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Evaluating the policy response to curb the opioid prescribing behaviour of physicians in the United States

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Abstract

Purpose – In 2017, the opioid epidemic was declared a public health emergency in the United States. The federal and state governments are still struggling to contain the crisis through various legislations and to stem the tide of overdoses and deaths. This paper looks specifically at the issue of high prescriptions of opioids disbursed to patients by physicians.

Design/methodology/approach – This paper evaluates this evolving policy issue through a critical review and synthesis of academic literature, government policy documents (at states and national levels) and articles in the popular press.

Findings – Over-prescription is a legal problem because it inevitably leads to diversion of these substances for non-medical usage. The Prescription Drug Monitoring Program (PDMP) laws have been passed by all 50 states and the main policy responses are covered. However, there are hindrances to their effectiveness, which have to be addressed. Two state level policy alternatives are discussed as potential solutions — PDMP mandates and Pain Management Clinic Laws (PMCLs). After a comparative evaluation, it is recommended that all states should pass the mandatory PDMP review and usage laws urgently.

Originality/value – This is the first detailed policy evaluation on the specific and time-sensitive aspect of physician over-prescribing, within the larger opioid abuse problem. Moreover, critique on the public health leadership issue is raised.

Keywords Prescription opioid, Overdose, USA, Physician behaviour, Health policy, Public health leadership

Paper type Research paper

Background

The problem statement is that the high prevalence of prescription opioid misuse is the driving factor behind the ongoing opioid crisis in the United States. Part of the impetus in the indiscriminate prescribing of opioids came from an endorsement by the American Pain Society (APS) which claimed in 1995 that "Pain is the fifth vital sign" and must therefore be aggressively treated with a wider use of these drugs (Kolodny *et al.*, 2015). Invariably, the prescription drugs act as a gateway to other illicit opioids and frequently, diversion of legally procured opioids occurs for non-medical and recreational uses. Overall, opioid abuse translates into overdose and death. The policy objective that the author seeks to pursue in this paper is to appraise options to regulate and reduce the prescriptions dispensed for opioids to the patients. The intended social goal to be achieved from solving this problem is that the age-adjusted death rate from these prescriptions will decrease across all states and counties, loss in human productivity will lessen and overall and the nation's healthcare costs for opioid misuse disorder treatment will decrease.

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Extent and magnitude of the problem of abusing prescription opioids

The overall national opioid dispensing rate declined between 2012 to 2020, and in 2020, it had fallen to the lowest in 15 years, at 43.3 prescriptions per 100 persons. However, there are large variations in prescribing behaviours at the state and county levels. For instance, health care providers in Alabama typically write three times as many of these prescriptions per person as in the lowest prescribing state, Hawaii. In 3.6 percent of U.S. counties, enough opioid prescriptions were provided for every person to have one. Counties or local government jurisdictions with higher prescribing generally have some characteristics in common such as: they are smaller cities or larger towns, have a higher percentage of white residents, have a higher density of dentists and primary care physicians per capita, more people that are uninsured or unemployed and more people with diabetes, arthritis, or a disability.

Prescription opioid medications include three types: natural (morphine, codeine), semi-synthetic (hydrocodone, hydromorphone, oxycodone, and buprenorphine) and fully synthetic (fentanyl, methadone, and meperidine) among others. Because they impact the brain areas controlling emotions, opioid medications can induce feelings of euphoria and a person may quickly become addicted by taking them for long periods or at high doses. This in turn increases the chances of opioid use disorder (addiction), overdose, and death. In 2020 alone, 68,630 overdose deaths occurred from opioids (74.8 percent of all drug overdose deaths). 40 percent of these were from prescription-based ones such as oxycodone and methadone, among others. The use of prescription opioids, commonly measured by morphine milligram equivalents (MMEs) dispensed, increased from 27 billion MMEs in 1992 to 246 billion MMEs in 2011 and has decreased since then. An estimated 100 billion MMEs were dispensed in 2020. The declines in opioid prescribing, measured in MMEs per capita, were largest in states that had previously had the highest rates of opioid prescribing. From 2018 to 2019, every state experienced a decline in MMEs per capita. Even with the decline in the volume of opioid prescriptions dispensed, the amount of prescription opioids dispensed per million people per day in the United States is approximately four times the median for member countries of the Organisation for Economic Co-operation and Development. Opioid use disorder (OUD) or overdose has cost the nation almost 1 trillion USD by some estimates, in terms of human lives, loss in productivity, and in resources expended for treatments.

