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Understanding the Regulatory Landscape to Prevent Opioid-Related Harm in the United States

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Abstract

In response to the opioid overdose crisis, certain laws, policies, regulations, and guidelines have been passed or issued at the federal, state, and local levels with the intention of mitigating the harms of opioid misuse and opioid use disorder. Although numerous studies have examined the effect of specific types of opioid-related laws, little attention has been paid to the complexity of the legal landscape and the implications of that complexity for the crisis. Disentangling the legal landscape is critical to better understand the differential impact that federal, state, and local decisions can have on opioid-related harms. This paper provides a baseline understanding of how these policy tools function and is aimed toward public health professionals, policy analysts, and everyone who is evaluating the public response to the opioid overdose crisis.

Introduction

The current opioid overdose epidemic began in the late 1990s and is characterized by three distinct and compounding waves, each defined by the type of opioid involved in the overdose crisis.[1] The first wave primarily involved prescription opioids, the second wave was largely fueled by heroin, and the third wave emerged from a surge in the popularity and availability of synthetic opioids, such as fentanyl and fentanyl analogs.[1] The Centers for Disease Control and Prevention (CDC) provisional data estimates that, in the 12-month period ending in December 2023, more than 107,000 individuals died from a drug overdose with more than 80,000 of those deaths involving opioids, although both overall and opioid-related overdose deaths are reportedly lower than 2022 counts.[2]

As the overdose crisis has devastated communities around the country, federal, state, and local governments have responded by implementing laws and policies designed to help (1) *prevent* opioid-related harm through measures such as restricting initial opioid prescriptions (generally to between 4 to 14 days' worth of medication at what policymakers consider the "lowest effective dose"); (2) *intervene* at the moment of an opioid-related overdose; and (3) *treat* opioid use disorder. Altogether, hundreds of federal, state, and local laws and policies have been put into place, indicating that lawmakers recognize the importance of law and policy in helping to address and reduce opioid-related harms. The content and scope of these laws and policies range widely,[3] from states designating a certain amount of funding for opioid treatment programs (OTPs)[4] to removing barriers to buprenorphine prescription through telehealth.[5] Furthermore, responsibility for enforcement of these laws and policies spans across federal and state entities, including formal legal systems, state medical boards, state pharmacy boards, and other local agencies. The resulting penalties for violations, assuming such laws and policies are enforced, also take many forms, including but not limited to loss of license and/or employment; loss of certain prescribing privileges; fines; and incarceration.[6,7]

Although this multifaceted, multilevel government response to the opioid overdose crisis is encouraging, studying the impact of these laws and policies is not straightforward. More specifically, while published studies have asked a series of questions about the effects of a range of laws and policies, given the large volume of various policies across different jurisdictions, it can be difficult to assess which laws and policies effectively prevent and reduce opioid-related harm. As a result, understanding the intricacies of laws, regulations, and policies is important to practitioners, researchers, and the public. Hundreds of millions of dollars are being spent by federal and state governments to research the effects of policies and interventions at the national, state, and local levels. One such program is the NIH HEALing Communities Study, which successfully engaged communities to select and implement thousands of evidence-based strategies over the course of the intervention, with nearly 100 publications displaying results from across the substance use spectrum. Additionally, some of the research products include mathematical simulation models that evaluate the effects of potential future policies and interventions.[8–11] There is, however, a need to continue to bridge the gap between policy recommendations and understanding who is responsible for policy implementation and enforcement. This paper provides a baseline understanding of what these policy mechanisms are and how they function. Although this paper does address general opioid-related policies and laws, there is a particular focus on prescription opioid policies and laws.

What's in a Name? Laws, Regulations, Policies, and Guidelines

Multiple terms are used to refer to different types of policy-related requirements, which can make it challenging to understand and measure impact. For example, in scientific literature and everyday parlance, the term "policy" may be used to refer to everything from an act passed by Congress to a decision to maintain a tobacco-free campus. However, *law*, *regulation*, *policy*, and *guideline or recommendation* are not identical terms and should not be used

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interchangeably. Rather, they have unique meanings that directly affect the degree of enforceability and scope of a requirement or restriction (see Table 1).

