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Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws

REBECCA L. HAFFAJEE*

The United States is in the midst of a prescription opioid overdose and misuse epidemic. Although many factors have contributed to the escalation of prescription painkiller misuse, it parallels increases in the supply and prescribing of opioids. Prominent state-level regulatory interventions, such as the establishment of prescription drug monitoring programs (“PDMPs”), recognize prescribers as opioid gatekeepers. Prescribers, who are uniquely situated to distinguish between appropriate use and misuse of opioids, are a natural target for regulation. PDMPs also target patients who seek to obtain high volumes of prescription opioids for illicit purposes.

PDMP policies are widespread but heterogeneous, largely uninformed by robust evidence or a systematic assessment of best practices. Whether these programs successfully reduce opioid misuse and overdoses remains unclear. As well, PDMPs present a number of legal and ethical challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. This Article articulates and synthesizes for the first time key criteria intended to assist state regulators in dynamically evaluating and justifying PDMPs and other public health laws. The criteria focus on the legality of the policy, approaches to measure its effectiveness, and normative considerations that should be factored into good laws. Such a framework is crucial for policymakers given the complexities and magnitude of this public health challenge, the rich arsenal of policy options from which to choose, and the slow and uncertain progress in combating prescription painkiller misuse. Concluding recommendations include implementing PDMPs with the following features: timely and complete data, strong incentives for prescriber participation, user guidelines and education, integration into clinical work flow, and robust confidentiality and privacy protections. Ongoing evaluation of programs to identify features appropriate for retention and replication is also crucial if PDMPs are to fulfill their potential to curb prescription opioid overdose and misuse.

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INTRODUCTION

The United States is in the midst of a prescription opioid misuse crisis. Although only five percent of the world's population lives here, we consume over eighty percent of the world's opioid supplies.¹ Drug overdoses, over half of which are related to prescription drugs, are now the leading cause of injury and death in the United States.² In 2014, opioids were involved in sixty-one percent of drug overdose deaths, or

1. Jane C. Ballantyne & Andrew Kolodny, *Preventing Prescription Opioid Abuse: Letter to the Editor*, 313 JAMA 1059, 1059 (2015).

2. *Prescription Drug Overdose Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugoverdose/data/overdose.html> (last visited Aug. 5, 2016).

28,647 deaths.³ The crisis has escalated to such levels over the past two decades that federal officials now characterize prescription drug misuse and overdose as a national “epidemic.”⁴

Prescription opioid deaths are a consequence of nonmedically indicated use of opioids. This practice, also termed prescription opioid misuse and abuse (this Article uses the term “misuses to capture both), consists of the unintentional or intentional use of medication without a prescription, in a manner other than as prescribed, or for the feeling or experience it causes.⁵ The prevalence of prescription opioid misuse is striking. In 2013 alone, 15.3 million Americans aged twelve and older used prescription drugs nonmedically, and 6.5 million had done so in the prior month.⁶ Moreover, prescription opioids may serve as gateway drugs. There is some evidence that addicts switch to even deadlier substances, such as heroin, when they can no longer access, afford, or tamper with prescription painkillers.⁷

The rise in prescription painkiller misuse is clearly correlated with the increasing supply and prescribing of opioids. The overall sale of

3. Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 1378, 1379 (2016) (finding that oxycodone and hydrocodone, the most commonly prescribed opioid pain relievers, are involved in more overdose deaths than any other type of opioid, including heroin). See MARGARET WARNER ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., DRUG POISONING DEATHS IN THE UNITED STATES, 1980–2008, 1 (2011); LI H. CHEN ET AL., NAT’L CTR. FOR HEALTH STATISTICS, DRUG-POISONING DEATHS INVOLVING OPIOID ANALGESICS: UNITED STATES, 1999–2011, 1 (2014) (specifying that misuse or abuse of prescription drugs is responsible for much of the recent increase in drug-poisoning deaths).

4. Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses—A U.S. Epidemic*, 61 MORBIDITY & MORTALITY WKLY. REP. 10, 10 (2012) (characterizing prescription drug misuse as “the fastest growing drug problem in the United States” and prescription drug overdose as “a U.S. Epidemic”); EXEC. OFFICE OF THE PRESIDENT, EPIDEMIC: RESPONDING TO AMERICA’S PRESCRIPTION DRUG ABUSE CRISIS I (2011) (calling the prescription drug misuse crisis an “epidemic”).

5. *Prescription Drug Misuse and Abuse*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <http://www.samhsa.gov/prescription-drug-misuse-abuse> (last visited Aug. 5, 2016).

6. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., RESULTS FROM THE 2013 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS (2014).

7. See Ian Frazier, *The Antidote: Can Staten Island’s Middle-Class Neighborhoods Defeat an Overdose Epidemic?*, THE NEW YORKER (Sept. 8, 2014), <http://www.newyorker.com/magazine/2014/09/08/antidote>; Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 NEW ENG. J. MED. 241, 245–47; THEODORE J. CICERO & MATTHEW S. ELLIS, JAMA PSYCHIATRY, ABUSE-DETERRENT FORMULATIONS AND THE PRESCRIPTION OPIOID ABUSE EPIDEMIC IN THE UNITED STATES: LESSONS LEARNED FROM OXYCONTIN (2015). *But see* Rose A. Rudd et al., *Increases in Heroin Overdose Deaths—28 States, 2010 to 2012*, 63 MORBIDITY & MORTALITY WKLY. REP. 849, 852 (2014) (“[a]lthough some persons might be discontinuing prescription opioids and initiating heroin use as a replacement, results from this study indicate that recent heroin death rate increases were not significantly associated with decreases in [opioid pain reliever] overdose mortality.”); Wilson M. Compton et al., *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 NEW ENG. J. MED. 154, 154–61 (2016) (finding that although a subgroup of nonmedical prescription opioid users may transition to heroin use—especially those persons with frequent nonmedical use and those with opioid misuse or dependence—the timing of policy-driven efforts to curb prescription opioid availability (which predated the increase in the rates of heroin use) makes it unlikely that the policies induced a substitution effect to heroin use).

opioid analgesic painkillers, which increased nearly four-fold between 1999 through 2010, parallels observed increases in opioid-related overdose deaths, emergency department visits, and treatment admissions.⁸ In 2012 alone, providers issued 259 million opioid prescriptions—enough for every adult to have their own bottle of pills.⁹

A heightened focus on pain management starting in the 1990s liberalized opioid prescribing.¹⁰ But in responding to the public health problem of under-treatment of pain, prescribers paradoxically have played a major role in creating another public health problem: the growth of prescription drug misuse. Twenty-five percent of nonmedical prescription painkiller users obtained their drugs directly from a doctor's prescription, while seventy percent of users accessed drugs from family or friends—almost ninety percent of whom had gotten their prescription from a doctor).¹¹ In other words, the vast majority of misused prescription drugs are sourced directly or indirectly from prescribers.¹²

Prescribers are uniquely situated to distinguish between appropriate use and misuse of opioids and prescribe accordingly. Several state regulatory interventions—most prominently, the establishment of prescription drug monitoring programs (“PDMPs”)—recognize prescribers as opioid gatekeepers.¹³ PDMPs also target “doctor shoppers” (patients with particularly high opioid consumption patterns), and diverters (individuals who transfer their prescribed drugs to others for illicit use). PDMPs have been adopted in all but one state, and the Centers for Disease Control and Prevention describes them as “among the most promising state-level

8. Ctrs. for Disease Control & Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008*, 60 MORBIDITY & MORTALITY WKLY. REP. 1487, 1488–91 (2011).

9. Christopher M. Jones et al., *Sources of Prescription Opioid Pain Relievers by Frequency of Past-Year Nonmedical Use: United States, 2008–2011*, 174 JAMA INTERNAL MED. 802, 802–03 (2014); Leonard J. Paulozzi et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines—United States, 2012*, 63 MORBIDITY & MORTALITY WKLY. REP. 563 (2014).

10. Andrea M. Garcia, *State Laws Regulating Prescribing of Controlled Substances: Balancing the Public Health Problems of Chronic Pain and Prescription Painkiller Abuse and Overdose*, 41 J.L. MED. & ETHICS (SUPP.) 42, 42–43 (2013); Tatyana Lyapustina & G. Caleb Alexander, *The Prescription Opioid Addiction and Abuse Epidemic: How it Happened and What We Can Do About It*, THE PHARMACEUTICAL J. (2015), <http://www.pharmaceutical-journal.com/opinion/comment/the-prescription-opioid-addiction-and-abuse-epidemic-how-it-happened-and-what-we-can-do-about-it/20068579.article> (discussing the rise in global prescribing of opioids for pain starting in the 1990s, and claiming that the increased morbidity and mortality from opioids has resulted from the degree to which they have been prescribed).

11. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 6.

12. See Jones et al., *supra* note 9, at 802–03 (observing that those at highest risk of overdose, or those who use prescription opioids nonmedically on a chronic basis (that is, for 200 or more days per year), were at the highest risk to obtain their drugs directly from a doctor (twenty-seven percent of the time)).

13. See Barath Chakravarthy et al., *Prescription Drug Monitoring Programs and Other Interventions to Combat Prescription Opioid Abuse*, 13 W. J. EMERGENCY MED. 422, 424 (2012).

interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk.”¹⁴

Although early evidence is emerging regarding the impact of these interventions on opioid prescribing, misuse, and overdoses, the rapid proliferation of heterogeneous PDMPs has been largely uninformed by robust evidence or a systematic assessment of best practices. Instead, state replication of PDMPs has exemplified disorganized policymaking in the face of a serious public health crisis. Moreover, PDMPs present a number of legal and normative challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. Thus, existing PDMPs offer an opportunity to reflect upon how state public health policymaking in this area can follow a more deliberate path towards success.

This Article argues for the use of state PDMPs with the following features: timely and complete data; strong incentives for prescriber participation; user guidelines and education; integration into clinical workflow; and strong confidentiality protections—including a requirement that law enforcement officials and licensing boards access individual-identifying data only with a court-issued warrant or subpoena. Ongoing evaluation of PDMPs to improve understanding of best practices is also needed. To arrive at these recommendations, this Article articulates and synthesizes, for the first time, key criteria intended to assist state regulators in dynamically evaluating and potentially justifying public health laws. The criteria focus on the following: (1) the form that regulation should take based on analysis of the policy’s legality; (2) measurement of law effectiveness; and (3) normative considerations that ought to be factored into good public health policy. Such a streamlined framework is a critical tool for state regulators, given the complexities and scope of prescription opioid misuse, the rich arsenal of policy options available to address it, and slow and uncertain progress in combating this problem. Although used to guide PDMP policymaking, this framework also can be applied to interventions designed to address public health threats that exhibit similar characteristics to prescription drug misuse—that is, those of significant magnitude and that may be addressed using a number of available policy options, the success of which is not yet obvious or common knowledge.¹⁵

14. *Prescription Drug Monitoring Programs (PDMPs)*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 5, 2015), <http://www.cdc.gov/drugoverdose/pdmp/index.html> (last visited Aug. 5, 2016).

