Law Enforcement and Executive Order: Duplication in Missouri’s Prescription Drug Monitoring Program

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LAW ENFORCEMENT AND EXECUTIVE ORDER: DUPLICATION IN MISSOURI'S PRESCRIPTION DRUG MONITORING PROGRAM

ABSTRACT

Missouri had long been scrutinized as the only state operating without a prescription drug monitoring program. These programs are seen as an effective way to monitor prescription opioids as opioid-related deaths have risen in the past decade. The opioid crisis has gained significant media attention and cast scrutiny on pharmaceutical companies, physicians, and state and federal governments. This comment explores the history of the opioid crisis and details Missouri’s struggle to implement a prescription drug monitoring program legislatively. In 2017, former Governor Eric Greitens signed an Executive Order directing the Missouri Department of Health and Senior Services to implement one of these programs. This program is centered on law enforcement, and as written, aims to monitor and collect data that is already available via alternative means. For Missouri to successfully combat the opioid crisis, the state needs to utilize resources already at its disposal to create an effective means of monitoring prescription opioids. At the time of publication, the program had been implemented; however, there is no available data currently available to determine the effectiveness of the program.
I. INTRODUCTION

Beginning in 1999, the use of opioids, both legal and illegal, has risen drastically; opioid-related deaths have increased significantly over the past decade. This crisis has quickly become one of the most discussed issues in the United States. Media coverage has increased with state and federal legislatures shining light on the issue as they struggle to find a solution. In October of 2016, President Trump declared the opioid crisis a “public health emergency.” At the time of his announcement, he had not requested any funds to combat the issue but plans on “really tough, really big, really great advertising” as a means to help minimize the number of those addicted to opioids in the nation. The President revisited this issue in his first State of the Union Address in January of 2018, and in March, the White House established a new website “where Americans can share their own stories about the dangers of opioid addiction.” Many states have undertaken differing and even multiple approaches to combat the number of opioid-related deaths they see in their state.

Missouri, like the nation, has not been immune to the effects of opioids. While opioids, when prescribed and used appropriately, can be effective at managing pain, the misuse of these drugs can lead to addiction and death. Missouri’s high use of opioids, especially in rural areas, is attributed to fewer options for pain management like physical therapy, older populations that are prescribed opioids for cancer or end-of-life treatment, and urban areas that have greater access to illegal drugs like heroin. While Missouri has been aware of this growing problem, the legislature has been unsuccessful in passing legislation to create a statewide prescription drug monitoring program (PDMP).

In July of 2017, Missouri Governor Eric Greitens attempted to tackle the use of opioids in Missouri by signing an executive order, directing the Department

3. Id.
6. See Gale Pryor, 6 Ways States are Fighting the Opioid Epidemic, ATHENA INSIGHT (May 19, 2017), https://www.athenahealth.com/insight/6-ways-states-are-fighting-opioid-epidemic.
8. Id.
of Health and Senior Services (DHSS) to implement a statewide PDMP using a three-step process. The program went into effect at the end of the 2017 calendar year, with data already being shared between prescribers and the state via a pharmacy benefit management firm. The program he proposed is not designed to operate as a traditional PDMP, but rather as a surveillance program. The data that Governor Greitens’s order collects is already available through other means in the state of Missouri. The state currently utilizes a statewide health information exchange (HIE) that shares electronic medical records (EMRs) with participants across the state, as well as smaller HIEs that operate regionally. In Missouri, the Bureau of Narcotics and Dangerous Drugs (BNDD) must maintain a registry of practitioners who deal with controlled substances, including Schedule II opioids, and there are currently reporting requirements for practitioners and pharmacists for controlled substances that are dispensed.

The Executive Order to implement a PDMP aims to combat the opioid crisis by punishing prescribers. However, the data that is collected and turned over to law enforcement is already available to law enforcement via multiple means, making Missouri’s PDMP an additional and duplicative step in monitoring prescription opioids. This comment will explore how and why there was a rise in the number of prescription opioids across the nation, discuss PDMPs as a way to monitor opioids, navigate Missouri’s struggle with opioid-related deaths and lack of legislation to combat those deaths, and examine why Missouri’s PDMP is a law enforcement-centered program that is duplicative of other systems that are already in place to monitor the amount of prescribed and dispensed opioids in the state. Finally, this comment will conclude with an evaluation of Nebraska and how the state has dealt with the increase in opioids as a best practice and potential model for Missouri, which the state should adopt as an alternative practice in monitoring opioids dispensed throughout the state.

II. OPIOID CRISIS

To first understand the impacts that opioids have had across the country, one must look to the history of opioids in the United States; prescribing practices have changed over time prior to landing in the current landscape where the amount of opioid use (and deaths) are called both a “crisis” and “epidemic.”

Opioid use in the United States did not begin over the past three decades; opioids were used recreationally and for pain management in the United States for centuries. When morphine was extracted from opium in 1803, it was used to treat pain in the Civil War. After seeing the addictive effects of opioids, scientists worked to develop a less addictive solution that maintained the effectiveness in relieving pain of opioids. This led to the development of heroin, which was more addictive than the morphine that was previously used. Medical professionals, seeing the addictive effects of both morphine and heroin, were concerned with opioid use, which resulted in a decline in medical opioids through the twentieth century. Research continued to search for alternatives, leading to the introduction of Vicodin and Percocet, which were made using synthetic opioids.