A law is drafted and put into place by a policymaker who is part of the legislative or executive branch of a federal, state, or local government. If a law is drafted and put into place by an elected legislative body (e.g., Congress, state legislature, or a local board of county commissioners or a city council), this type of law is referred to as *legislation* and results in either a *statute* (if passed by Congress or state legislature) or an *ordinance* (if passed by a local legislative body). Importantly, it is the legislative branch of the government that determines areas in which a particular federal, state, or local agency may govern.

A *law* written by a federal, state, or local agency is called a *regulation* or a *rule*. A regulation is therefore a type of law. All regulations are laws, but not all laws are regulations (e.g., legislation). Rules and regulations may be much longer and more detailed than the companion legislation. For example, a state statute may authorize the operation of OTPs within a state. However, it is the oversight agency tasked with licensing the programs and the providers who work at these programs who draft and adopt a rule or regulation that governs the specific operation of the facility. This may include determining treatment eligibility at an OTP, identifying detoxification protocols, authorizing licensed providers to work at these facilities, and writing discharge procedures. Regulations have wide-ranging implications, such as the Drug Enforcement Administration (DEA) requirement that a health professional have a DEA license to prescribe controlled substances.[12] This regulation aligns with legislation in the Controlled Substances Act, which governs substances like opioids with the potential to be abused.

Policy is a broad term that is widely used within the public health and medical community to refer to a variety of actions. It is a written statement designed to encourage, restrict, or shape certain behaviors or actions. A policy can refer to either a codified law, such as a statute or a regulation, or a "small p" policy. A *small p policy* is a protocol or procedure that may require, restrict, or encourage something. One distinction between a law and a small p policy is the type and number of people to which they apply. A small p policy generally applies to a smaller number of people and only within a specific setting.

A *guideline or recommendation* is like a law in that it may apply to many people but is distinct from a law in that it is often not enforceable. For example, the federal CDC 2016 guideline on prescribing opioids to treat chronic pain was designed to inform medical providers around the country rather than in just one state.[13] Those guidelines were then updated in 2022 to provide additional evidence, clarifications to 2016 guidance, and further recommendations. However, unlike a law, guidelines are voluntary.

These policy mechanisms are part of the legal landscape shaping the prevention, intervention, and treatment of opioid-related harm. The most ideal type of mechanism depends on several things, such as (1) the intended outcome; (2) the desire for uniform, streamlined actions; and (3) the ability to monitor and enforce noncompliance. Whether a particular legal or policy action is a law, small p policy, or guideline matters in terms of *enforceability and scope*. First, a guideline may not be enforceable: there may not be an authority to contact if someone is in violation and there may not be penalties to levy against offending individuals. By contrast, if something is prohibited by an enforceable law or policy, the designated enforcement agency can apply civil, criminal, or disciplinary penalties listed in the law against the offending party. For example, Purdue Pharma, once a major supplier of opioid pain medicines, was later subject to criminal and civil lawsuits for its role in contributing to hundreds of thousands of fatal opioid overdoses.[14] These lawsuits resulted in a declaration of bankruptcy in 2019.

Laws and policies designed to improve and promote desirable public health outcomes can be interventional, infrastructural, or incidental in nature.[15] Federal laws that sort prescription opioid drugs into designated schedules according to their potency and risk of misuse are arguably infrastructural. Schedules may be reevaluated, such as the reclassification of hydrocodone from Schedule III to Schedule II, which resulted in stricter controls due to concerns about abuse and addiction. The federal Controlled Substances Act and other federal

Table 1. Overview of distinctions between laws, statutes, regulations, policies, recommendations, and executive orders