15. The framework may also be used after identifying “critical opportunities” for public health lawmaking, or areas “in which law is under-performing as a public health tool in relation to the problem of interest.” Law can under-perform because legal interventions are few (or nonexistent) or because they are executing poorly, such as causing undesirable consequences. A critical opportunity satisfies three criteria: (1) it targets a significant public health threat; (2) its etiology is well-understood to support the use of law as an intervention; and (3) one or more plausible legal interventions are available to address the threat but are not being used to their full advantage. Michelle M. Mello et al., *Critical Opportunities for Public Health Law: A Call for Action*, 103 AM. J. PUB. HEALTH 1979–80 (2013).

This Article proceeds as follows. Part I describes the current prescription drug misuse crisis, establishing it as a public health threat of substantial magnitude that evolved from a history of ebbing and flowing in opioid prescribing in the United States. Part I also outlines the panoply of regulatory interventions available to address this epidemic, including, most prominently, PDMPs implemented by state governments. Part II then lays out a framework for evaluating public health laws implemented by the states, which bear great responsibility to protect population health, and applies it to PDMPs. Key criteria are articulated that probe legal powers to regulate (including legal barriers to implementation), the effectiveness of the law at achieving identified primary and secondary health outcomes, and salient ethical issues raised by public health regulation. Finally, specific recommendations for PDMPs, generated by application of the evaluative framework, are set forth, with the goal of maximizing the chances that these policies will be a public health success.

I. PRESCRIPTION DRUG MISUSE: A PUBLIC HEALTH EPIDEMIC

The current prescription drug misuse and overdose epidemic evolved from over a century of ebbing and flowing in prescription drug use in America. This is the third wave of misuse, following two earlier eras of problematic opioid use and regulatory responses.¹⁶ The first escalation in misuse occurred in the late 19th century during a time when opioids were altogether unregulated.¹⁷ Opioids, including heroin, were commonly prescribed for menstrual pain, among other maladies, often resulting in iatrogenic morphine addiction.¹⁸ Regulation ensued, in the form of the 1906 Pure Food and Drug Act, which required the content of drugs (including opioids) to be listed on their labels, and the 1914 Harrison Narcotics Act, which regulated physicians by mandating that they write prescriptions for opioids, taxing them for such prescriptions, and requiring that they maintain records of drugs dispensed.¹⁹ The Act also restricted the quantity of opiates that could be contained in medicines.²⁰ Regulation and increased medical education and treatment options, had the intended effect of reducing opioid overprescribing.²¹

16. Austin Frakt, *Painkiller Abuse, a Cyclical Challenge*, N.Y. TIMES (Dec. 22, 2014), http://www.nytimes.com/2014/12/23/upshot/painkiller-abuse-a-cyclical-challenge.html?abt=0002&abg=1&_r=0.

17. *Id.*

18. *Id.*; Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 561 (2015) (discussing the limited options, other than opium and morphine, available to physicians in this era when treating pain symptoms).

19. *Id.*; Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 57 (2010).

20. Weber, *supra* note 19, at 57.

21. Kolodny et al., *supra* note 18, at 562.

The second wave of misuse came in the mid-1950s, as reports of increases in opioid use and overdose deaths proliferated across the country.²² Regulatory responses included laws permitting involuntary hospitalizations of addicts, the establishment of methadone clinics for treating addiction under the Controlled Substances Act (“CSA”), and formation of the Drug Enforcement Administration (“DEA”) to coordinate federal anti-drug efforts.²³

In the decades after this second wave, the under-treatment of pain was increasingly recognized as a serious public health challenge that necessitated changes to prescribing behavior. The United Nations even declared access to pain medication a human right in 1961.²⁴ This swing toward the liberalization of opioid prescribing contributed substantially to the current misuse and overdose epidemic. In response, various stakeholders—including state and federal regulators, insurers, drug manufacturers, and providers—have adopted a panoply of interventions targeting the supply of, demand for, and misuse of opioids.

A. THE LIBERALIZATION OF OPIOID PRESCRIBING FOR PAIN

Under-treatment of pain is itself a serious public health challenge in the United States. An Institute of Medicine committee estimated that every year chronic pain affects about 100 million people and costs up to \$560–635 billion in lost productivity and medical treatment.²⁵ Starting in the 1980s, inadequate treatment of chronic pain received heightened scrutiny. Before this time, physicians prescribed narcotics for short-term, acute pain, or for pain related to cancer or end-of-life care.²⁶ Two medical journal articles—the first published in 1980 in the *New England Journal of Medicine*, and the second in *Pain* in 1986—opened the door to more liberal prescribing of painkillers.²⁷ Both studies concluded that narcotics can be safely prescribed for chronic pain to many patients with little risk of inducing addiction.²⁸

In 1995, Purdue Pharma introduced an extended-release, highly potent form of the painkiller oxycodone, known as OxyContin, which marked the onset of increased opioid use.²⁹ Around the same time, drug manufacturers began to market their opioid drugs for chronic, non-

22. Frakt, *supra* note 16.

23. *Id.*

24. *Id.*

25. INST. OF MED. OF THE NAT’L ACADS., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH (2011). The Institute of Medicine is now known as the National Academy of Sciences.

26. Celine Gounder, *Who is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), <http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic>.

27. *Id.*; Frakt, *supra* note 16.

28. *Id.*

29. Kolodny et al., *supra* note 18, at 562.

cancer pain via advertisements in well-respected journals, through continuing medical education courses for doctors, and by contributing financial support to not-for-profit organizations, such as the American Academy of Pain Management, the American Pain Society, and the Federation of State Medical Boards.³⁰ Highly-regarded physicians—such as Dr. Russell Portenoy, co-author of the *Pain* study and director of the American Pain Society—served as the faces behind many of these drug company promotions.³¹ In 1996, the American Pain Society launched an aggressive campaign entitled “Pain as the Fifth Vital Sign,” the message of which was embraced by the Veterans Affairs health system and The Joint Commission, which accredits health care organizations, including hospitals.³² In 2004, the Federation of State Medical Boards passed a model policy on the use of controlled substances to treat pain.³³ The policy encouraged state medical boards to consider under-treatment of pain an equally serious violation of the standard of care as over-treatment.³⁴

Additionally, over the past several decades, more subtle forces have encouraged doctors to generously prescribe opioids. Patient satisfaction assessments pervade the modern practice of medicine (and even impact payment under pay-for-performance schemes), thereby motivating certain physicians to prescribe opioids if requested by patients.³⁵ The medical insurer practice of reimbursing well for prescription pain medications further reinforces the use of opioids to treat subjective pain.³⁶ Cumulatively, stakeholder group activities, financial incentives, and patient satisfaction considerations contributed significantly to sharp increases in opioid prescribing observed in the 1990s–2000s and laid the foundations for misuse.

During this same period, a number of academics proposed legal strategies to promote opioid prescribing for pain. Building upon one prominent case in which a California court found a physician to have committed elder abuse by failing to prescribe drugs adequately to manage a patient’s pain,³⁷ some academics advocated for increased state court recognition of tort claims against physicians who under-prescribe

30. *Id.*; Frakt, *supra* note 16.

31. Gounder, *supra* note 26.

32. Kolodny et al., *supra* note 18, at 562.

33. Garcia, *supra* note 10, at 43.

34. *Id.*; Gounder, *supra* note 26.

35. Anna Lembke, *Why Doctors Prescribe Opioids to Known Opioid Abusers*, 367 NEW ENG. J. MED. 1580, 1580–81 (2012).

36. *Id.*; Aleksandra Zgierska et al., *Patient Satisfaction, Prescription Drug Abuse, and Potential Unintended Consequences*, 307 JAMA 1377, 1377–78 (2012).

37. Garcia, *supra* note 10, at 42–43.

painkillers³⁸ or institutions that fail to satisfy a standard of care for effective pain relief.³⁹ Others have recommended the development of a comprehensive, coordinated, national policy to address the inadequate management of pain, rather than the patchwork of state and federal policies in existence.⁴⁰ Still others have questioned the appropriateness of criminal liability for prescribers under the CSA and instead supported an increased role for state medical boards in policing physician controlled substance prescribing.⁴¹ Many of these viewpoints, however, relied on older science that supported the effectiveness of opioids for treating chronic, non-cancer pain—a clinical viewpoint that is now regularly challenged and up for debate.⁴² Concerns with under-prescribing now must be balanced with those about over-prescribing, given our current epidemic of prescription drug misuse.

B. THE RISE OF PRESCRIPTION PAINKILLER MISUSE

Prescription opioid misuse in the United States has risen to epidemic proportions in recent years. Nonmedical use⁴³ of prescription drugs occurs in four therapeutic classes (pain relievers, tranquilizers, stimulants, and sedatives); opioid pain relievers, however, are the most commonly misused medication by far.⁴⁴ The percentage of Americans aged twenty and older who nonmedically use pain relievers in a month has held relatively stable at around seven percent over the past decade, after increasing from five percent between 1999–2002.⁴⁵ However, this statistic fails to capture an increase in the intensity of use and misuse. For

38. See Michael J. Reynolds, *Morphine or Malpractice: Should Courts Recognize a Legal Duty to Prescribe Opiates for Treating Chronic Pain*, 15 J. C.R. & ECON. DEV. 79 (2000); Barry R. Furtow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28, 30–36 (2001); Gilah R. Mayer, Comment, *Bergman v. Chin: Why an Elder Abuse Case Is a Stride in the Direction of Civil Culpability for Physicians Who Undertreat Patients Suffering from Terminal Pain*, 37 NEW ENG. L. REV. 313 (2003).

39. Furtow, *supra* note 38, at 37–42; Ben A. Rich, *The Politics of Pain: Rhetoric or Reform?*, 8 DEPAUL J. HEALTH CARE L. 519, 542 (2005).

40. Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 135 (2004).

41. Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21, 22 (2003); Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS J. HEALTH L. & POL'Y 231 (2008).

42. See NAT'L INSTS. OF HEALTH, *PATHWAYS TO PREVENTION: THE ROLE OF OPIOIDS IN THE TREATMENT OF CHRONIC PAIN* 35 (2014) (suggesting that for most patients, there are likely to be more effective approaches to managing chronic pain than opioid therapies).

43. For a definition of “nonmedical use,” see *State Estimates of Nonmedical Use of Prescription Pain Relievers*, NAT'L SURVEY ON DRUG USE & HEALTH (Jan. 8, 2013), <http://www.samhsa.gov/data/sites/default/files/NSDUH115/NSDUH115/sr115-nonmedical-use-pain-relievers.htm>.

44. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 6, at 15–18.

