are not complete.