The most credited reason for the increase in prescribing opioids in past decades relates back to the state of medicine during the 1990s. During this time, physicians were told that they were not adequately treating patients’ pain. Patients were surveyed as they left hospitals after receiving treatment, and while their ailment or reason for visit may have been treated, their pain was not. In addition, there is evidence that untreated pain hampers healing and recovery from opioid addiction, which can lead to self-medication and the purchase of illegal opioids. There then came a greater push for physicians not only to treat ailments, diseases, and the like, but also to treat patients’ pain. Pain was introduced as the “fifth vital sign” to be assessed during treatment, and pain was treated as a public health issue. In response, pharmaceutical companies began to more aggressively market opioids, such as OxyContin. Physicians faced
backlash when they were told they were not adequately treating pain; physicians are now facing backlash for prescribing too many opioids in the attempt to treat pain. Now, physicians face finger pointing and blame from families affected by opioids, legislatures, and even the media, not to mention punishment from law enforcement and licensing boards.23

The increase in the amount of prescription opioids, such as oxycodone, hydrocodone, and methadone, has risen since 1999, and opioid-related deaths are associated with that increase since that time.24 The Centers for Disease Control and Prevention (CDC) report data on four categories of opioids: natural, synthetic, methadone, and heroin.25 The CDC estimates that 115 Americans die from an opioid overdose every day.26 While the CDC is reporting increases in prescription opioids and deaths related to overdoses, they admit that the data they report may not be complete.27 This may be attributed not only to an increase in prescription drugs, but also an increase in the illegal use of heroin and fentanyl.28 The CDC is not the only agency reporting an increase in opioid-related deaths; law enforcement is also reporting greater numbers of synthetic opioids on the market.29 Even in the early 2000s when authorities were seeing tampering and illegal selling of prescriptions, pharmaceutical sales of opioids continued to increase.30 In addition to the increase in deaths, “adverse health consequences resulting from prescription drug misuse—including overdose events, emergency department (‘ED’) visits, and inpatient admissions—have escalated dramatically.”31 The rise in opioid-related deaths has increased more quickly in the United States than in other countries.32

While there has been an increase in opioid overdoses, the majority of patients “prescribed opioids do not misuse them.”33 A common use of opioids is

28. Opioid Data Analysis, supra note 25.
29. Id.
32. NAT’L ACADS. OF SCI., ENG’G, & MED., supra note 13, at ix.
33. Id. at S-2.
to manage chronic pain in patients suffering from cancer and end-of-life treatment. Those who are being treated for acute pain with opioids, however, may experience the positive and euphoric feelings of the drugs, leading to the addiction that patients may face. The physicians prescribing opioids are not the only cause to the increase of opioids; “while increased opioid prescribing for chronic pain has been a vector of the opioid epidemic, researchers agree that such structural factors as lack of economic opportunity, poor working conditions, and eroded social capital in depressed communities, accompanied by hopelessness and despair, are root causes of the misuse of opioids . . .” Physicians should not have to shoulder all the blame for this issue; there are many factors that have led to the increase of opioids, and the focus should be on how to prevent opioid abuse and overdose.

A. State Strategies to Address Opioid Misuse

States have not sat idly by waiting for the opioid crisis to solve itself; numerous strategies have been presented to states as suggestions on how to limit opioid-related deaths. The Commission on Combatting Drug Addiction and Opioid Crisis released a draft of a report that outlines suggestions for states to follow in working to limit the number of opioid-related deaths. Some of the suggestions for prescribers include Medication Assistance Treatment programs and PDMPs with interstate sharing systems allowing prescribers to have access to patient prescription data. Other suggested approaches include: setting prescribing limits and guidelines for physicians, which would limit the dose and amounts of opioids; expanding access to treatment to those suffering addiction, including providing sufficient insurance coverage for inpatient treatment facilities; working to minimize the long wait for those seeking treatment in those facilities; and expanding access to the drug Naloxone, which “blocks the effects of opioids to reverse overdoses within minutes.” Continuing Medical Education for prescribers is a commonly recommended strategy that relates directly to the amount of prescription opioids on the market. Fully implementing this strategy will necessitate “a fundamental shift in the

34. Id. at 3–29.
35. Id. at 1–19.
37. See Medication-Assisted Treatment, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (last updated Feb. 7, 2018), https://www.samhsa.gov/medication-assisted-treatment (explaining this approach implements “the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a ‘whole-patient’ approach to the treatment of substance use disorders.”).
38. COMM’N ON COMBATING DRUG ADDICTION & THE OPIOID CRISIS, supra note 36, at 7.
nation’s approach to mandating pain-related education for all health professionals who provide care to individuals with pain. Prescribing guidelines may be able to improve provider prescribing behavior, but may be most effective when accompanied by education and other measures to facilitate implementation.\textsuperscript{40} The Food and Drug Administration (FDA) recommends employing mitigation strategies in an attempt to be proactive in combatting opioid use as well as creating a greater push for abuse-deterrent opioids, for example, pills that are more difficult to crush and be used recreationally.\textsuperscript{41}