45. STEVEN M. FRENK ET AL., *PRESCRIPTION OPIOID ANALGESIC USE AMONG ADULTS: UNITED STATES, 1999–2012* 1–2 (2015).

example, from 1999–2002 to 2011–2012, the percentage of opioid analgesic users who used a stronger-than-morphine equivalent opioid (per dose) in the past thirty days increased from seventeen percent to thirty-seven percent.⁴⁶

Moreover, adverse health consequences resulting from prescription drug misuse—including overdose events, emergency department (“ED”) visits, and inpatient admissions—have escalated dramatically. Fatal opioid overdoses exploded from 1.4 per 100,000 people in 1999 to 9.0 per 100,000 people in 2014.⁴⁷ The rate of emergency department visits involving nonmedical use of prescription drugs—primarily of opioids—more than doubled from 214 visits per 100,000 people in 2004 to 458 in 2011.⁴⁸ About half of these deaths and ED visits also involved at least one other drug, including benzodiazepines, cocaine, or heroin.⁴⁹ The proportion of substance abuse treatment admissions citing pain reliever misuse also more than quadrupled from 1998 and 2008.⁵⁰

Prescription opioid use and misuse persists among people from diverse demographic backgrounds, albeit certain groups exhibit slightly higher rates of use and overdose risk. Adults aged forty and older are slightly more likely to use opioid analgesics than adults aged twenty to thirty-nine; women are slightly more likely than men to use opioids; and non-Hispanic white adults are more likely to use prescription painkillers than Hispanic adults.⁵¹ People at heightened risk for opioid overdose include women, those consuming high daily doses of opioids, those taking medication for chronic pain, “doctor-shoppers,”⁵² users of multiple abusable substances, and those with substance abuse or other mental health issues.⁵³

46. *Id.* at 2.

47. CHEN ET AL., *supra* note 3, at 2; Rudd et al., *supra* note 3, at 1378.

48. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE DAWN REPORT: HIGHLIGHTS OF THE 2011 DRUG ABUSE WARNING NETWORK (DAWN) FINDINGS ON DRUG-RELATED EMERGENCY DEPARTMENT VISITS 5 (2013).

49. *Id.*; WARNER ET AL., *supra* note 3, at 1.

50. EXEC. OFFICE OF THE PRESIDENT, 2010 NATIONAL SURVEY ON DRUG USE AND HEALTH: HIGHLIGHTS (2011).

51. FRENK ET AL., *supra* note 45, at 3–6.

52. Clinical definitions of “doctor shoppers” differ. See Scott G. Weiner et al., *Characteristics of Emergency Department “Doctor Shoppers,”* 48 J. EMERGENCY MED. 424, 425 (2014) (defining “doctor shoppers” as patients that had eight or more Schedule II-V prescriptions filled from eight or more providers in one year); Douglas C. McDonald & Kenneth E. Carlson, *Estimating the Prevalence of Opioid Diversion by “Doctor Shoppers” in the United States,* 8 PLOS ONE 1, (2013) (using different thresholds to define “doctor shoppers” to estimate opioid diversion prevalence). See Joseph Logan et al., *Opioid Prescribing in Emergency Departments: The Prevalence of Potentially Inappropriate Prescribing and Misuse,* 51 MED. CARE 646 (2013) (identifying the following as indicators of potential inappropriate use: opioid prescriptions overlapping by one week or more; overlapping opioid and benzodiazepine prescriptions; high daily doses of greater than or equal to 100 morphine milligram equivalents; long-acting/extended-release (“LA/ER”) opioids for acute pain; and overlapping LA/ER opioids).

53. Kate M. Dunn et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study,* 152 ANNALS INTERNAL MED. 85, 87–91 (2010); Amy S.B. Bohnert et al., *Association Between Opioid*

There is little room for optimism. Evidence from 2011–2013 did indicate a leveling off in opioid prescribing rates and overdoses nationally,⁵⁴ which some researchers attributed to the August 2010 reformulation of OxyContin to a more tamper-resistant form.⁵⁵ However, more recent evidence shows that national prescription opioid overdose death rates again significantly increased from 2013–2014,⁵⁶ suggesting that existing policy interventions may not be sufficient to tackle the epidemic. Over this same period, moreover, heroin abuse rates increased, suggesting that some—though not all—prescription drug misusers switched to an illegal, cheaper, and deadlier alternative when they could no longer access prescription opioids.⁵⁷

C. REGULATORY RESPONSES

Federal and state policymakers, among others, have responded with a multitude of interventions to address opioid misuse and overdoses. TABLE I catalogues prominent interventions and identifies the stakeholders that typically take these measures. Although not exhaustive, this list illustrates the many strategies available and the complex array of implementers. These strategies are characterized within the public health prevention paradigm used for epidemiologic responses to other communicable and non-communicable diseases. Opioid addiction—compulsive opioid seeking and use despite the often negative consequences⁵⁸—is the chronic disease that can result from prescription opioid misuse.⁵⁹

Addiction prevention strategies can be organized into categories that focus on: (1) *primary prevention* of new cases of opioid addiction; (2) *secondary prevention* to identify and treat early cases of addiction; and

Prescribing Patterns and Opioid Overdose-Related Deaths, 305 JAMA 1315, 1315–21 (2011); Alan G. White et al., *Analytic Models to Identify Patients at Risk for Prescription Opioid Abuse*, 15 AM. J. MANAGED CARE 897, 897–906 (2009); B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 DRUG & ALCOHOL DEPENDENCE 99 (2010). See Anupam B. Jena et al., *Opioid Prescribing by Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims*, 348 BRITISH MED. J. 1393 (2014) (finding that concurrent opioid prescribing by multiple providers in Medicare patients is associated with higher rates of opioid-related hospital admissions).

54. See Dart et al., *supra* note 7, at 241.

55. *Id.*; Marc R. Laroche et al., *Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene*, 175 JAMA INTERNAL MED. 978 (2015); CICERO & ELLIS, *supra* note 7, at 424.

56. Rudd et al., *supra* note 3, at 1378–79.

57. Dart et al., *supra* note 7; Laroche et al., *supra* note 55; Brian Owens, *Tackling Prescription Drug Abuse*, THE PHARMACEUTICAL J. (June 11, 2015), <http://www.pharmaceuticaljournal.com/news-and-analysis/features/tackling-prescription-drug-abuse/20068685.article?adfesuccess=1>; Compton et al., *supra* note 7.

58. U.S. DEP'T OF HEALTH & HUMAN SERVS., PRESCRIPTION DRUG ABUSE 3 (2014). Addiction can also include physical dependence, or where an individual experiences withdrawal symptoms when use of a drug is suddenly stopped or reduced. *Id.*

59. Kolodny et al., *supra* note 18, at 565.

(3) *tertiary prevention* to effectively treat those already addicted.⁶⁰ The goal of primary prevention is to reduce the incidence of disease—in this case, to prevent the initiation of opioid addiction. Prescriber guidelines are an example of primary prevention, because they seek to encourage more informed opioid prescribing. Secondary prevention measures aim to identify and treat a serious health condition after onset but before serious complications ensue,⁶¹ such as detecting doctor shoppers by means of a PDMP. Finally, tertiary prevention measures provide therapy and rehabilitation once a disease is firmly established.⁶² Access to the opioid antagonist drugs (such as naloxone) is an example of tertiary prevention.

Undoubtedly, some combination of these prevention measures is required to comprehensively address prescription opioid-related morbidity and mortality—but which specific interventions are most worthwhile to pursue? This Article focuses on a specific type of intervention: prescription drug monitoring programs, which will be referred to as “PDMPs” throughout. Other prevention measures are unquestionably key components to comprehensively addressing the epidemic, but PDMPs are a popular, state-level, legal mechanism that have gained the reputation of having incredible promise for addressing opioid misuse.⁶³ They primarily target prescribing, a significant upstream driver of prescription opioid misuse because it serves as the prerequisite to most opioid addiction—whether by initial prescription, repeat prescriptions, or obtaining drugs from friends or family members or diverters.⁶⁴ And, PDMPs have experienced widespread—albeit disorganized—roll-out among the states, such that policies exhibit widely varying features not rigorously informed by evidence or systematic criteria for determining their success.

60. *Id.* at 565–69.

61. *Id.*

62. *Id.*

63. Chakravarthy et al., *supra* note 13, at 424.

64. Wilson M. Compton et al., *Prescription Opioid Abuse: Problems and Responses*, 80 PREVENTIVE MED. 5 (2015). See Jones et al., *supra* note 9, at 802–03 (underscoring the need to target prescribers, as they commonly source opioids to frequent users).

TABLE I. INTERVENTIONS TO CURB PRESCRIPTION DRUG MISUSE

Stage	Objective	Examples of Interventions	Implementing Stakeholders
Primary prevention	Prevent initiation of prescription opioid addiction	Opioid prescriber education and guidelines*	<ul style="list-style-type: none"> • State and local governments • Health care providers • Federal government <ul style="list-style-type: none"> ○ U.S. Food and Drug Administration (“FDA”): Risk Evaluation and Mitigation Strategy (“REMS”)⁶⁵ required of extended-release/long-acting (“ER/LA”) opioid drug sponsors
		Pain management clinic (“pill mill”) ⁶⁶ regulation*	<ul style="list-style-type: none"> • State governments • Federal government <ul style="list-style-type: none"> ○ Drug Enforcement Agency (“DEA”)
		Opioid drug approval*	<ul style="list-style-type: none"> • Federal government <ul style="list-style-type: none"> ○ FDA:REMS required for ER/LA opioids
		Abuse-deterrent drug formulations*	<ul style="list-style-type: none"> • Opioid drug developers
		Medication take-back or disposal programs*	<ul style="list-style-type: none"> • Federal government <ul style="list-style-type: none"> ○ DEA • State or local governments • Retail pharmacies
Secondary prevention	Identify and treat prescription opioid addiction after onset but before serious complications develop	Prescription drug monitoring programs**	<ul style="list-style-type: none"> • State governments • Insurers
		Urine testing for drugs**	<ul style="list-style-type: none"> • Health care providers • Insurers
		Drug supply management ** <ul style="list-style-type: none"> • Formulary development • Quantity limits • Reimbursement incentives 	<ul style="list-style-type: none"> • Insurers • Pharmacy benefit managers
		Anti-“doctor shopping” laws ⁶⁷	<ul style="list-style-type: none"> • State and local governments

65. Under the Food and Drug Administration Amendments Act (“FDAAA”) of 2007, REMS was introduced as a risk-management strategy intended to reduce known or serious safety hazards associated with a drug or biologic product. The FDAAA grants the FDA authority to require sponsors to submit a REMS prior to drug approval if it determines that such a measure is necessary to ensure that drug benefits outweigh risks, or after approval if new safety information emerges to necessitate such a strategy. INST. OF MED., ETHICAL & SCI. ISSUES IN STUDYING THE SAFETY OF APPROVED DRUGS 42–43 (2012). *See infra* note 152 for a discussion of the REMS for ER/LA opioid medications.