Term	General Meaning	Who Must Comply (Scope of Impact)	Degree of Enforcement	Examples
Law	Elected legislature or designated agency requires or encourages or authorizes someone to do something Can refer to either: 1. a statute (i.e., legislation passed by the city council, state legislature, or federal Congress); or 2. a regulation passed by a local, state, or federal agency	Everyone within the jurisdiction (e.g., medical practitioners who wish to practice medicine); individuals specifically named (e.g., physicians who prescribe Rx opioids)	Stated in the law: civil and criminal penalties can be assessed for noncompliance; a law may not always have specific penalties (e.g., when authorizing someone)	State laws: licensure of OTPs; credentialing of physicians who prescribe methadone; creation of PDMPs; establishing prescription requirements and limits Local laws: licensure of pharmacies; taxation
Statute or Legislation	Law that is drafted and passed by an elected legislative body (i.e., local city council, state legislature, or federal Congress)	Everyone within the jurisdiction (e.g., medical practitioners who wish to practice medicine); individuals specifically named (e.g., physicians who prescribe Rx opioids)	Stated in the law: civil and criminal penalties can be assessed for noncompliance; violations can result in loss of license due to action by state board	State laws: licensure of OTPs; credentialing of physicians who prescribe methadone Local laws: licensure of pharmacies; taxation
Regulation	Law that is drafted by an agency authorized to oversee a certain aspect of lawmaking (e.g., local department of health, state medical licensing board, FDA)	Everyone who falls under the authority of the agency (e.g., licensed medical practitioners)	Stated in the regulation: civil and criminal penalties can be assessed for noncompliance; the agency's authority to promulgate and enforce regulations is determined by the corresponding local, state, or federal legislature	Licensure of OTP facilities, eligibility requirements for admitted patients, and credentialing requirements of staff; FDA-mandated REMS; DEA license required for health professionals dispensing controlled substances
Policy ("big P")	A statute or regulation and other relevant interpretive materials (e.g., case law or guidance documents interpreting the law)	Everyone who falls under the authority of the agency (e.g., licensed medical practitioners)	Stated in the law: court opinions, agency guidelines, attorney general opinions, and other supporting or interpretive materials may help inform the scope and applicability	State naloxone access law; implementation of a governor's task force that is monitoring opioid-related overdose trends in the state
Policy ("small p")	A set of requirements or restrictions that only apply to a specific setting (e.g., access to detoxification and opioid use disorder treatment in jails and prisons) or to certain professionals (e.g., hospital staff employment)	Anyone who is subject to the requirements of the setting (e.g., employees, patients, incarcerated individuals, customers)	Stated in the "small p" policy: this may include termination from employment or civil or criminal penalties	Tobacco- and drug-free workplace policies
Guidance Document (Recommendation)	Provides further clarification into the meaning and scope of a codified law or into an agency or authority figure's insight into the meaning and scope of a codified law	The designated individuals or entities subject to the requirements or restrictions described (e.g., insurance reimbursement)	None, unless specifically stated: these documents are generally meant to inform without being enforceable	CDC's Guideline for Prescribing Opioids for Chronic Pain; Black Box Warnings for opioids, the strongest safety warning issued by the FDA

(continued)

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Table 1. Overview of distinctions between laws, statutes, regulations, policies, recommendations, and executive orders *(continued)*

Term	General Meaning	Who Must Comply (Scope of Impact)	Degree of Enforcement	Examples
Executive Order	Restriction, prohibition, or declaration by an executive leader (i.e., local mayor, state governor, federal US president)	Anyone who is subject to the requirements of the setting (e.g., employees, patients, incarcerated individuals, customers)	Enforceable for the duration of the executive's tenure but subject to immediate withdrawal upon a newly elected executive	President Trump's proposed "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder"; President Biden's administration revised this buprenorphine waiver and published it in the *Federal Register* in April 2021—certain medical providers may now prescribe buprenorphine to up to 30 patients without a US DEA license

Notes: Rx = prescription; OTP = opioid treatment program; PDMP = prescription drug monitoring program; FDA = Food & Drug Administration; REMS = risk evaluation and mitigation strategy; DEA = Drug Enforcement Administration; CDC = Centers for Disease Control and Prevention.

laws determine the circumstances under which these prescriptions may be prescribed and dispensed by medical providers and practitioners with specific credentials and training. This federal landscape determines the "infrastructure" of how readily available opioids are by making determinations like (1) making pain-relieving opioid drugs available by prescription only; (2) limiting the prescribing of opioid drugs to specific indicated purposes and by specific providers with certain credentials or training; (3) establishing the potency and dosage of prescription drugs; (4) putting abuse-deterrent requirements into place that opioid drug manufacturers must comply with (such as OxyContin, RoxyBond and others in collaboration with the Food and Drug Administration [FDA]); and (5) additionally restricting the setting or type of facility that can administer, prescribe, or dispense these drugs. Moreover, laws expanding access to medications for opioid use disorder (MOUD) help individuals who have developed opioid use disorders. The federal reduction of regulations placing limits on the number of patients a provider can treat with buprenorphine and the elimination of mandated special training now permits more clinicians to prescribe buprenorphine for MOUD.[16]