Thirteen states have implemented limits on prescription opioid amounts in order to limit opioid use.\textsuperscript{42} Working to prevent opioid addiction from the start is another way to limit the number of prescribed opioids, as well as identifying and treating early cases of addiction and effectively treating those who are currently addicted.\textsuperscript{43} Some states require a physical examination prior to prescribing opioids, or at least an evaluation of the patient “that is deemed ‘appropriate’… instead of or in addition to the physical examination laws.”\textsuperscript{44} Opioid misuse strategies can be categorized into three stages: primary, secondary, and tertiary prevention.\textsuperscript{45} These intervention strategies address opioid use from initiation to prescription (i.e. prescriber education, manufacturer regulation), to screening for addiction (including urine testing and PDMPs), and finally to addressing addiction through rehabilitation.\textsuperscript{46}

\textbf{B. PDMPs}

Of the many suggestions and strategies, all states (including Missouri as of 2017) have chosen to implement PDMPs.\textsuperscript{47} PDMPs can be used not only to limit the number and dosage of opioids a patient receives, but they also help a prescriber or pharmacist identify any potential conflicts a patient may have with

\textsuperscript{40} NAT’L ACADS. OF SCIS., ENG’G, & MED., supra note 13, at S-10.

\textsuperscript{41} Dani Kass, 3 Takeaways from the FDA Head’s New Opioid Rx Standards, LEXIS LAW360 1–2 (July 12, 2017), https://advance.lexis.com/document/?pdmfid=1000516&curid=8901a68c-b09a-4612-b403-1c07b1d5a28a&pddocfullpath=%2Fshared%2Fdocument%2Flegalnews%2Furn%3AcontentItem%3A5P0S-N6B1-F22N-X290-00000-00&pdcontentcomponentid=122080&pdteaserkey=sr0&ecomp=kyfk&earg=sr0&kprid=0997b46d-12ac-4d45-bb68-45eb2aef646e.

\textsuperscript{42} Pryor, supra note 6.

\textsuperscript{43} Haffajee, supra note 31, at 1631–32.

\textsuperscript{44} Prescription Drug Physical Examination Requirements, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Jan. 29, 2015), https://www.cdc.gov/phlp/docs/pdpe-requirements.pdf.

\textsuperscript{45} Haffajee, supra note 31, at 1633–34.

\textsuperscript{46} Id.

existing medications.\textsuperscript{48} PDMPs are an achievable means of allowing prescribers to track prescription information for a patient, even though state laws differ in what information can be viewed and tracked.\textsuperscript{49} Goals of a PDMP include: improving patient treatment decisions; influencing prescribing practices; assisting in the identification of “doctor shoppers;” and serving as a tool for law enforcement.\textsuperscript{50} When a physician utilizes a PDMP, she can see if the patient has on-going opioid prescriptions, if the patient is receiving the same prescription from multiple doctors,\textsuperscript{51} and even the dose, supply, and prescriber of other prescriptions,\textsuperscript{52} allowing the physician to determine if the patient is an addict or abuser of prescription opioids. Studies suggest the mandatory use of PDMPs is best practice; unsurprisingly, PDMPs have been shown to be most effective in states that mandate their use.\textsuperscript{53} When use is not mandated, little more than half of physicians regularly utilize their state’s PDMP,\textsuperscript{54} undercutting the value a PDMP could have to prescribers and their state’s efforts to more closely monitor and limit the number of prescription opioids dispensed. To more effectively utilize PDMPs:

The U.S. Department of Health and Human Services, in concert with state organizations that administer prescription drug monitoring programs, should conduct or sponsor research on how data from these programs can best be leveraged for patient safety (e.g., data on drug–drug interactions), for surveillance of policy and other interventions focused on controlled substances (e.g., data on trends in opioid prescribing, effects of prescriber guidelines), for health service planning (e.g., data on discrepancies in dispensing of medications for treatment of opioid use disorder), and for use in clinical care (i.e., in clinical decision making and patient–provider communication).\textsuperscript{55}

The data found in a PDMP can have beneficial effects beyond merely tracking prescription history.

There are generally two goals when implementing a PDMP: public health and law enforcement. PDMPs that utilize public health as their primary goal

\textsuperscript{48} Austin Frakt, \emph{A Helpful Tool to Combat the Opioid Crisis}, \textsc{N.Y.\textsc{Times}} (Sept. 11, 2017), https://www.nytimes.com/2017/09/11/upshot/a-helpful-tool-to-combat-the-opioid-crisis.html.

\textsuperscript{49} NAT’L ACADS. OF SCI., ENG’G, & MED., supra note 13, at S-10.

\textsuperscript{50} Lainie Rutkow et al., \emph{Prescription Drug Monitoring Program Design and Function: A Qualitative Analysis}, \textsc{180 Drug & Alcohol Dependence} 395, 397 (2017) (explaining while a PDMP can be used as a tool for law enforcement, “providing data to health care providers was, in general, the primary purpose of the PDMP.”).

\textsuperscript{51} Frakt, supra note 48.

\textsuperscript{52} Haffajee, supra note 31, at 1634.


\textsuperscript{54} Weiner et al., supra note 53, at 1.