66. “Pill mills” are those facilities where pain management is the primary practice component, or which provide pain treatment to a majority (greater than fifty percent) of patients, or both. CTRS. FOR DISEASE CONTROL & PREVENTION, MENU OF PAIN MANAGEMENT CLINIC REGULATION I (2012).

Stage	Objective	Examples of Interventions	Implementing Stakeholders
Tertiary prevention	Address firmly established opioid addiction through therapeutic or rehabilitative measures	Opioid addiction treatment	<ul style="list-style-type: none"> • Insurers • Health care providers • Governments (federal, state, local)
		Access to opioid overdose reversal drugs	<ul style="list-style-type: none"> • State and local governments • Insurers and PBMs
		Syringe exchange programs	<ul style="list-style-type: none"> • State and local governments • Non-governmental organizations

* These interventions can also be considered secondary prevention measures.

** These interventions could be considered primary, secondary, or tertiary prevention measures, because they aim to identify either misusers or diverters and prevent them from accessing opioids (which can then be passed on to “unexposed” persons) and can be used to direct misusers into treatment programs.

I. State PDMPs

State PDMPs are the most prevalent state policy mechanism used to address prescription drug misuse, with forty-nine states and the District of Columbia having enacted programs.⁶⁸ PDMPs digitally store controlled substance dispensing information in a centralized, statewide database and make that information accessible to “authorized users,” including prescribers, pharmacists, and sometimes law enforcement officials and state medical boards.⁶⁹ When they query the system about a patient, authorized users typically see the dose, supply, and prescriber of scheduled drugs that the patient has recently filled.⁷⁰ Authorized users can only access the data with log-in credentials provided upon registering with the PDMP.

PDMPs seek to satisfy many goals, most prominently to support providers in facilitating the legitimate medical use of controlled substances, while avoiding prescription drug misuse.⁷¹ Armed with PDMP-supplied information about a patient, prescribers and pharmacists can communicate

67. “Doctor shopping” is defined as when a patient obtains controlled substances from multiple healthcare providers without the prescribers’ knowledge of the other prescriptions. *CTRS. FOR DISEASE CONTROL & PREVENTION, DOCTOR SHOPPING LAWS 1* (2012).

68. *NAT’L ALL. FOR MODEL STATE DRUG LAWS, ANNUAL REVIEW OF PRESCRIPTION MONITORING PROGRAMS 2* (2014).

69. *PRESCRIPTION DRUG MONITORING PROGRAM CTR. OF EXCELLENCE AT BRANDEIS, BRIEFING ON PDMP EFFECTIVENESS 3* (2014).

70. Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 *JAMA* 891 (2015).

71. *KRISTIN FINKLEA ET AL., CONG. RESEARCH SERV., PRESCRIPTION DRUG MONITORING PROGRAMS 3* (2014) (additionally identifying public health trend surveillance as a PDMP purpose).

with the patient about his or her prescription histories, address potentially dangerous co-prescribing of substances, refrain from supplying opioids to a doctor shopper⁷² or diverter, comfortably provide prescription drugs to an individual who doesn't raise concerns about misuse, and direct individuals into substance abuse treatment therapy when clinically indicated.⁷³ When enough providers share dispensing information and access patient profiles via PDMPs, opioid misusers and diverters have a harder time "gaming" the system by seeking drugs from multiple providers or pharmacies. As well, PDMPs are intended to help regulators investigate clinicians with inappropriate prescribing and dispensing patterns as well as patients with drug fill behaviors indicative of misuse or diversion.⁷⁴ In sum, PDMPs aim to improve individual as well as population health, by improving prescribing and dispensing decisions made for each patient, and by limiting the negative externalities generated by the over-supply of opioids.⁷⁵

State legislatures create PDMPs by statute and outline program details by regulation, often leaving many of the operational particulars to the executive agency in which the program is housed.⁷⁶ Advances in information technology facilitated state implementation of electronic PDMPs in the 1990s–2000s.⁷⁷ These programs succeeded earlier, less-widespread paper prescription monitoring systems (also known as carbon copy or triplicate paper programs), the first of which was created in California in 1939.⁷⁸ Since the first electronic PDMP was established in Oklahoma in 1990, these programs have rapidly proliferated.⁷⁹ In 2001, sixteen states had authorized the creation of a program by statute; and by June 2012, forty-nine states and one territory had passed such laws (with forty-one states having an operational program).⁸⁰ Today, every state except Missouri has an operational PDMP.⁸¹

72. See *supra* note 52 for clinical definitions of "doctor shoppers."

73. Haffajee et al., *supra* note 70, at 891.

74. FINKLEA ET AL., *supra* note 71, at 3.

75. See G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308 JAMA 1865, 1865–66 (2012) (suggesting that a public health approach to the treatment of pain calls for greater clinical judiciousness in prescribing of opioids given the harmful effects that clinicians' treatment decisions have on other individuals beyond the patient being treated).

76. PDMPs are most commonly housed within health agencies or boards of pharmacy, although some are housed within law enforcement or other agencies. The housing agency distributes PDMP data to individuals authorized under state law to receive the information. Richard A. Deyo et al., *Measures Such as Interstate Cooperation Would Improve the Efficacy of Programs to Track Controlled Drug Prescriptions*, 32 HEALTH AFF. 603, 604 (2013).

77. *Id.*

78. *Id.*

79. THOMAS CLARK ET AL., *PRESCRIPTION DRUG MONITORING PROGRAMS: AN ASSESSMENT OF THE EVIDENCE FOR BEST PRACTICES 3*, THE PRESCRIPTION DRUG MONITORING PROGRAM CTR. OF EXCELLENCE, BRANDEIS UNIV. (2012).

80. *Id.* at 5.

81. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 2.

PDMPs vary widely along a number of dimensions,⁸² including: who can query the data (and for what purposes);⁸³ whether unsolicited reports are sent to users;⁸⁴ whether prescribers and/or dispensers can delegate access to an authorized agent;⁸⁵ whether notification of a patient is required when his/her data is accessed;⁸⁶ the extent to which data is shared with other states;⁸⁷ how frequently the data is updated;⁸⁸ and whether training is required for users.⁸⁹ PDMPs increasingly monitor (or track) drugs that are included in Schedules II through V of the DEA's controlled substances schedules.⁹⁰ Recent innovations gaining traction with states include mandates that clinicians query the data for information regarding a patient, under specified circumstances.⁹¹ Also on the PDMP policy horizon is the integration of PDMP data into clinical

82. See *id.* for an updated comparison of program features. See generally Deyo et al., *supra* note 76, at 605–07 (describing the variations in program design and controversies surrounding prescription drug monitoring programs).

83. Forty-eight states include prescribers, dispensers, licensing boards, and law enforcement officials as “authorized users.” Only eighteen states require law enforcement to access the data only with a warrant, subpoena, or other judicial process, whereas thirty states allow such access pursuant merely to an active investigation. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 25–26, 31.

84. Forty-five states send unsolicited reports to individuals varying from prescribers, to law enforcement officials, to licensing officials. The triggers for and information included in these reports vary widely. *Id.* at 45.

85. In thirty-four states, prescribers and/or dispensers can delegate access to an agent who can log into the system on their behalf. Agents can include a physician's assistant, nurse practitioner, pharmacy technician, or other health personnel. *Id.* at 21.

86. Patients must be notified when their PDMP data is accessed in eleven states. *Id.* at 9.

87. Although forty-five states have authorized interstate data sharing, only thirty-two states currently share data. *Id.* at 34; *Interstate Data Sharing*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR. (Aug. 2015), http://www.pdmpassist.org/pdf/Interstate_Data_Sharing.pdf (last visited Aug. 5, 2016).

88. Over half of state PDMPs update the data weekly or less frequently, while only one program offers real-time data. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 12–13.

89. PDMP training is required of authorized users in only thirteen states, although most states offer optional training. *Id.* at 36.

90. Schedule I drugs have high misuse potential and are not prescribed legally (they currently have no medically accepted use in the United States)—thus, drugs such as heroin or ecstasy cannot be tracked. Schedule II drugs are those with a high potential for misuse but a medically accepted use, such as oxycodone, morphine, and stimulants. Schedule III drugs are those with moderate misuse potential and a medically accepted use, such as buprenorphine. Schedule IV drugs are those with low misuse potential and a medically accepted use, such as benzodiazepines and hypnotics. Finally, Schedule V drugs are those with the lowest potential for misuse and a medically accepted use, such as cough syrups with codeine and anti-diarrheals. Controlled Substances Act, 21 U.S.C. § 801 (West 2016).

91. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 3, 40 (identifying twenty-four states as having some form of mandate, although conditions and exemptions vary widely). See Haffajee et al., *supra* note 70, at 891–92 (outlining the pros and cons of requiring prescribers to participate in querying PDMP systems, and arguing that while mandates may be called for, given the magnitude of prescription drug misuse and early indications of mandate effectiveness, more robust evidence and guidelines to support their implementation are necessary to avoid potentially dire unintended consequences—such as under-prescribing of opioids for legitimate pain).

workflow (such as electronic medical records) and improved interstate sharing of data to track those individuals who travel across state lines in pursuit of prescription drugs.⁹²

PDMPs are perhaps so attractive because they hold the potential to both facilitate legitimate prescribing of controlled substances, and also mitigate prescription drug misuse.⁹³ The appropriate prescribing of controlled substances can reduce their misuse and diversion. At the same time, law enforcement, licensing board, and surveillance efforts can protect the public's health by limiting diversion.⁹⁴

Despite these best intentions, we do not have a firm understanding of PDMPs' effectiveness, nor of the potential for unintended PDMP consequences or other legal or ethical quagmires. Interest groups, however, have attempted to identify a number of PDMP "best practices" to help guide their implementation. They include the following: a comprehensive list of drugs monitored; unsolicited reporting to providers; medical provider education on PDMP use; a wide array of authorized users; real-time or frequent data collection; interstate sharing of data; and disclosure of de-identified data for research purposes.⁹⁵ These characteristics appear to be identified largely based on face validity and anecdotal or associative observations, rather than rigorous evidence.⁹⁶ In short, justification for these features is wanting. The framework presented herein can assist in systematically analyzing PDMP effectiveness, legality, and normative appeal, with the goal of identifying desirable features that, if adopted, could facilitate the achievement of public health goals and increase the likelihood that these policies will succeed.

II. A FRAMEWORK FOR EVALUATING PDMP SUCCESS

State policymakers stand to benefit from an evaluative framework that can be used to assess the success of PDMP efforts at curbing prescription drug misuse for several reasons. First, the rapid escalation and magnitude of the prescription drug misuse and overdoses—with forty-four people in the United States now dying every day from prescription painkiller overdose⁹⁷—are remarkable and somewhat

92. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 3.