Notably, however, states have borne the primary responsibility to limit opioid prescriptions, and many state laws designed to prevent or treat opioid use disorder and prevent opioid overdose are interventional by design.[17] State laws restricting the quantity or dosage of prescription opioids aim to lower the risk of the patient developing physical dependence on opioids. For example, in Vermont, providers are restricted to prescribing opioids for 0 to 5 days for patients in moderate to severe acute pain and for up to 7 days for patients in extreme acute pain.[18,19] In Florida, the introduction of laws limiting prescription quantities and establishing a prescription drug monitoring program (PDMP) helped contribute to a reduction in "pill mills" with inappropriately large numbers of opioid prescriptions.[20] Importantly, most state laws still allow for doctors to override prescription limitations by allowing exceptions for chronic pain, and many laws exempt certain care, such as cancer or palliative care, from prescription limits otherwise defined by law. Furthermore, doctors may often be given broad leeway to make exceptions if doing so is deemed necessary in their "professional judgment."

Although state policymaking has primarily been centered around prescription quantities and associated limitations,[21] state lawmakers have enacted other measures to reduce harm such as providing

naloxone access and enacting Good Samaritan laws to reduce opioid-related deaths. In North Carolina, for example, policymakers enacted a law providing limited immunity to a person "who witnesses an overdose and seeks help for the victim" further clarifying that such a person "cannot be prosecuted for possession of drug paraphernalia or small amounts of drugs or be considered in violation of a condition of parole, probation, or post-release for those crimes if the evidence for those crimes was obtained because the person called for help."[22]

Disentangling Recommendations From Laws Versus Guidelines

Although a law is more easily enforceable than a guideline, not all laws explicitly require or restrict a certain behavior or activity. Sometimes, lawmakers put laws into place that simply describe a particular problem facing the jurisdiction. For example, a state legislature may enact a piece of legislation called "Legislative Intent" or "Legislative Declaration." This is for a particular lawmaking body to describe the scope of a particular problem it is hoping to mitigate, prevent, or reduce.

Recently, state jurisdictions have restricted the prescribing of opioids for pain management. Some states have done this through the passage of enforceable laws requiring certain medical providers to attain specific types of licensure or complete educational requirements regarding the risks of prescribing opioids, such as Indiana and West Virginia, where practitioners are required to undergo continuing education through board-certified courses (e.g., Burns Ind. Code Ann. § 35–48–3-3.5; 32 M.R.S. § 3300-F; W. Va. Code § 16–5Y-5). In other jurisdictions, organizations such as the state's hospital association have issued opioid prescribing guidelines, which outline recommendations to help providers make decisions about prescribing opioids. Opioid prescribing can be restricted in many ways, such as (1) state lawmakers passing or adopting a *state law that requires or prohibits* certain prescribing actions and behaviors; (2) state lawmakers passing or adopting a *state law that recommends but does not require or prohibit* certain prescribing actions and behaviors; (3) an *organization within the state issuing guidelines* that recommend that providers follow certain decision-making protocols when prescribing opioids; (4) the *governor requiring or prohibiting* certain provider decision-making protocols when prescribing opioids through an executive order; (5) the *governor recommending* specific decision-making protocols when prescribing opioids through an executive order; or (6) *an appointed task force within the state recommending* certain decision-making protocols when prescribing opioids.

In other words, *several types of entities*—state lawmakers, the executive branch leader, or organizations within the state (e.g., medical licensing board)—can *require, prohibit, or recommend* certain actions. A state law does not have to require or prohibit the prescribing of certain opioids; it can recommend that providers take certain actions or encourage providers to follow a decision-making protocol when prescribing or dispensing opioids. Relatedly, a governor can issue an executive order requiring or restricting the prescribing of opioids or simply recommending certain actions. An executive order is enforceable and subject to penalties, if specified. State laws are generally designed to be long-term but may sometimes be intentionally temporary, such as when a law is written to include a specific expiration or "sunset" date on which the law will naturally end.