\textsuperscript{55} NAT’L ACADS. OF SCI., ENG’G, & MED., supra note 13, at S-11.
have a greater focus on lowering the amount of opioid-related deaths and access to treatment and education to those suffering opioid addiction.\textsuperscript{56} Public health should not be only on the minds of those initiating a PDMP; the FDA should also incorporate public health issues when making “regulatory decisions regarding opioids.”\textsuperscript{57} In the CDC’s suggested strategies for states to fight the abuse of opioids, the strategies suggested focus on evaluating programs that are currently in place, not punishing prescribers or patients with the involvement of law enforcement.\textsuperscript{58} Because the amount of opioid use is considered a public health concern, PDMPs should keep public health goals at the forefront of their implementation to address a more holistic approach to confronting opioid abuse.

PDMPs with law enforcement as their primary goal focus on the prescription abuse side of the opioid crisis.\textsuperscript{59} They do this by working to punish the prescribers and dispensers of opioids as well as the patients who abuse them.\textsuperscript{60} This focus on law enforcement creates tension among the medical community, leaving physicians feeling like there is someone “looking over their shoulders.”\textsuperscript{61} Physicians, working in fields that prescribe a higher than average amount of opioids, such as end-of-life and cancer, see law enforcement’s hand in their practice as a “nuisance.”\textsuperscript{62} Law enforcement PDMPs look for instances of overprescribing, or deviating from the standard of care, but this term does not fully recognize all situations in which a patient may misuse a prescription; opioid-seeking patients may be turning around and illegally selling their medication.\textsuperscript{63} In a state that does not mandate the use of the PDMP, physicians may choose not to utilize this tool for fear of retribution by law enforcement. Fear of punishment may deter some physicians, which may mean less prescription opioids, but this refusal may encourage patients to obtain opioids illegally. Patients who have legitimate need for opioids but are denied by physicians who fear law enforcement may turn to other illegal means of pain


\textsuperscript{57} NAT’L ACADS. OF SCIS., ENG’G, & MED., supra note 13, at 6–26.


\textsuperscript{59} Islam & McRae, supra note 56, at 3.

\textsuperscript{60} Id. at 5.


\textsuperscript{62} Islam & McRae, supra note 56, at 3.

\textsuperscript{63} Kelly K. Dineen & James M. DuBois, Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?, 42 AM. J. L. & MED. 7, 13 (2016).
The majority of people who are abusing opioids are getting them illegally.65 While most PDMPs allow the authorities to gain access to information stored on a PDMP,66 state law varies in the scope of the obtainable evidence,67 and even though law enforcement can obtain evidence from a PDMP, this does not mean that the goal of the PDMP is law enforcement. The two most common means by which an authorized recipient may receive data from PDMP are: (1) “probable cause, search warrant, subpoena, or other judicial process;” and (2) “pursuant to an active investigation or as part of official duties.”68 State medical licensing boards still have the right to punish physicians whose prescribing practices fall below the standard of care, without any interference or investigation conducted by law enforcement.69 This should be an efficient check on prescribing practices without the involvement of law enforcement.

With these dual goals, “states must balance the various means used to achieve these various purposes against the patients’ expectations of privacy” as well as “help states regulate controlled substances and prevent abuse of these substances by providing prescribers, dispensers, and law enforcement with the information necessary to identify individuals that may be diverting prescription drugs from legitimate channels to sell or use illicitly.”70 One of the criticisms of PDMPs is the fear that the information shared on these systems will constitute a breach of privacy for the patient by allowing a physician to gain access to that patient’s prescribing history, even when treating the patient only once. However, PDMPs that focus on law enforcement justify their use by balancing the need for patient privacy with the need for law enforcement to regulate opioid use.71 Different states have different requirements for law enforcement to gain access to the data. For example, Oregon requires “a search warrant or showing of probable cause,” while Pennsylvania requires “approval from the attorney general” for access.72 Additionally, “Maine, Nebraska, and Vermont are the only states currently that do not have a specific provision in their prescription monitoring program laws for access by law enforcement or judicial authorities.

64. Ostrom, supra note 61.
67. Id.
70. Unger, supra note 66, at 368.
71. Id.
72. Id.
However, Nebraska is the only state that specifically prohibits access by law enforcement.”

PDMPs that allow law enforcement to seek medical information in order to punish physicians and abusers must then be tasked with making medical decisions, including: “(1) the point at which a medical purpose becomes illegitimate; (2) the boundaries of usual practice; and (3) the extent to which crossing those boundaries warrants criminal liability.” Properly trained law enforcement would still lack the capabilities to make medical determinations during the course of treatment for a patient. This would mean that law enforcement would have the ability to say a patient does not need a certain number of pills or a certain dosage to treat the many ailments for which opioids are prescribed. When functioning in this way, the PDMP is essentially a tool that law enforcement uses to punish, not one that is used to address the underlying issues of addiction.