Values, perspectives, and stakeholders that have shaped public policy debate on this issue

In 2015, two economists from Princeton University in the United States, Anne Case and Angus Deaton, first pointed out that working-age white men and women without four-year college degrees were dying at unprecedented rates, of suicide, drug overdose, and alcohol poisoning, in what they dubbed as: "deaths of despair" (Case and Deaton, 2015). It was attributed to three reasons. First, misleadingly aggressive marketing tactics of pharmaceutical companies such as Purdue, the failure of the Food and Drug Administration in stopping them (Purdue) and eventually, some officers of the Drug Enforcement Administration and State attorney generals took up the gauntlet against them. The second reason is said to be the deindustrialization of much of rural and urban Appalachian region leading to mass joblessness, demoralization, and loss of employer-sponsored healthcare. These were the states of Arkansas, Kentucky, Mississippi and West Virginia, among others. In this second case, much of the blame is to be shared between employers and the healthcare sector. Employers found it cheaper to close factories or outsource to contractors rather than pay exorbitant health benefits. The third reason is said to be occupationally induced pain and injuries in the said population with limited financial recourse to treatment. Outcry from various non-profit and academic circles as well as the media, later caused the government to start taking the issue seriously. The focus was placed on addiction-treatment centers and suicide-prevention programs as these were the options

with least political implications. However, the rates of suicide and addiction remain very high. There are parallels here with the AIDs crisis of the nineties (Parker *et al.*, 2019). At the time, it was assumed that availability of HIV medicine would suffice, even without socio-behavioral interventions, this was shown to be a fallacy. Among opioid-addicted patients, non-adherence to treatment schedules is widespread.

Legislative history of the opioid crisis

In 2017, President Donald Trump declared the opioid crisis as a national public health emergency. Between 2016 and 2018, at least three federal laws were passed to address the crisis by lowering the demand for and supply of opioids and with this, public funds started getting appropriated towards the issue. These were: the Comprehensive Addiction and Recovery Act (CARA) of 2016; the SUPPORT for Patients and Communities Act (with SUPPORT standing for: 'Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment'); and the 21st Century Cures Act. CARA specifically, allocated $50 million in grants towards improving PDMPs (Prescription Drug Monitoring Programs). Total federal funding for federal agencies such as the Department of Health and Human Services (HHS), aimed specifically at this issue, tripled between 2017 and 2020.

Healthcare laws are typically formulated in a cooperative mode at both the federal and state levels. The federal government often publishes advisory materials on key health topics and no direct intervention or allocation of funds will be made unless it is a matter of a public health emergency. Overall, policy responses to the opioid crisis may be categorised into six kinds of interventions (Parker *et al.*, 2018), namely: (1) Regulating prescribing behaviour (PDMPs, PMCLs and prescriber training); (2) Public education and drug take-back programs; (3) Responding to overdoses (with Naloxone access and Good Samaritan laws); (4) Expanding access to addiction treatment (through Medicaid coverage, non-medication treatment and syringe services; (5) Criminal penalties for traffickers and drug courts for users; and (6) Civil litigation against pharmaceutical companies and disciplinary action against physicians. By far though, the most important legislative response to the stated problem has been to set up the Prescription Drug Monitoring Program (PDMP) and curb over-prescribing. In the next section, the author discusses the modalities of this policy and the current state of implementation by states and the emerging evidence around its efficacy.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are state-based electronic databases that capture prescriptions for controlled substances, including prescription opioids. The database is interconnected among payers, providers, pharmacies and law enforcement agencies. Currently, all 50 states have enacted a corresponding PDMP legislation and established a PDMP at the state level. State and federal laws and regulations allow PDMPs the authority to operate, detail the authorized users, and establish criteria for the querying and use of the PDMP data. The federal government has a centre, PDMP Training and Technical Assistance Center (TTAC), based at the Institute for Intergovernmental Research, which maintains a website that tracks developments across all PDMP infrastructure — https://www.pdmpassist.org/State. This website is funded through a grant from the Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice. There is a Model Act 2020 provided by the federal government with the aim of giving guidance to state administrators when considering developing state laws. The TTAC also provides comprehensive quarterly and annual summaries of proposed and enacted laws and regulations affecting PDMPs. Doctors are expected to check the PDMP before prescribing opioids and pharmacies are expected to check before dispensing against a prescription; however, usage and review by

physicians and pharmacies are not at the desired levels hindering the effectiveness of the program.

Moreover, functionalities, data availability, interconnections with external databases such as law enforcement database and permissions for data access vary widely, indicating that implementation has been uneven and inconsistent at the states' level. For example, only 7 states currently have inter-state data sharing agreements with 41 to 50 partner states. Only 17 states have their databases linked to alternate data sources such as that of fatality from overdoses related data. Interconnection with other state/federal databases helps in data validation and better public health management. In all, 51 jurisdictions, with the exception of Kansas and South Dakota, mandate PDMP use by prescribers but only 23 jurisdictions mandate it for dispensers.