93. *Id.*; CLARK ET AL., *supra* note 79, at 5.

94. CLARK ET AL., *supra* note 79, at 5.

95. *Id.*; NAT'L CONFERENCE OF INS. LEGISLATORS, PROPOSED BEST PRACTICES TO ADDRESS OPIOID ABUSE, MISUSE AND DIVERSION §§ 1–4 (2013).

96. CLARK ET AL., *supra* note 79 (reviewing the PDMP evidence comprehensively but failing to differentiate between studies appropriate for causal inference—that is, those that demonstrate effects attributable to PDMPs—and those of a merely associative or anecdotal nature). *See infra* Parts III.B.2–3 for further discussion on evaluating PDMP effectiveness.

97. *Drug Overdose Deaths in the United States Hit Record Numbers in 2014*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited Aug. 5, 2016).

unprecedented. Such a crisis warrants a robust and effective response, which has led to rapid dissemination across the states of new legal approaches, including PDMPs, before their effects have been thoroughly evaluated. Second, the intervention possibilities—from various PDMP features to other types of interventions altogether (see TABLE I for a non-exhaustive list)—are numerous and could be overwhelming to policymakers. Third, some indications of a leveling of opioid prescribing and misuse from 2011–2013 are encouraging, but naturally beg the question: Can we attribute any of these changes to state PDMPs?

It is incumbent upon policymakers at all levels to implement the most prudent set of interventions possible to target prescription opioid misuse, given current knowledge and limited resources. The states are a reasonable and critical locus for policymaking.⁹⁸ This Article does not mean to imply that states are the exclusive or always optimal level at which to regulate.⁹⁹ Indeed, the federal government is very involved in regulation of controlled substances, particularly under the CSA and via FDA drug approval (see TABLE I). However, the states have broadly regulated to address prescription drug misuse and overdose using their plenary powers to police the health, safety, and welfare of their citizens.¹⁰⁰ As compared to the federal government, states are closer in proximity to these issues: They can better tailor prevention strategies to the specific nature of and variation in prescribing and misuse risks across their jurisdictions, and are directly accountable to their citizens when it comes to adverse health and related consequences.¹⁰¹ Moreover, states have typically assumed authority over the practice of medicine and other health professions as well as health more generally,¹⁰² and thus the

98. See Garcia, *supra* note 10, at 43.

99. See Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J.L. & MED. 85, 86–87 (2014) (advocating for a national prescription drug reporting program that builds upon pharmacy benefit manager networks to crack down on prescription drug misuse); see also Roger S. Magnusson, *Mapping the Scope and Opportunities for Public Health Law in Liberal Democracies*, 35 J.L. MED. & ETHICS 571, 572 (2007) (noting that public health regulatory functions are “shared” between different tiers of government, and together these elements at the national and sub-national levels create a range of specific laws, processes, and remedies for improving health outcomes).

100. States have initiated many prominent laws to address prescription drug misuse and overdose beyond PDMPs. Other legal strategies include pain clinic (or “pill mill”) laws; drug dose and limit laws; physical examination requirements; doctor shopping laws; tamper-resistant form requirements; prescription drug identification laws; and Good Samaritan laws that provide protection to those who reasonably assist others experiencing misuse or overdose. See *Public Health Law Program: State Laws on Prescription Drug Misuse and Abuse*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/phlp/publications/topic/prescription.html> (last visited Aug. 5, 2016).

101. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 118 (2d ed. 2008); Scott Burris & Evan Anderson, *Legal Regulation of Health-Related Behavior: A Half Century of Public Health Law Research*, 9 ANN. REV. L. & SOC. SCI. 95, 107 (2013).

102. See *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954); Michelle M. Mello & Kathryn Zeiler, *Disease Prevention and Health Outcomes, Empirical Health Law Scholarship: The State of the Field*, 96 GEO. L.J. 649, 654 (2008) (noting that states have been the primary site of lawmaking for important

prescribing of controlled substances (the source of most prescription drugs that are misused) falls squarely within their purview. This Article addresses the balance of regulation between state and federal governments as it relates to how states can best target PDMPs,¹⁰³ but it does not cover non-governmental-based initiatives.

The separation of public health powers among different branches of government, albeit fundamental to the way policies are conceived and carried out, is not a focus of this Article. “State policymakers” or “state regulators,” as referred to herein, signify members of both the legislative and executive branches of state governments. Members of the legislature, who are elected and politically accountable to the public, are typically responsible for creating health policy and allocating resources required to carry it out.¹⁰⁴ Executive agencies, most notably departments of public health,¹⁰⁵ assume increasingly expansive public health functions in the states—ranging from proposing laws to the legislature, to issuing rules to carry out policy, to enforcing policy.¹⁰⁶ The framework proposed views state policymakers as a monolithic group, capable of dividing and delegating public health powers as between themselves efficiently and in accordance with administrative law requirements.

This discussion also focuses on state *public health laws*,¹⁰⁷ namely PDMPs, rather than other types of interventions.¹⁰⁸ Law is increasingly recognized as an important determinant of health and a valuable and effective tool in the public health arsenal.¹⁰⁹ Law has been shown to have a powerful impact in a number of public health domains, such as motor

aspects of health markets, including public health-related areas such as seatbelt and workplace wellness, tobacco and alcohol, and unhealthful food and beverages in schools).

103. See *infra* Part II.A.2.

104. GOSTIN, *supra* note 101, at 83.

105. *Id.* at 161.

106. *Id.* at 83–84, 166–69.

107. “Public health law” has been famously defined by Lawrence O. Gostin as “the study of the legal powers and duties of government to assure the conditions for people to be healthy (that is, to identify, prevent, and ameliorate risks to health in the population), and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health.” *Id.* at 4. Themes that emerge from this definition and that will recur throughout this Article include: “(1) government power and duty, (2) coercion and limits of state power, (3) government partners in the ‘public health system,’ (4) the population focus, (5) communities and civic participation, (6) the prevention orientation, and (7) social justice.” Lawrence O. Gostin, *A Theory and Definition of Public Health Law*, 10 J. HEALTH CARE L. & POL’Y 1, 1 (2007).

108. Magnusson, *supra* note 99, at 572 (observing that law is only one of a multitude of “modes” of regulation that reflect different strategies toward compliance and enforcement).

109. Mello et al., *supra* note 15, at 1979 (discussing law’s recent success in preventing childhood lead poisoning and workplace injuries). See Scott Burris et al., *Making the Case for Laws That Improve Health: A Framework for Public Health Law Research*, 88 MILBANK Q. 169, 170 (2011); Wendy E. Parmet, *The Individual Mandate: Implications for Public Health Law*, 39 J.L. MED. & ETHICS 401, 411 (2011).

vehicle safety, particularly when based on robust evidence.¹¹⁰ Specifically, state laws are starting to proliferate in public health: The adoption of legal interventions in a number of areas (PDMPs included) over the past several decades has followed a steep curve from initial adoption in one jurisdiction to nearly fifty-state saturation.¹¹¹ Non-legal interventions are also critical to addressing opioid misuse and the public's health more generally, but the use of PDMP laws—"on the books" (such as constitutions, statutes, rules, and judicial opinions) and as implemented in practice¹¹²—by policymakers to address opioid misuse constitutes the focus of this discussion.

This Article articulates a framework to assist state lawmakers' decisionmaking when considering whether and how to respond to a significant public health threat, and uses it to directly guide PDMP implementation.¹¹³ This framework, which can be generalized to contexts beyond prescription drug misuse, sets forth key criteria with which to justify and assess public health laws—both when considering initial policy enactment and in evaluating regulations once implemented. The goal is to identify the optimal *form* that a public health law should take once a serious public health challenge has been identified. Broadly, the evaluative criteria include: (1) legal powers to regulate and barriers to implementation; (2) effectiveness of regulation; and (3) ethical and normative considerations.

This evaluative framework integrates and builds upon earlier public health law scholarship, including work on evidence-based lawmaking¹¹⁴ and justificatory conditions for public health legal interventions.¹¹⁵ Mello and Zeiler outline an ideal iterative process of research and policymaking that a health law, informed by evidence, would take—a so-called "lifecycle" for an empirical health law success story.¹¹⁶ In their lifecycle, society first identifies a significant public health risk factor derived from

110. Burris & Anderson, *supra* note 101, at 107.

111. *Id.*

112. Burris et al., *supra* note 109, at 174–75. "Legal interventions," as discussed herein, may include a full range of government use of legal authority, such as adoption of new laws, amendments or clarifications to existing laws, and removal of laws thought to be ineffective. Mello et al., *supra* note 15, at 1980.

113. Gostin has outlined at least five models, or levers, for legal intervention designed to prevent injury and disease and promote the public's health: (1) the power to tax and spend; (2) the power to alter the informational environment; (3) direct regulation of individuals (such as motorcycle helmet laws), professionals (such as licenses), or businesses (such as inspections); (4) indirect regulation through the tort system; and (5) deregulation. Lawrence O. Gostin, *Public Health Law: A Renaissance*, 30 J.L. MED. & ETHICS 136, 137–38 (2002). This Article deals primarily with the first three intervention levers, or affirmative regulatory acts engaged in by policymakers.

114. See generally Mello & Zeiler, *supra* note 102; Burris et al., *supra* note 109 (discussing the newly founded Public Health Law Research Program and its mission, structure, and goals).

115. See generally GOSTIN, *supra* note 101 (discussing the legal foundations of public health research).

116. See Mello & Zeiler, *supra* note 102, at 668–69.

clear epidemiological evidence.¹¹⁷ Risk factors are exposures or attributes that are associated with an increased likelihood of developing a disease or injury.¹¹⁸ *Significant* risk factors can be characterized as variables that greatly increase the risk of developing a disease, or those that are associated with severe harm. Second, in response to such risks, policymakers, researchers, or other key stakeholders may propose and experiment with innovative legal solutions, among other types of policy responses.¹¹⁹ Third, these experiments should be evaluated by researchers and policymakers, ideally in cooperation. Finally, those public health laws identified as successful should be retained, strengthened, and replicated in additional jurisdictions, while those deemed unsuccessful should be abandoned (or amended) in favor of policy alternatives.¹²⁰

Lawrence Gostin has articulated certain prerequisite conditions for public health laws, reminding us that regulation is not justified merely in the name of population health.¹²¹ Such laws must be defended given that they incur public and private costs and can impact the legitimacy of future policymaking.¹²² Gostin thus proposes five criteria with which to evaluate whether a public health regulation is warranted: (1) significant risk; (2) effectiveness; (3) economic cost; (4) burden on individuals; and (5) fairness.¹²³

FIGURE 1 lays out the four stages articulated in Mello and Zeiler's lifecycle,¹²⁴ but goes a step further to specify the specific criteria with which to actually evaluate policy experiments and the ways in which these criteria should be applied to justify any particular law's existence. Innovative concepts incorporated into this figure include: (1) that evaluative criteria should be applied both at the law adoption stage as well as the retrospective evaluation (of existing policy) stage; (2) that the evaluation should be an ongoing process, rather than a one-time occurrence; and (3) that states should revisit a policy upon each round of evaluation to consider whether to retain, amend, or abandon a law.