C. Missouri’s Struggle with Opioids

Missouri has not been immune to the opioid crisis, seeing the number of deaths rise due to opioid abuse and overdose. In 2016, over 900 Missourians died from overdosing on opioids. According to the Missouri DHSS, of those deaths, approximately 500 were from non-heroin opioids, while the remaining were attributed to heroin. Rural areas in Missouri are some of the hardest hit, with Howell County ranked thirtieth in opioid usage nationally. The addictive effects of opioids have been widely reported, with opioids generating feelings of euphoria and painlessness. The chance of addiction of prescription opioids is common; “about 35 percent of people prescribed a month’s supply of painkillers become hooked for at least a year.” Patients who are properly prescribed opioids may become addicted, but when patients are cut off from legal, prescription opioids, many turn to illegal opioids like heroin and black market fentanyl to continue to experience the euphoric effects of opioids and prevent withdrawals.
For years, Missouri had no clear direction on how to handle the increasing number of patients who abuse their legal opioid prescription or those abusing illegal opiates. Missouri Attorney General Josh Hawley attempted action by suing pharmaceutical companies claiming their “fraud and deception” led to the opioid crisis in Missouri, and Hawley is seeking damages and civil penalties for the alleged misrepresentation of the addictive effects of opioids.\footnote{Missouri Attorney General Sues 3 Drug Companies Over State’s Opioid Crisis, CBS NEWS (June 21, 2017), https://www.cbsnews.com/news/opioid-crisis-missouri-attorney-general-josh-hawley-sues-pharmaceutical-companies/.} Missouri joins other states in these actions, with Mississippi being the first state to bring suit in 2015.\footnote{Id.} While suing pharmaceutical companies for their role in the boom in prescription opioids may address the larger social issue of why opioid use became so popular, Missouri remained the only state without a PDMP for years. State legislature struggled to pass legislation implementing and funding a PDMP for years.\footnote{Morgan, supra note 9.} In 2012, legislation to create a PDMP reached the Senate floor but was filibustered by Senator Schaaf, a physician, citing patient privacy concerns.\footnote{Megan Thielking, Missouri is the Only State Not Monitoring Prescription Drug Use. Will It Finally Create a Database?, STAT NEWS (Mar. 7, 2017), https://www.statnews.com/2017/03/07/missouri-prescription-drug-database/.} Senator Schaaf and a small number of other senators have effectively prevented a PDMP bill from reaching the senate floor.\footnote{Id.} Schaaf has admitted willingness to implement a PDMP legislatively but has conditioned his support; the bill would need to require physician participation and hold them liable for overdoses if the system is not appropriately used.\footnote{Allison Pecorin, Missouri Senator Says He’ll No Longer Block Prescription Drug Monitoring Program, KAN. CITY STAR (Apr. 4, 2017), http://www.kansascity.com/news/politics-government/article142718669.html.} Senator Rehder, author of the bill, agreed to consider his amendments.\footnote{Id.}

When it appeared that Missouri could not successfully pass legislation to implement one of the most common suggestions for combatting the opioid crisis (and one which every other state implemented in some way), St. Louis County in Missouri took action. In the spring of 2017, St. Louis County instituted a PDMP that would operate first in the county but would eventually be opened to counties across the state.\footnote{St. Louis County Prescription Drug Monitoring Program, ST. LOUIS COUNTY, MO., http://www.stlouisco.com/HealthandWellness/PDMP (last visited June 17, 2018).} The St. Louis County PDMP monitors the dispensing of Schedule II-IV controlled substances and requires pharmacies to report the prescriptions within those categories.\footnote{Id.} The PDMP also requires pharmacies to

\footnotesize{\begin{itemize}
\item[83.] Id.
\item[84.] Morgan, supra note 9.
\item[85.] Megan Thielking, Missouri is the Only State Not Monitoring Prescription Drug Use. Will It Finally Create a Database?, STAT NEWS (Mar. 7, 2017), https://www.statnews.com/2017/03/07/missouri-prescription-drug-database/.
\item[86.] Id.
\item[88.] Id.
\item[90.] Id.
\end{itemize}}
report controlled prescriptions to their county public health department. While this began as a county program (as opposed to a statewide PDMP), St. Louis County offered any county in Missouri to join their efforts and become a part of this program; since its initial implementation, other counties, which account for fifty-eight percent of Missouri’s population, have joined. The St. Louis County PDMP was up and running in April of 2017. The goals of this program are based in public health:

1. Improve controlled substance prescribing by providing critical information regarding a patient’s controlled substance prescription history,
2. Inform clinical practice by identifying patients at high-risk who would benefit from early interventions, and
3. Reduce the number of people who misuse, abuse, or overdose while making sure patients have access to safe, effective treatment.

III. LAW ENFORCEMENT AND EXECUTIVE ORDER

Continued media coverage, criticism of Missouri for being the only state operating without a statewide PDMP, the failed attempts to once again to pass legislation to implement such a program, and the scrutiny of Missouri’s lack of action led Governor Greitens to address the continued rise of opioid-related deaths. On July 17, 2017, Governor Eric Greitens announced Executive Order 17-18, which directed the Missouri DHSS to develop and implement a PDMP. This order laid out three phases for this process. The first phase was to enter into a contract with pharmacy benefit management organizations to analyze the dispensing data. Phase Two requires dispensers statewide to submit the data to DHSS, which will then determine if there is a need for investigation. If so, they will work with law enforcement and licensing boards. The final phase is to work with private companies and government entities to purchase technology to monitor data. After Greitens announced the PDMP in July, Greitens’ s goal was to get the program implemented and running before the opioid crisis in Missouri worsened.