Policy alternatives

A 2021 report to the US Congress on states' challenges in Prescription Drug Monitoring Program (PDMP) implementation by the Centers for Medicare and Medicaid Services (CMS), outlined the current inadequacies of state level implementation. To effectively bridge this gap, an ex-ante assessment is conducted for two proposed policy alternatives as follows: (1) Mandatory PDMP review and use for prescribing and dispensing, and (2) Pain clinic laws. Note that both need to be passed and enacted at the individual state level.

Policy alternative 1: Mandatory PDMP review and use for prescribing and dispensing

Policy description. This policy alternative aims to close the current loopholes in the PDMP statutes of different states so that this system can seamlessly operate and help law-enforcement swiftly identify and punish the violators. It requires that states pass legislation to mandate not just enrolment, but also usage and review of the database by prescribing doctors and dispensing pharmacies before a prescription is released. There should be no restriction in data access for health care providers. States should pass additional laws such as for sending unsolicited reports to providers, licensing boards, regulatory and law enforcement agencies, as well as public and private insurers and pharmacy benefit managers. Data updates should be real-time and prompted by pharmacies and physician offices. States, third-party intermediaries, and interstate data sharing hubs should delineate the boundaries of legal rules that will facilitate the exchange of PDMP data with stakeholders in the PDMP network. States should ensure that all PDMP statutes address the privacy and security concerns of patients.

Legislative history. In 1972, the state of New York passed its Controlled Substance Act, also known as the Rockefeller Laws. It required the establishment of a PDMP, the legality of which was immediately brought under challenge. The final judgement in this matter was passed by the Supreme Court (Supreme Court of United States, 1977), which unequivocally stated that the PDMP was not unconstitutional, and that collection of this information did not violate patient confidentiality. This law paved the way for subsequent states passing PDMP laws, namely Virginia, in 2002, with others following suit. The issue that still persists however is that most states have not mandated the usage of the PDMP, despite this protection provided by the judiciary. One reason may be that political lobbies and legislators may have prevented this.

Evidence and operational feasibility. Buchmueller and Carey (2018) investigated the effects of state PDMPs on Medicare claims. The authors find that a PDMP that has a mandatory review clause attached to it, significantly reduces doctor shopping behaviour. Doctor shopping is a behaviour in which a patient seeks out multiple medical providers to gain illicit access to prescription medicines (Sansone and Sansone, 2012). In Kentucky, there is robust

evidence of PDMP mandates reducing prescribing rate for the patient sub-population with the highest past incidence of OUD mortality, i.e., ages 25-54 (Gupta *et al.*, 2022). The trade-offs in this solution are mostly in respect of patient privacy. The expansive surveillance and data sharing that we propose can directly clash with HIPAA rules. These create multiple complications for privacy officers in various state departments, hospitals and pharmacies that are stakeholders in the PDMP.

Political feasibility. Private hospitals, doctor practices and pharmacies may be unwilling to share details about their patients' and treatments. This law poses several adverse potential circumstances to the current business model of 'over-treatment' that the healthcare industry engages in. I certainly also foresee that pharmaceutical companies may not be very enthused about this transparency requirement in respect of their sales. This is because, in the future, the PDMP may have far-reaching consequences not just for controlled substances, but other drugs as well. Consequently, it is possible that private sector lobbies may become active against these statutes.

Challenges in implementation. Some of the implementation challenges with respect to this policy alternative are germane to the technical design of the PDMP system itself. The first challenge is that in a situation where patients can travel to other states for filling prescriptions, it is not useful if the state PDMP does not have data sharing agreements with other states (PDMP Training and Technical Assistance Center, 2021). The second challenge is with respect to data inter-operability standards; it is important that the PDMP be integrated with hospital electronic health record (EHR) systems so that doctors may easily use it (Department of Health and Human Services, 2013). Both of these aspects have faced resistance from the industry, providers or other parties in light of current patient privacy rules.

Policy alternative 2: Pain clinic laws

Policy description. Pain Management Clinic Laws (PMCLs) are state policies designed to regulate practices that primarily treat chronic pain and to target high-volume suppliers of prescription pain medication (Chisom, 2020). Based on the most current data available from the PDAPS (Prescription Drug Abuse Policy System), a policy surveillance centre sponsored the US National Institute on Drug Abuse (NIDA), there are only 12 states that have passed some form of these laws (PDAPS 2018). Some key features in these laws pertain to mandatory checking of the PDMP, physician ownership requirements of the practice, drug testing requirements on patients and inspections of the clinics by government officials. By imposing stringent requirements on opioid disbursement through PCMLs, states can keep an eye on those clinics designated as 'high-risk, that disproportionately account for high-volume prescriptions. There are some associated laws that interface with pain clinic laws; 38 states have put in place some sort of limits on days' supply of opioid that can be prescribed to patients.