Moreover, the specific evaluative criteria set forth in FIGURE 1 differ from Gostin's in several key regards. First, whereas Gostin does not focus on a particular level of authority or jurisdiction, these criteria are intended to organize *state* policymaker inquiries with respect to implementing public health laws. Second, the criteria explicitly recognize legality as a consideration to be incorporated into evaluation. Third, they re-

117. *Id.* See GOSTIN, *supra* note 101, at 55.

118. *Health Topics: Risk Factors*, WORLD HEALTH ORG., http://www.who.int/topics/risk_factors/en/ (last visited Aug. 5, 2016).

119. Mello & Zeiler, *supra* note 102, at 669.

120. *Id.*

121. GOSTIN, *supra* note 101, at 43–76.

122. *Id.*

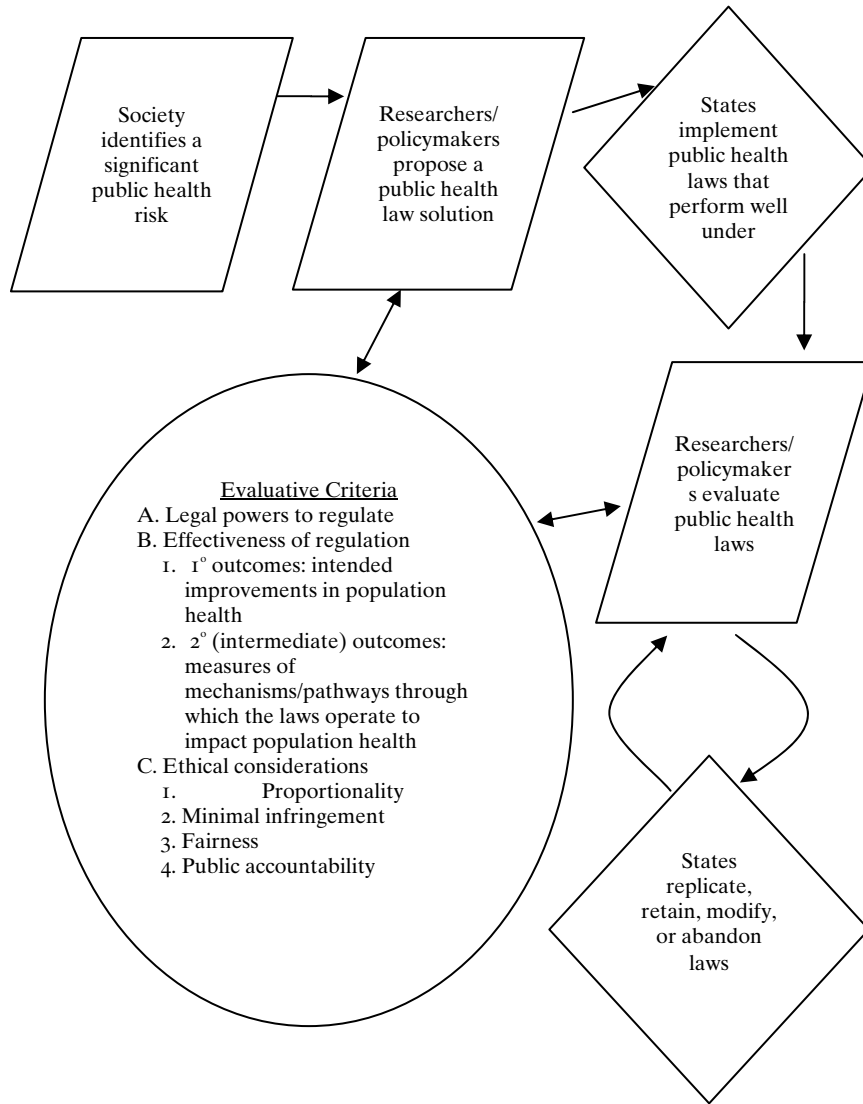
123. *Id.* at 55.

124. Mello & Zeiler, *supra* note 102, at 668.

characterize and substantially expand upon the inquiries regarding policy effectiveness and ethical appeal, drawing upon principles of research design and practice-based public health ethics, respectively. The key evaluative criteria further detailed below do not necessarily need to be “satisfied” per se, but should be considered carefully and compared between policy options, if multiple exist. Performing favorably under these criteria lends credibility to public health laws and enhances state policymaker and stakeholder confidence in their value. Consideration of these criteria also may help to address issues of antiquity, inconsistency, redundancy, and ambiguity that can render state public health laws ineffective.¹²⁵ In the discussion that follows, the three criteria will be outlined and directly applied to PDMPs in an effort to organize and inform this policymaking agenda.

125. Gostin, *supra* note 113, at 136–37 (discussing entrenched problems with state public health laws—that is, that they are often outdated, built up in layers over varying periods of time, and very fragmented among the fifty states—that call for reform so that law conforms with modern scientific and legal standards, is consistent across jurisdictions, and is more uniform in how it addresses different types of health threats).

FIGURE I. FRAMEWORK FOR EVALUATING STATE PUBLIC HEALTH LAWS



A. LEGAL POWERS TO REGULATE

A threshold inquiry for state policymakers when considering PDMPs and other public health laws is whether the requisite legal powers to regulate exist, and/or whether legal barriers may frustrate implementation. This inquiry drives to the heart of longstanding debates about the appropriate balance of public health powers between different levels of government, and constitutional limits on such powers in the name of civil liberties. Legal powers, duties, and restraints, to use Gostin's terms,¹²⁶ define the space available for public health intervention and should be considered dynamically, given the potential for changes in judicial interpretation of these parameters. State policymakers should specifically ask: (1) whether they have the affirmative constitutional power to act to promote or protect the public's health; (2) whether the actions planned or taken exceed their powers by encroaching upon regulatory territory already occupied by the federal government; and (3) whether the law in question infringes upon protected individual rights.¹²⁷

In general terms, state implementation of PDMPs stands on solid legal footing. Nevertheless, the ways in which PDMPs are designed raise a number of legal issues that warrant consideration, including the federal government's possible role in program implementation, privacy issues associated with the retention of personal health information in the databases, and the use of the data by law enforcement and licensing boards.

1. *Federalism and the Power to Regulate the Public's Health*

Federalism divides available lawmaking power between two levels of government: federal and state.¹²⁸ The federal government acts with limited, enumerated powers granted by the Constitution, while the remaining powers, including the police power, are left to the states.¹²⁹ State governments have long held the authority, and sometimes duty,¹³⁰

126. GOSTIN, *supra* note 101.

127. See James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 311 (1998).

128. GOSTIN, *supra* note 101, at 78.

129. Hodge, Jr., *supra* note 127, at 311. The Tenth Amendment states: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved for the States respectively, or to the people." U.S. CONST. amend. X.

130. The Constitution is largely cast in negative terms, particularly with respect to public health protection among the states. See, e.g., *DeShaney v. Winnebago Cty. Dep't of Soc. Servs.*, 489 U.S. 189 (1989) (holding that the Wisconsin State Department of Social Services had no affirmative duty to provide protection to a four-year-old boy who was beaten severely and incurred permanent brain damage after the Department received reports of the abuse and took no action). There are, however, certain instances whereby the Constitution creates an affirmative duty for the government to protect people from harm or provide health services, including: (1) for persons held in state custody (such as prisons and mental institutions) who have been deprived of their liberty and are thus unable to care

to protect and preserve public health, a critical role which dates to the *Federalist Papers* and preceded the Constitution.¹³¹ As articulated in what is widely viewed as a leading judicial decision in public health, *Jacobson v. Massachusetts*, decided in 1905, state police powers include broad powers to pursue reasonable regulations that promote the public health, safety, welfare, or morals.¹³² While *Jacobson* dealt with infectious disease—namely, the right of the City of Cambridge, Massachusetts to require smallpox vaccination—the police power articulated therein serves as the basis for a vast array of state public health laws ranging into areas of non-communicable disease and injury.¹³³ Beyond the police power, states also possess *parens patriae* powers to act as guardians of those who cannot protect themselves legally, namely children and incompetent persons.¹³⁴

Although *Jacobson* is settled law and the states possess significant power to police and protect the public's health, they do not exclusively inhabit the domain.¹³⁵ Rather, the federal government has a role to play in the areas in which it has clearly articulated jurisdiction under the Constitution. Federal public health powers typically are found in the U.S. Congress's powers to tax, spend, regulate interstate commerce, and employ the means reasonably necessary to achieving other federal objectives (implied under the Necessary and Proper Clause).¹³⁶ If there is overlap between federal and state laws in these arenas, then federal law supersedes (or preempts) that of the states—even where states have

for themselves; or (2) if the state increased the threat of harm, and is responsible for creating danger. GOSTIN, *supra* note 101, at 87.

131. Wendy E. Parmet, *After September 11: Rethinking Public Health Federalism*, 30 J.L. MED. & ETHICS 201, 202 (2002) (noting that the *Federalist Papers* refer to the “domestic police” of the states as among the powers not available to the federal government); Hodge, Jr. *supra* note 127, at 314; *Gibbons v. Ogden*, 22 U.S. 1, 87 (1824) (“[t]he constitution gives nothing to the States or to the people. Their rights existed before it was formed, and are derived from the nature of sovereignty and the principles of freedom.”). See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

132. GOSTIN, *supra* note 101, at 78, 121–26 (quoting Justice Harlan’s decision in *Jacobson v. Massachusetts*, to say that “[t]he safety and the health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily concern the National Government.”).

133. Wendy E. Parmet et al., *Individual Rights Versus the Public’s Health—100 Years After Jacobson v. Massachusetts*, 352 NEW ENG. J. MED. 652, 653 (2005).

134. This power is typically invoked by a state to make decisions on behalf of those who cannot make decisions for themselves, or to justify the state’s more general interest in societal welfare and health. See GOSTIN, *supra* note 101, at 95–98.

135. Parmet, *supra* note 131, at 202.

136. U.S. CONST. art. I, § 8. For a more in-depth discussion of the federal enumerated powers relevant to public health, see GOSTIN, *supra* note 101, at 98–109; Parmet, *supra* note 131, at 203–07; Hodge, Jr., *supra* note 127, at 328–330; Lawrence O. Gostin, *Public Health Theory and Practice in the Constitutional Design*, 11 HEALTH MATRIX 265, 271–72 (2011); James G. Hodge, Jr., *Implementing Modern Public Health Goals Through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. HEALTH L. & POL’Y 93 (1997).

acted appropriately within their police powers.¹³⁷ In short, the federal government can serve as a limiting factor to state public health regulation.