93. St. Louis County Prescription Drug Monitoring Program, supra note 89.
95. Id.
96. Id.
97. Id.
While proponents of a statewide PDMP praised the Governor for taking action to help end opioid-related deaths in Missouri, those with more cynicism criticized Greitens as merely attempting to appease constituents and his donors. The announcement of the Executive Order was made at Express Scripts’ office in St. Louis, indicating that Express Scripts was expected to receive the bid to begin Phase One and help implement the monitoring program, which they later did.99 Another criticism on the proposal was that it “focuse[d] on the prescribers and distributors of medications, such as doctors and pharmacists, who are already regulated by the state.”100 While the Missouri House Minority Leader Gail Beatty called the original announcement a “publicity stunt,” the status of the PDMP for Missouri was stalled for months before becoming operational in November 2017.101

Another cause for concern among critics was the order’s break from traditional PDMPs. According to the Executive Order, prescribers do not have access to a patient’s prescription information, which prevents them from making medical decisions in the moment based on a patient’s past prescription history.102 Without that information, a physician who writes a prescription for someone who may have another active opioid prescription may be punished simply because they were unable to access that information using a PDMP. The initial belief was that the program proposed by Governor Greitens would actually be weaker than the PDMP St. Louis County put in place months earlier.103

The language from the Executive Order makes it clear that the goal of Missouri’s PDMP is law enforcement as opposed to public health. Physicians and prescribers do not have access to the prescription history of a particular patient under this order,104 and there is no mention in the Executive Order about helping those addicted to opioids.105 While there has long been a national microscope on physicians’ prescribing practice of opioids, the Executive Order in Missouri seems to up the ante. Fear of criminal prosecution may lead physicians to avoid prescribing opioids at all, even in cases of legitimate need.106

The Executive Order directs the data to be sent to DHSS or a designee to analyze

99. Id.; Suntrup & Liss, supra note 11.
102. Mo. Exec. Order No. 17-18 (July 17, 2017); Hancock & Marso, supra note 100.
103. Hancock & Marso, supra note 100.
104. Id.
106. Dineen & DuBois, supra note 63, at 38.
and determine if there is an issue in prescribing history; in order to determine if there was actually a violation, the order calls for an investigation.\textsuperscript{107} However, if the data is going to DHSS and law enforcement, that information may not fully actualize the situation that took place before the clinician. Data only offers so much information, and as will be discussed later, DHSS already has access to data relating to practitioners who dispense opioids. As a law enforcement order that prevents physicians from access to the data, this program will not work to fight the crisis it was put in place to solve.

The Executive Order is ambiguous and vague on what would trigger an investigation into prescribing and dispensing practices. PDMPs in other states (and St. Louis County) do not include reports for opioids that are prescribed to patients suffering from cancer or receiving end-of-life treatment.\textsuperscript{108} Counties that feature older residents suffering from chronic pain may trigger higher reporting rates than a county with younger residents. Certain physicians’ practice areas may lend themselves to higher opioid prescribing rates than those practicing in other areas, such as pain management, surgery, and rehabilitation, as opposed to those practicing in pediatrics, dermatology, and pathology.\textsuperscript{109} The Executive Order is not clear what actions will be taken if dispenser data is not reported.

IV. DUPLICATION AND EXECUTIVE ORDER

While the Executive Order that Governor Greitens signed in July of 2017 was finally operational in November of 2017, the order as written remains problematic. If we take this order as written, the focus of the order is to punish physicians without a focus on utilizing the goals of public health to combat the opioid crisis. The information the PDMP seeks is available to law enforcement via other methods. This PDMP is not the most efficient means to combat the crisis and create a streamlined patient-care system.

The BNDD in the DHSS for Missouri requires all practitioners maintain strict record keeping regarding controlled substances. The guidelines they have for prescribers include specific criteria that must be met when dispensing controlled substances, including: (1) “[t]he prescriber must be properly registered;” (2) “[t]he patient must desire treatment for a legitimate illness or condition;” (3) “[a] practitioner must establish a legitimate need through assessment, utilizing pertinent technical diagnostic modalities [and] [t]here must be a legitimate practitioner/patient relationship;” and (4) “[t]here must be reasonable correlations between the drugs prescribed and the patient’s legitimate

\textsuperscript{107} Mo. Exec. Order No. 17-18 (July 17, 2017).
\textsuperscript{108} St. Louis County Prescription Drug Monitoring Program, supra note 89.
needs.” Before the practitioner writes a prescription, the controlled substances have been “tracked from the day they are made until they are dispensed to a patient.” When a physician determines there is need for prescription opioids, they must keep a log of “all controlled substances received, administered, dispensed, or otherwise disposed of” as well as a separate record of controlled substances documented in the patient’s chart, including the strength, quantities, and refills. Those “charts are open for inspection and copying” by BNDD and must be made available within three days if requested. Practitioners are to have the ability to review the record of controlled substances to determine which patients are receiving which drugs and how often.

Pharmacists in Missouri are also guided by strict rules when filling prescriptions for controlled substances. Any time a controlled substance moves from one person to another, there must be documentation demonstrating the changing of hands, and all records regarding controlled substances must be kept for at least two years per state and federal law. These records must be “readily retrievable” and turned over to BNDD for “inspection and copying” as necessary. A pharmacy is required to take inventory of controlled substances received into the facility and to keep a receipt of the drugs stocked, as well as maintain a record of all controlled substances that are filled. Information that is required when dispensing opioids includes: date of dispense, patient name, patient address, drug name, strength, dosage form, and quantity. Employees of pharmacies are also warned to be aware of “professional patients:” those who “patronize 3 or more pharmacies routinely.”