One major difference between a *law that requires* certain opioid prescribing practices, such as limiting daily dosage, and a *guideline that recommends* opioid prescribing practices is the extent to which noncompliance can be penalized. It is still possible to hold accountable a physician who routinely prescribes opioids in a manner that is misaligned with the recommended guidelines. A physician who prescribes opioids in a manner that violates legal guidelines may face *disciplinary penalties* that include a suspended or revoked medical license and termination from employment. In addition, this physician may face a civil or criminal lawsuit from patients harmed by these prescribing practices.

State laws that restrict opioid prescribing tend to establish a specific enforcement agency that is authorized to investigate potential acts of noncompliance and assess penalties. A state agency that is authorized to investigate may be able to

promptly request and receive certain health records related to the incident in question and to alert the medical licensing board or the physician's employer of the investigation. State lawmakers who restrict opioid prescribing by law can build and establish centralized and systematic data collection and monitoring systems, which can make it easier to identify and act with respect to individual providers who may not comply and to monitor statewide trends in prescribing that may inform future lawmaking.

CDC is a federal agency that has the authority to issue both federally enforceable laws and recommended guidelines and is situated within the Department of Health and Human Services.[23] In 2016, CDC released a comprehensive set of opioid prescribing guidelines to help inform and shape the decision-making of medical providers seeking to offer pain relief treatment options for their patients. When CDC issued these guidelines, only a few states had enacted and implemented laws restricting the initial or refill prescriptions of prescription opioids and civil, criminal, and disciplinary protections for medical providers who prescribe or dispense the opioid overdose-reversal drug naloxone.[24] CDC has provided updated guidelines for prescribing opioids for pain in 2022.[25]

Who Implements and Enforces the Law or Policy?

Federal, state, and local governments play an important role in creating laws that restrict or guide the actions of medical providers, patients, and enforcement agencies. At each level of government, elected legislative bodies and appointed or nonelected agency officials play a critical role in creating laws that have shaped the availability of prescription opioids. Although federal, state, and local governments have the authority to put certain types of laws into place, there are specific parameters around (1) what types of laws each level of government can create and put into place and (2) the extent to which agencies can issue rules and regulations.

At each level of government, the federal, state, or local legislative body generally gives the corresponding federal, state, or local agency the authority to draft rules and regulations in certain areas of law. At the federal level, Congress is the legislative body that determines the areas over which the FDA, a federal agency, has the authority to regulate the approval and manufacturing of pharmaceutical drugs. If it is not clear whether Congress has given a federal agency the authority to regulate a certain substance or product, then a court may determine that the federal agency does not have this authority and may strike down the rules or regulations the federal agency has adopted.

Although laws and federal agency rules or regulations (once passed) can only be changed or removed through formal process, a presidential executive order can be removed unilaterally by the succeeding president. This occurred when President Trump passed an executive order at the end of his term in office to waive federal licensing requirements for providers wishing to prescribe buprenorphine. He left office before his proposal to relax the federal buprenorphine prescribing requirements had been published in the *Federal Register*. When President Biden took office, he chose to not publish the original regulations written by the Trump Administration. After tasking the Department of Health and Human Services to review the optimal scope of this buprenorphine waiver and ensuring its legality and validity, the Biden Administration then published its version of this waiver in April 2021 (86 Fed. Reg. 22439).

The Differential Roles of Federal, State, and Local Governments

There are certain areas of law over which more than one level of government can regulate (Table 2). For example, federal, state, and local governments generally each have the authority to require reporting on dispensation of opioids. When this occurs, the federal government will often establish the minimum requirement, or "floor," that must be complied with across the country.[26] If the federal government or other constitutional considerations have not preempted state and local governments from governing in this same area, state or local governments can establish stricter requirements that reflect the "ceiling." One example of how different ceiling requirements can result in different degrees of reporting for the same product, depending on

Table 2. Distinctions based on type of jurisdiction

Type of Jurisdiction	Source of Lawmaking Authority: Legislature	Source of Lawmaking Authority: Regulatory Agency	Exclusive Authority	Which Level of Government Prevails if Conflict	Examples
Federal government	Congressional authority: granted by US Constitution	Federal agency authority: granted by Congress	Product safety, dosage, labeling	Federal government	Opioid drug manufacturing standards
State government	State legislative authority: granted by state constitution	State agency authority: granted by state legislature	Designated policy areas, when preempting	Federal/state conflict: federal wins State/local conflict: state wins	State prescription drug monitoring program
Local government (e.g., city, county, town, village)	Local legislature: granted by charter, home rule, or other founding document	Local agency authority: granted by local legislative body	Yes, if stated	Federal/local: federal wins Local/state: state wins	Zoning, permitting laws

where it is sold, is the application of federal Controlled Substance Act reporting versus state PDMP reporting, such as in West Virginia where more restrictive opioid prescribing laws were implemented in 2018.[27]