The pendulum of power to regulate to promote the public's health has swung between state and federal governments over the course of the twentieth century. First came the era of expansive state powers post-*Jacobson*. Next, federal authority in the public health arena increased during the New Deal era when the Supreme Court broadened its interpretations of the commerce, taxing, and spending powers with national interests in mind—evidencing the so-called “death” of federalism.¹³⁸ Most recently, state powers have been newly invigorated by a series of cases that restrict federal power. Specifically, the Court has curtailed Congress's power to “commandeer” the states to carry out federal programmatic objectives,¹³⁹ and has limited the scope of the commerce power.¹⁴⁰ Although national public health goals are unifying, they must be accomplished without infringing on state sovereignty.¹⁴¹

137. U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . .”). See GOSTIN, *supra* note 101, at 80 (discussing the different types of federal preemption, including “express preemption,” where a federal statute explicitly declares that it preempts state or local law; and “implied preemption,” where Congress's intent to supersede state or local law is clearly implied in legislative language or history. Implied preemption is further subdivided into two categories: (1) field preemption, whereby federal regulation is so encompassing as to dominate an entire field and leave no space for state or local action; and (2) conflict preemption, whereby compliance with state law would frustrate or make impossible compliance with federal law). Federal action in an area of public health regulation need not necessarily invalidate any state regulation, however. Federal laws often serve as a floor, above which state regulation can impose more stringent standards. See, e.g., Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5,410, 5,418, 5,430 (Feb. 2, 2010) (to be codified at 45 C.F.R. pt. 146).

138. Hodge, Jr., *supra* note 127, at 311–12 (quoting JOSEPH LESSER, *THE COURSE OF FEDERALISM IN AMERICA, AN HISTORICAL OVERVIEW*, IN *FEDERALISM: THE SHIFTING BALANCE* 11 (Janice C. Griffith ed., 1987)).

139. See, e.g., *New York v. United States*, 505 U.S. 142, 149 (1992) (striking down a “take title” provision of the Low-Level Radioactive Waste Management Act Amendments of 1985, which required states to take ownership of and assume liability for waste if they did not dispose of radioactive wastes in a particular way); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012) (ruling that Congress exceeded its powers by requiring in the Affordable Care Act that states expand Medicaid eligibility up to 133% of the federal poverty level in order to receive any Medicaid federal funds). *But see* *South Dakota v. Dole*, 483 U.S. 203 (1987) (upholding a federal law withholding five percent of federal highway funds from states that allowed people under twenty-one to buy alcoholic beverages).

140. See, e.g., *United States v. Lopez*, 514 U.S. 549, 549 (1995) (holding that Congress lacked the authority under the Commerce Powers, to make gun possession around schools under the Gun-Free School Zones Act of 1990 a federal criminal offense); *United States v. Morrison*, 529 U.S. 598 (2000) (finding that Congress lacked the authority to enact the Violence Against Women Act under the Commerce Clause).

141. Hodge, Jr., *supra* note 127, at 356 (referring to this trend as signifying a “new federalism” era in which public health action must be balanced among federal and state levels of government).

Again, traditional state functions are central to the public's health and thus enjoy significant legal protection from federal intrusion.¹⁴²

2. *State and Federal Authority to Monitor Prescription Drugs*

Regulating controlled substances to prevent misuse and associated health and safety problems falls squarely within states' police powers and their *parens patriae* powers to act as guardians for those unable to protect themselves, although the question of federal preemption arises as a potential limitation to that exercise. Several state attorneys general have successfully brought *parens patriae* lawsuits against Purdue Pharma, the maker of OxyContin, under negligent marketing and public nuisance theories to assert their state's "quasi-sovereign" interests in the health, safety, and welfare of its citizens.¹⁴³ State police power also has been exerted in numerous ways in the context of prescription opioid misuse, including via law enforcement activities to identify doctor shoppers, diverters, and high-volume prescribers, as well as through regulation of health care professionals involved in prescribing and dispensing.¹⁴⁴ States have significantly expanded their legislative efforts in this area since the 1970s, enacting myriad laws that have generally gone unchallenged as valid exercises of state police powers.¹⁴⁵ Against this backdrop, there is little debate that PDMP general establishment falls squarely within the purview of state authority, to the extent PDMPs regulate the clinical practices of prescribing and dispensing of narcotic medicines. That said, and as discussed in Part II.A.4, PDMPs do raise certain privacy objections related to the storage and use of prescription data.¹⁴⁶

142. *Id.*

143. See Richard C. Ausness, Symposium Article, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1146–56 (2014).

144. See *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. . . . The state's discretion in that field extends naturally to the regulation of all professions concerned with health."). The authority of the states to regulate the practice of medicine is longstanding and extends to the field of narcotic prescribing. See Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 201–23 (1999) (providing a history of the police power and the regulation of medical practice).

145. See *Public Health Law Program: State Laws on Prescription Drug Misuse and Abuse*, *supra* note 100 and accompanying text. Certain states have sought to regulate the *supply* of a certain controlled substance, for example when Governor Deval Patrick of Massachusetts issued a public health emergency declaration that empowered the public health commissioner to use emergency powers to prohibit the prescribing and dispensing of hydrocodone-only medication (Zohydro, Zogenix), which had been recently approved by the FDA. This type of action, however, encroaches upon the federal government's supreme role in drug safety approval—specifically, the FDA's—and was found unconstitutional when challenged by Zogenix. See Rebecca Haffajee et al., *What Is a Public Health "Emergency"?*, 371 NEW ENG. J. MED. 986, 986–88 (2014).

146. See *infra* Part II.A.4.

Although the states implement PDMPs with the requisite police power authority, the federal government possesses concurrent authority to regulate prescription drugs together with the states, a power derived from the Commerce Clause.¹⁴⁷ Under the Commerce Power, the U.S. Congress may regulate: (1) the channels of interstate commerce; (2) the instrumentalities of commerce (including persons and things in interstate commerce); or (3) economic activities that have a substantial effect on interstate commerce.¹⁴⁸ The Supreme Court has found narcotic drugs to satisfy all three prongs of this test, as they are “things” that flow through an interstate supply chain (from manufacturer to distributor to pharmacy to patient), the distribution of which impacts this interstate flow.¹⁴⁹

Congress’s regulation of controlled substances dates back to the early 1900s.¹⁵⁰ But, it truly expanded with the enactment of the CSA in 1970 and creation in 1973 of the DEA, an agency charged with policing the issuance and dispensing of controlled substances, including prescription drugs.¹⁵¹ To prescribe controlled substances in Schedules II through V, licensed prescribers must register with the DEA every three years and follow other administrative requirements.¹⁵² To avoid criminal liability under the CSA, a prescriber may issue controlled substance prescriptions only “for a legitimate medical purpose” when “acting in the usual course of his professional practice.”¹⁵³

147. U.S. CONST. art. I, § 8, cl. 3.

148. *Perez v. United States*, 402 U.S. 146, 150 (1971).

149. See Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Police Powers to Reduce Prescription Drug Abuse*, 16 J. HEALTH CARE L. & POL’Y 271, 283–92 (2013) (describing in detail the Supreme Court’s application of the Commerce Power in the context of federal regulation of narcotics to advocate for national prescriber education to reduce prescription drug abuse).

150. See Shepherd, *supra* note 99, at 101.

151. See *DEA Mission Statement*, DRUG ENF’T ADMIN., <http://www.dea.gov/about/mission.shtml> (last visited Aug. 5, 2016). In addition, the federal government also established the FDA, which in 2012 used its powers to require ER/LA opioid manufacturers to develop a REMS given that the potential risks of the drugs outweighed the benefits. The REMS policy requires these drug developers to manage the risk of accidental or intentional abuse and risks to patients who are prescribed the drugs but do not clinically need them, primarily by financing the education of prescribers and patients regarding opioid risks and proper prescribing, storage, and disposal practices. Valarie Blake, *Fighting Prescription Drug Abuse with Federal and State Law*, 15 AM. MED. ASS’N J. ETHICS 443, 443–44 (2013). See generally John F. Peppin et al., *Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategy (REMS) for Opioids in Pain Management*, 27 ISSUES L. & MED. 91 (2011) (suggesting that REMS is unlikely to reduce the bulk of prescription drug abuse that occurs with non-patients); Hilary Homenko, *Rehabilitating Opioid Regulation: A Prescription for the FDA’s Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273 (2012).

152. 21 U.S.C. §§ 823, 827–29 (West 2012). See *supra* note 90 and accompanying text for a summary of the federal controlled substance Schedules.

153. 21 C.F.R. § 1306.04(a) (2013). Prescribers may also be held liable under certain state controlled substance acts for unauthorized prescribing practices.

Despite this expansive federal oversight of controlled substances and jurisprudence relating to the Commerce Power, the federal government has not chosen to use its Commerce Power to create any national prescription monitoring program or curtail state plenary powers to do so.¹⁵⁴ Instead, it supports the states in monitoring prescription drugs, thereby lending additional support to the idea that Congress has little intention of preempting state PDMP creation. Specifically, the U.S. Department of Justice has encouraged state PDMPs by creating the Harold Rogers Prescription Drug Monitoring Program in 2002 to fund program creation, the National Alliance for Model State Drug Laws to help with policy coordination, and a Prescription Drug Monitoring Program Center of Excellence at Brandeis University to identify best practices.¹⁵⁵ None of this federal activity would be construed as commandeering of the states, as the funds and support provided for PDMPs relate directly to these programs and do not require program establishment or operation.¹⁵⁶

The federal government, however, has not ceded this entire arena to the states. As a reciprocal gesture for its support for PDMPs, the federal government has elicited state cooperation with investigative activities relating to prescription drug misuse. The DEA has requested certain state PDMP data pursuant to administrative subpoenas, as authorized under the CSA, to investigate drug crimes—an action that raised supremacy issues that ultimately went unresolved in *Oregon Prescription Drug Monitoring Program v. United States DEA*.¹⁵⁷ In this case, the DEA was attempting to use its administrative subpoena power to access Oregon PDMP records for an individual patient and for all drugs prescribed by two physicians, absent a warrant.¹⁵⁸ The Oregon PDMP refused to comply with these subpoenas on the basis that doing so would violate Oregon law, which says that PDMP data constitutes protected health information and law enforcement can only access the data

154. In other words, the federal government has neither expressly preempted state PDMPs nor enacted other controlled substance monitoring laws that would impliedly preempt state *creation of* PDMPs. See Barnes & Arndt, *supra* note 149, at 292–95 (discussing circuit court decisions that reaffirm the constitutionality of CSA regulations, but that have also found such regulations do not invalidate state police powers to regulate medicine).