While prescribers and pharmacists have to keep stringent records regarding the dispensing of controlled substances (including opioids), the BNDD has also historically worked with DHSS to ensure controlled substances are being properly handled and dispensed. The DHSS “works with law enforcement and other agencies to minimize the abuse of controlled substances in the state.”

Of the activities in which BNDD participates, one mirrors the previously

111. Id. at 6.
112. Id. at 9–10.
113. Id. at 10.
114. Id. at 9.
115. BUREAU OF NARCOTICS & DANGEROUS DRUGS, MO. DEP’T OF HEALTH & SENIOR SERVS., CONTROLLED SUBSTANCE GUIDELINES FOR MISSOURI PHARMACIES 6 (May 11, 2016).
116. Id.
117. Id. at 6–7.
118. Id. at 7.
119. Id.
mentioned behavior that practitioners and pharmacists must undertake: DHSS must “maintain[] a registry, as required by state law, of the individuals and firms who prescribe, dispense or otherwise conduct activities which involve controlled substances.”\(^\text{121}\) Other activities include: conducting inspections of records held by those who dispense opioids; following up on complaints filed about potential mishandling of controlled substances; completing audits of those who handle opioids; and working “to correct or prevent unlawful practices, when detected, through education, or … administrative action against the registration of the firms or individuals involved.”\(^\text{122}\) Working with the primary goal of law enforcement, the information that BNDD requests is to be de-identified of individual patient information. When requesting information to investigate whether controlled substances are being misused, the specific information that they seek includes the prescriber, pharmacy, drug name, strength and quantity, and date the drug was dispensed.\(^\text{123}\)

The majority of Missouri also participates in a statewide HIE. Missouri Health Connection (MHC) is a system for participants across the state of Missouri to share EMRs. Currently, MHC has approximately 1,930 health systems and hospitals participating across the state.\(^\text{124}\) The sharing of EMRs allows a physician treating a patient visiting St. Louis to view the patient’s medical history and records from the patient’s primary care provider in Springfield. The sharing of this information can be vital, especially in determining which, if any, prescriptions the physician should write. While the purpose of the MHC is to create a system for efficient information sharing and better patient outcomes, the information from this system is shared among providers.\(^\text{125}\)

While by law practitioners and pharmacists must keep records of controlled substances that are prescribed and dispensed, MHC’s President Angie Bass believes that for law enforcement to be involved effectively, “data in the right place is key.”\(^\text{126}\) MHC has implemented tools in order to help streamline the process of checking patient information; when a patient with an EMR in the system has a recent prescription for opioids, the current treating physician will be alerted within the system.\(^\text{127}\) The purpose of these alerts is to achieve “better

\(^{121}\) Id.

\(^{122}\) Id.

\(^{123}\) Id.


\(^{126}\) Telephone Interview with Angie Bass, President & Chief Exec. Officer, Mo. Health Connection (Nov. 15, 2017).

\(^{127}\) Id.
care coordination and clinical decision support.” Alerts within the system would be generated by prescription history and are meant to help the current physician from prescribing a duplicate prescription or a prescription that might react negatively with a different prescription of record. MHC plans to add more tools in 2018 to help those with access to EMRs become even more efficient in treating patients and identifying potential drug seekers. The MHC HIE is similar to a PDMP because providers can see the prescription history of the patient, but this information is not turned over to law enforcement without a subpoena or as required by law. Even though this is not a traditional PDMP, it has the capability of operating like one if MHC has mandatory statewide participation; if implemented in this way, the HIE would not be a law enforcement-centered PDMP like the one established by Executive Order in Missouri.

Clearly, there are already guidelines in place for physicians and pharmacists to follow regarding the prescription and dispensing of controlled substances, including opioids. These guidelines are meant to track potentially dangerous drugs that have high chances of misuse and addiction. The BNDD, under the Missouri DHSS, also works with these entities to ensure that each and every pill is accounted for, as well as investigate and audit diversions, or losses, of controlled substances. The DHSS maintains their own records of those who handle or dispense controlled substances but also can request information regarding a controlled substance from both prescribers and pharmacists if there is an irregularity or sign of potential abuse, either through theft, loss, or overprescribing. MHC works to ensure that all EMRs contain necessary and vital information to help physicians to make the appropriate choice when prescribing.

With all this information currently available, what value will Missouri’s new PDMP add? While the Executive Order may attempt to streamline data on opioid prescriptions, that information is already available. Contracting with a pharmacy benefit management organization to analyze the data and then requiring dispensers to submit that data to DHSS to determine if there is a need for investigation is repetitive of the role that BNDD (working within DHSS) already plays in investigations and audits of facilities with controlled substances. While Phase Three of the Executive Order, to purchase technology to monitor data, could help the entire state, MHC, operating across the state, allows physicians to monitor health information for a patient in front of them. While this is a local, specific form of monitoring, it is keeping the judgment in the hands of the medical professionals as opposed to law enforcement.