Legislative history. Florida was the first state to pass laws regulating 'pill mills' in 2010 and 2011. These clinics were associated with 81 percent of all substance use disorder related deaths in the state in 2010. A physician prescribing opioid could make thousands of dollars in a day, often in cash, and owners and physicians could afford expensive defense attorneys. Analysis of extensive geo-coded data from police departments in Florida consistently showed that new and closed Pain Management Clinics (PMCs) and community pharmacies were clustered along violent crime hotspots (Gau *et al.*, 2017). Laws allowing law enforcement agencies to seize assets and a collaborative approach with a prosecutor involved from the beginning of an investigation were some things that were put into practice. The implementation of these laws resulted in the closure of nearly 250 clinics in Florida over the course of the next 3 years (Johnson *et al.*, 2014). Evidently, the implementation had support

from both parties, including the justice department and the law enforcement agencies. However, there has been no parallel legislation at the federal level. The CDC recently published high-level guidelines for regulating PMCs (Centers for Disease Control and Prevention, 2016) along with detailed guidelines for physicians to treat pain with minimal use of opioids. Laws regulating dosage have been more extensively adopted by states that have shied away from directly taking action against pain clinics.

Evidence and operational feasibility. Chisom (2020) studied data from 12 states with PCMLs as of 2018, over four years following the implementation of PMCLs. He found that PMCLs typically reduce the availability of these medicines by 13 percent, and decreases admissions to specialty treatments for overdoses by 27 percent. Likewise, Rutkow *et al.* (2015) put forth that the simultaneous implementation of pill mill laws and PDMPs had a statistically significant effect on high-risk providers compared to low-risk providers. It can be inferred that the stakeholders most likely to benefit from PMCLs are the law enforcement agencies. States where there is a strong correlation between drug abuse and crime may be benefitted by these laws. There are also few trade-offs. The first trade-off is that genuine patients with pain and patients with cancer would have to face hardship in procuring the required medicines. A second trade-off is that the quantity of opioids distributed in bordering states tend to markedly increase. Third, some researchers also found evidence of increase in overdose deaths from heroin, indicating potential spill-overs to illegal opioids.

Political feasibility. Various government agencies have taken appropriate steps that can bolster the regulation of pain clinics. For example, the Centers for Medicare and Medicaid Services (CMS) removed pain management questions from the HCAHPS survey (Hospital Consumer Assessment of Healthcare Providers and Systems), signifying the shift in medical thought that pain management, especially in the case of non-cancer pain, is not a goal in itself. Subsequently, the Centers for Disease Control and Prevention (CDC) have published a set of guidelines for prescribing opioids for chronic pain conditions (Dowell *et al.*, 2022). This is relevant and applicable to pain clinics. The Federation of State Medical Boards, which is a professional organization maintains a consolidated tracker of all laws and guidelines passed by each state in reference to the management of chronic pain. It may be said that support from the non-profit and government sector is high for these laws. I believe that in the current political atmosphere, there is strong likelihood that these laws will get passed in other states if introduced as legislation.

Challenges in implementation. One recent court judgement raises some challenge to prosecuting under the PMCLs (Lopez, 2022). The judges sided with doctors arguing that prosecution must strive to better prove 'intent' to harm patients or diverting medicines to non-medical usage by prescribing excess opioids. This implies that the law is currently weakly designed and may need more amendments and details to be useful in regulating PMCs. Further, enforcement requires substantial manpower and fund commitments in conducting the investigations (Ramirez, 2011).

Policy recommendation and conclusion

The author recommends that all of the states that have not yet mandated PDMP review urgently pass the required legislation and implement it. Policy alternative 1 is more critical and sensitive to time. Both laws are politically contentious because of their far-reaching repercussions. With respect to the pill mill law (policy alternative 2), even though Florida is a classic case study about its usefulness, more work will be needed to make the law useful for prosecution in other states. Besides, all PMCLs necessarily require usage of PDMPs if they have to be effective. As such, policy alternative 1 should be of higher priority for states.

Three suggestions are further proposed in making the PDMP program more effective to curb the erratic prescribing behaviour. First, the PDMP vision at state level should be made

after consulting best practices and incorporating maximum functionality in its information technology infrastructure. See Colorado's vision document for a model PDMP network structure (Office of e-Health Innovation, 2020). The second suggestion is that Inter-state data sharing agreements should be in place with all states, that is the state PDMP systems should be interlinked as comprehensively as possible at the federal level. Third, the Overdose Fatality Reviews (OFRs) database should be interlinked with the PDMP databases. Currently the PDMP systems are not integrated with OFRs; with this functionality it would be possible to directly link deaths to the prescription providers with criminal liability. This study has important implications for public health leadership (Page, 2016). Based on how the policy prescriptions fare in the United States, other nations may also emulate these policies for solving their opioid related problems in the future.

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