Importantly, each of the federal and state interventions named previously are put into place and enforced through the federal or state government's passage of a law. For example, FDA's approval of prescription opioids is not based on its recommendations that pharmaceutical companies create a substance that may or may not actually help patients suffering from various types of pain; rather, FDA determines whether to approve or reject a specific prescription drug application through a rigorous review of the drug company's proven findings of efficacy. Similarly, state governments do not simply allow methadone clinics to operate by filling out the form for a business license and then registering this business with the secretary of state's office. Instead, methadone clinics and other types of clinical facilities that wish to offer detoxification and pain management treatment must comply with a series of state laws mandating these facilities to demonstrate that they meet a series of requirements, such as medical staff qualifications, consistent and strict adherence to admitting patients based on the established eligibility criteria or complying with take-home protocols upon discharge.

As mentioned, state lawmakers are typically able to mandate regulation compliance through enacting state laws. In the absence of a state law, individual methadone clinics could hypothetically establish their own staffing requirements and patient treatment protocols, resulting in a patchwork of inconsistent treatment protocols. Moreover, this same reasoning is often why the licensure of medical practitioners and the registration of specific treatment facilities are determined and enforced at the state level. Absent statewide requirements, each city or county could set different criteria in administering care, which could result in patients in certain parts of the state receiving suboptimal care.

As demonstrated through the legalization or decriminalization of either medical or adult-use cannabis in most states across the country, and because of the absence of enforcement of federal policies in this area, state laws play an important role in determining how the use and possession of certain "controlled substances" will be penalized, tolerated, or authorized. Oregon, which was one of the first states to legalize adult-use cannabis, recently decriminalized the use and possession of most illicit controlled substances (Oregon Ballot Measure 110; Or. Rev. Stat. § 475.005 *et seq*.). This means that possessing small amounts of substances below a designated threshold of illicit substances such as cocaine or heroin is no longer considered a criminal activity that will by itself lead to arrest, criminal charges, prosecution, and criminal conviction (https://www.oregon.gov/OHA/HSD/AMH/Pages/Measure110.aspx). Local law enforcement throughout the state is obligated to comply with these new statewide laws.

Although local laws are more limited, only pertaining to and enforceable within the bounds of a specific city, county, or other local jurisdiction, they can play an important role in shaping the day-to-day lives of a city's retail environment, traffic patterns, law enforcement practices and procedures, and operating health care and medical facilities. Local jurisdictions are often authorized to establish and enforce public health protocols such as indoor masking. Counties and cities can play an important role in promoting access to stable and safe housing, adequate food, good public schools, and other quality-of-life measures. County agencies often play a critical role in collecting public health outcomes data, which a designated state entity then collects and relies on to measure important measures of health and well-being.

Implications and Unintended Consequences of Opioid Laws, Policies, or Guidelines

Passing or adopting a state law that requires or restricts certain opioid prescribing practices can make it easier to monitor and enforce potential acts of noncompliance and track overall prescribing trends. However, the misinterpretation of laws and guidelines that restrict opioid prescribing can lead to unintended consequences, such as limiting access to pain management that results in some patients no longer having access to the care they need.[28] Moreover, not all prescription opioids are designed to achieve the same goal, and restrictions on one type of opioid may adversely and unnecessarily limit access to other types of opioids. Certain prescription opioids such as OxyContin are designed to treat pain. The opioid antagonist naloxone is formulated specifically to revive a person experiencing an opioid-related overdose. MOUD drugs such as methadone, buprenorphine, naltrexone, and suboxone have been approved by FDA to help an individual treat and manage opioid use disorder.