129. Telephone Interview with Angie Bass, supra note 126.
130. Request for Prescribing and Dispensing Information, supra note 120.
A. Nebraska as a Model for Missouri

For Missouri to have the opportunity to truly be successful in minimizing opioid-related deaths and cutting down on overprescribing and abusers, the state legislature should look to the state of Nebraska and its PDMP as a possible model. Nebraska, which was the first state to mandate use of its PDMP, has created a partnership that combines its HIE with the PDMP, allowing the two to exist together. Nebraskans believe that this combination allows the state “to close the loop with all prescriptions.” Called the NeHII, the purpose is to “aid providers in making treatment decisions with a more robust medical history of their patient thus aiding and improving the quality and safety of patient care.”

The system utilizes a program called DrFirst Medication History that allows prescribers, for “purposes of preventing adverse drug events and prescription drug monitoring,” to submit a request to “serve up queried medication history to the requestor.” DrFirst then takes the prescription data generated during the visit and submits that information to the PDMP, which will allow pharmacists and other dispensers to access that information at the time of treatment.

The transmission of electronic data allows the pharmacists to have access not only to current prescriptions waiting to be filled, but also to the prescription history, which may help identify patients who are abusing the system and seeking opioids with the purpose of abusing them. This system enables health care providers to “monitor the care and treatment” of the patients they are treating and confirm that the prescriptions “are used for medically appropriate purposes.” Proponents recognize that this system has the potential to help curb the state’s opioid-related problems in a real and meaningful way by allowing physicians and pharmacists to have access to the information.

The program not only allows access to patient information in the course of treatment, but also alerts practitioners when “patients access several dispensed opioid prescriptions and indicate instances in which overlapping prescriptions

133. What is the Prescription Drug Monitoring Program?, supra note 131.
135. Goedert, supra note 132.
137. What is the Prescription Drug Monitoring Program?, supra note 131.
138. Monica, supra note 136.
of opioid medication are being dispensed to the same patient.”139 When identifying some of these markers that indicate abuse, physicians and pharmacists can work to intervene with the patient by reducing the dose amount or substituting a different treatment plan.140 In this way, it is clear that the focus of the combined HIE and PDMP is to address the public health concerns related to opioid abuse, not merely punish abusers and prescribers. While this new program was seen as an added layer in an already complicated industry, there was little resistance to the program, and now Nebraska is experiencing a “100 percent compliance rate for prescription reporting.”141 By combining the PDMP with the HIE, Nebraska has created a public health-centered program working to identify and address issues prior to administering opioids.

If Missouri still feels, either from political pressure or public relations, that they need its PDMP to combat the use of opioids in the state, then Missouri should adopt a model similar to Nebraska’s by integrating the PDMP into the HIE system already in place. PDMPs can be an effective tool in identifying and addressing those who are abusing opioids. For the PDMP to be most effective, it must be centered on addressing the public health issue of opioid addiction as opposed to focusing on punishment. Nebraska has incorporated its PDMP with a focus on public health with its EMR system. By doing so, they have closed the gap of duplicate information, allowing physicians and pharmacists to see prescription history of a patient to determine not only if they are merely an opioid seeker, but also offer efficient or alternative treatment. If this model is adopted by Missouri, this could allow physicians to deliver patient-centered care and to make the best decisions about a patient’s course of treatment in the moment based on the information found on the HIE. Both pharmacists and physicians would still be required to track the number of controlled substances that are dispensed and remain subject to inspection by the BNDD allowing for a continued check by law enforcement on opioids.

V. CONCLUSION

The United States has been struggling to address the growing number of opioid-related deaths and overdoses for the past two decades. Every state has responded by implementing a PDMP in order to track opioid prescriptions, with Missouri joining the other forty-nine in 2017. These programs tend to be designed with one of two goals: public health and law enforcement. In order to most effectively end the cycle of addiction to opioids, these programs need a public health-centered approach to not only prevent abusers from obtaining multiple prescriptions for opioids, but to also offer intervention strategies to help those who are addicted.

139. Id.
140. See id.
141. Goedert, supra note 132.
St. Louis County, Missouri attempted to address the issues occurring in the community by starting a county-operated PDMP. Once this program began in 2017, many other counties across the state joined the PDMP to have access to their resources. Governor Eric Greitens also decided the state needed to do more and signed the Executive Order directing the DHSS to implement a statewide PDMP. This program, as written, aims to punish prescribers and abusers. More importantly, the law already requires all prescribers and dispensers of controlled substances to record the information that the PDMP seeks, and that data is available to the BNDD upon request. The BNDD also already has the power, from the DHSS, to investigate and audit those who deal with controlled substances.

This PDMP will likely prove to be an additional drain on resources (the contract with the pharmacy benefit organization and the purchase of technology to monitor the data), requiring additional funds to monitor information that is already being recorded. If Missouri chooses to continue with their statewide PDMP, the program should be integrated with the HIE that Missouri already has in place. Like Nebraska, this would allow physicians to get access to prescription history (something not currently allowed under Missouri’s PDMP) and treat patients while consulting their EMR to look for any problematic drug combinations or overprescribing of opioids. In this way, Missouri will be taking a more holistic approach to combatting opioid-related deaths and overdoses while continuing to provide efficient, patient-centered care.

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