Restrictions on the dosage or supply of prescription opioids could leave some patients with chronic pain or other medical challenges without a viable pain management treatment protocol. For example, North Carolina lawmakers passed legislation to monitor opioid prescribing in 2017 when it passed the Strengthen Opioid Misuse Prevention Act (STOP) Act.[29] This law strictly limits the lawful period permitted for initial opioid prescribing to either: 5 days "for acute pain," or 7 days "for post-operative acute pain relief immediately following a surgical procedure." Although state laws restricting the prescribing of opioids are well-intended attempts to reduce patients' exposure to substances that may lead to dependence and other harms, these restrictions may unintentionally limit access to medications that make it possible for some patients to function in daily life with reduced pain. Such restrictions can obstruct medical providers' discretion to make individualized decisions about prescribing based on the specific needs of individual patients. Additionally, it has been shown that these limitations overall have little effect both because people can get new prescriptions after the initial prescription and because the limited number of days enforced for the initial prescriptions do not vary much from what doctors had previously been prescribing.[30]

Blanket restrictions could also reduce the availability of certain types of MOUD, thereby denying individuals access to opioid use disorder treatment.[31] Similarly, an opioid prescription restriction that does not have any flexibility in the care and treatment of special populations, such as pregnant women, may result in more harm than good. A longer-term supply of opioid medication at a certain dosage may be appropriate for one patient while potentially dangerous for another. Moreover, researchers have argued that MOUD such as buprenorphine may be helpful not only in managing opioid use disorder but also as a treatment medication to help individuals with chronic pain.[32]

Federal, state, and local governments have put a wide set of laws into place to address the opioid overdose crisis. These laws range from restrictions and requirements pertaining to the actual manufacturing and specific formulation of prescription opioids (through the federal FDA) to how medical practitioners are authorized to prescribe and dispense opioids and the specific settings in which the general population or certain types of patients (e.g., pregnant women, incarcerated populations) are authorized to receive prescription opioids (through state laws). For example, while there are no specific laws prohibiting

pregnant women from receiving prescription opioids, women who are pregnant and take opioids in higher doses or for longer than recommended by their health care providers have an increased chance for pregnancy problems and thus must be monitored closely.

State governments play a significant role in determining and authorizing the types of settings in which opioids may be offered and determining enforcement of limitations on initial and refills of prescriptions and required supply of naloxone and the role that harm reduction efforts may play in the state. This may include laws authorizing naloxone administration to reverse an opioid-related overdose in an emergency room or expanding community distribution efforts; dedicating state funding to expand access to MOUD such as methadone[4]; restricting initial and refill opioid prescribing and monitoring practitioners' compliance with these restrictions through state-run PDMPs; and establishing the lawful operation of facilities that offer treatment for opioid use disorder, such as methadone clinics, residential OTPs, or outpatient treatment in a doctor's office.[33] State laws, including state PDMP laws, have a growing body of evidence suggesting a positive impact in reducing opioid-related harm.[34] Other forms of state legislation increase access to treatment. North Carolina's recent passage of Medicaid expansion increases access to hundreds of thousands of North Carolinians including those with untreated opioid use disorder. In the first year of implementation, more than 600,000 North Carolinians enrolled in Medicaid expansion, providing access to critical treatment and preventative services to underserved populations.[35]

Medicaid expansion is a powerful tool to address the opioid crisis and has been associated with reductions in total opioid overdose deaths.[36,37] Taken together, state-laws, policies, and guidelines hold major influence on the direction of the opioid epidemic. Mathematical models that consider implications and unintended consequences of societal actions toward overdose epidemics could add realism by considering implementation mechanisms of simulated polices and interventions.

Finally, although the literature on the positive impact of laws regarding programs such as PDMPs continues to grow,[38] the evidence base on the effectiveness of other types of state laws in reducing opioid-related mortality and various types of harm is mixed.[39] Other studies that have examined one type of opioid law, such as state laws that restrict the lawful prescribing of opioid substances above an established morphine equivalent, have found that the variation in the specific requirements of these laws makes it challenging to conclude which type of state (and federal) law is likely to have the most positive impact.[40] Further understanding and evaluation of the various types of laws, policies, and guidelines that shape the direction of the opioid epidemic and those affected by it is warranted and needed to identify gaps, misunderstandings, and effective strategies and initiatives in the ever-changing climate of the crisis.

Data Availability Statement

In this publication, we do not report on, analyze, or generate any data.

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