155. Deyo et al., *supra* note 76, at 604–05.

156. See *New York v. United States*, 505 U.S. 142 (1992).

157. *Or. Prescription Drug Monitoring Program v. United States Drug Enf't Admin.*, 998 F. Supp. 2d 957, 960 (D. Or. 2014). The DEA appealed the district court's ruling and is awaiting a decision from the Ninth Circuit Court of Appeals. The ultimate outcome of the case could influence the standards across jurisdictions regarding DEA (and state law enforcement) access to PDMP data. The CSA empowers the Attorney General, and executive agencies acting pursuant to his/her authority (including the DEA), with broad authority to issue administrative subpoenas for information "relevant or material" to an investigation relating to his/her functions "with respect to controlled substances." 21 U.S.C. § 876(a) (West 2012).

158. See *Or. Prescription Drug Monitoring Program*, 998 F. Supp. 2d at 960–61.

pursuant to a *valid court order based on probable cause* for an authorized drug-related investigation involving an individual.¹⁵⁹ In a former instance when the Oregon PDMP objected to a DEA request for PDMP data (pursuant to an administrative subpoena) on all Schedule II through IV controlled substance prescriptions issued by a particular physician over a seven month period, a U.S. magistrate judge found Oregon's court order requirement to be preempted by the CSA.¹⁶⁰ In *Oregon Prescription Drug Monitoring Program*, the court never reached the supremacy issue presented, however, instead deciding that the DEA's use of administrative subpoenas violated the Fourth Amendment, as discussed below in Part II.A.4.

Given the concurrent jurisdiction of federal and state governments to monitor prescription drugs, what is the appropriate balance of powers—particularly when presented with a complex and serious public health problem like prescription opioid misuse? Strong arguments can be made for federal intervention, given markedly heterogeneous programs across states, limited state resources, and the interstate components of drug prescribing and dispensing involved. State PDMPs exhibit widely varying features, most of which appear chaotically conceived and uninformed by rigorous studies of effectiveness (as most programs were adopted before much of an evidence base existed). State authorities may lack the resources or expertise to operationalize PDMPs optimally, even with federal assistance.¹⁶¹ Furthermore, prescription drug misuse is not confined within state borders, as demonstrated by growing evidence of doctor shopping across state lines¹⁶² and mail order pharmacies that can send controlled substances across states.¹⁶³ All of these factors weigh in favor of uniform federal standards that could, in theory, more comprehensively and deliberately address prescription drug misuse.¹⁶⁴

While the federal government has the authority and a set of justifications to have its own PDMP, the creation of such a program would require a major overhaul of deeply entrenched state programs. State PDMPs represent huge investments; replacing them with a federal system would seem wasteful and counter-productive just as we are

159. *Id.*; OR. REV. STAT. § 431.966(2)(a)(C) (West 2016).

160. *Or. Prescription Drug Monitoring Program v. United States Drug Enf't Admin.*, 998 F. Supp. 2d 957, 960 (D. Or. 2014). In other words, the magistrate judge found the DEA's investigatory authority reigned supreme over Oregon state law's data access requirements. *Id.*

161. CLARK ET AL., *supra* note 79, at 57–62; GOSTIN, *supra* note 101, at 81.

162. *See, e.g.*, Douglas C. McDonald & Kenneth E. Carlson, *The Ecology of Prescription Opioid Abuse in the USA: Geographic Variation in Patients' Use of Multiple Prescribers ("Doctor Shopping")*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1258 (2014) (estimating that thirty percent of doctor shoppers obtained prescriptions across state lines); Ken Lammers, Jr., *Rise of the Pills*, 15 UDCDCSL L. REV. 91, 102 (2011) (providing anecdotal evidence of doctor shopping across state lines).

163. *See* Anupam B. Jena et al., *Prescription Medication Abuse and Illegitimate Internet-Based Pharmacies*, 155 ANNALS INTERNAL MED. 848 (2011).

164. GOSTIN, *supra* note 101, at 81; Parmet, *supra* note 131, at 208.

beginning to detect what may be promising health results.¹⁶⁵ State governments (and local governments to which they may delegate power) are closer to the issues and have more flexibility than the federal government to cater the programs to their citizenry's public health needs, opinions, and geographies—all of which can serve to enhance PDMP results.¹⁶⁶ Certain states may wish to implement specific features or PDMPs in combination with other interventions for a greater impact. For example, Florida chose to combine a PDMP with regulation of pill mills, given the high concentration of these practices.¹⁶⁷ States can also function as “laboratories” to test new interventions and inform evidence-based policy in other jurisdictions.¹⁶⁸ The progressive, widespread adoption of PDMPs from the 1990s through 2000s provides rich heterogeneity in programs across states to allow for natural experiments that test different features for the best results. In sum, leaving state PDMPs intact for continued evaluation and potentially improvement seems preferable. As a stronger evidence base about effective PDMP practices emerges, there will be room for increased federal influence to achieve some consistency across programs: The federal government should condition future state PDMP funding on adoption of these identified practices.¹⁶⁹ But at the moment, while states seem to be an appropriate level at which to implement PDMPs, policymakers face tough decisions with respect to the form that these laws take, as guided by consideration of individual liberties, effectiveness, and other ethical dimensions.

3. *Constitutional Limits on Public Health Regulation*

Although state governments have broad authority to act in ways that limit private interests in favor of the greater community,¹⁷⁰ these infringements do have legal bounds. Individual liberty, autonomy, privacy, and economic freedom enjoy protection from certain government

165. See *infra* Part II.B.3 for a discussion of the PDMP effectiveness literature.

166. See GOSTIN, *supra* note 101, at 81; Hodge, Jr., *supra* note 127, at 356.

167. See, e.g., Lainie Rutkow et al., *Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use*, 10 JAMA INTERNAL MED. 1642 (2015) (finding that Florida's PDMP and pill mill laws were associated with modest decreases in total opioid volume supplied, as well as in morphine milligram equivalents per transaction and opioid prescriptions).

168. Mello & Zeiler, *supra* note 102, at 654, 671–79 (discussing that state-based law provides the opportunity for evaluation thanks to time-varying adoption of reform across jurisdictions, often for reasons unrelated to the outcome variable of interest. The federal National Minimum Drinking Age Act, which tied the minimum drinking age to national highway funds, was adopted after studies of state innovations attributed beneficial health impacts to higher drinking ages).

169. See *South Dakota v. Dole*, 483 U.S. 203 (1987).

170. Parmet, *supra* note 109, at 401–11 (discussing the interdependency of health and the public good nature of many interventions as justifications for public health interventions, such as the individual mandate in the Affordable Care Act).

intrusion under the Bill of Rights, as well as state constitutions and laws.¹⁷¹ In addition to articulating the breadth of state authority to protect the public's health, *Jacobson* was the first case to carefully articulate a framework for the protection of individual liberties in the exercise of police power, which has been elaborated upon and developed in subsequent case law interpreting the Constitution.¹⁷² The permissibility of public health laws turns on scientific justification and the manner in which they are applied.¹⁷³ Specifically, public health powers are constitutional only if exercised in accordance with the following legal principles: (1) extraterritoriality; (2) necessity; (3) reasonableness; (4) due process rights; and (5) equal protection principles.¹⁷⁴ Freedom of expression principles further impose significant barriers to public health regulation. For general framing purposes, the above principles are outlined in brief and then applied in detail as relevant to PDMPs.

For any given public health law, state policymakers should undertake a careful constitutional analysis to anticipate private objections that could frustrate implementation. First, states can regulate matters within their borders, but not extraterritorially.¹⁷⁵ Second, the exercise of police power should be necessary to prevent an actual or looming threat to public health, rather than a potential or hypothetical one.¹⁷⁶ Third, the exercise of state power must be reasonable. Here a policymaker would ask two questions: (1) will the legal action taken plausibly be effective in achieving its objective (that is, are the means reasonably related to the ends)?; and (2) are there any obviously less burdensome alternatives that could have been implemented instead?¹⁷⁷

Furthermore, individual rights to due process and equal protection are constitutionally protected and must be considered in the affirmative

171. GOSTIN, *supra* note 101, at 85–86, 114–16. State constitutions and laws also provide parameters for policymaker actions, but are too plentiful to be addressed comprehensively in this Article.

172. See generally Wendy K. Mariner et al., *Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581 (2005) (tracing the evolution of conceptions of state police powers and individual liberty over the century since *Jacobson*, finding that the Court's recognition of the relative importance of liberty has strengthened over time).

173. Parmet et al., *supra* note 133, at 654.

174. Although the facts in *Jacobson* did not require the Supreme Court to articulate equal protection as a constitutionally required limitation, this standard had previously been articulated in *Jew Ho v. Williamson*. GOSTIN, *supra* note 101, at 128 (citing *Jew Ho v. Williamson*, 103 F. 10 (N.D. Cal. 1900)).

175. The police power is a state's "recognized [] authority [] to enact . . . all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

176. GOSTIN, *supra* note 101, at 126–27 (the subject of compulsory intervention must pose an actual, demonstrable threat to the community); *Jacobson*, 197 U.S. at 39 (not requiring that the vaccination be administered against anyone who "with reasonable certainty" can show that he is not the "fit subject of vaccination . . . by reason of his then condition, [which] would seriously impair his health or probably cause his death.").

177. See *Jacobson*, 197 U.S. at 31; GOSTIN, *supra* note 101, at 127.

government exercise of public health powers. Individuals are free from unwanted intrusions—including searches and seizures—in places in which they have a legitimate expectation of privacy (such as their body or property).¹⁷⁸ Under the Fourth Amendment, a search is usually found unreasonable absent a warrant from a judge showing probable cause,¹⁷⁹ with limited exceptions.¹⁸⁰ The concept of liberty is also protected under the Fifth Amendment¹⁸¹ and can be framed as two separate obligations: procedural due process and substantive due process. Procedural due process entitles individuals to fair procedures—typically, notice, a fair hearing, and counsel¹⁸²—when the government deprives them of life, liberty, or property.¹⁸³ Substantive due process relates to the protected zone of individual liberty or privacy, where the government cannot enter without adequate justification.¹⁸⁴ And finally, any state government-drawn distinction between similarly situated persons—for example,

178. GOSTIN, *supra* note 101, at 403. The Fourth Amendment guarantees “the right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures,” and is extended to state governments via the Fourteenth Amendment. U.S. CONST. amend. IV. *See* *Wilson v. Health & Hosp. Corp. of Marion Cty.*, 620 F.2d 1201 (7th Cir. 1980) (finding that health official searches absent warrants or consent violated individual’s reasonable expectation of privacy under the Fourth Amendment).

179. *See, e.g.,* *Camara v. Mun. Court*, 387 U.S. 523, 534 (1967) (holding that a housing inspection of an apartment was a violation of the Fourth Amendment absent a warrant or consent); *See v. City of Seattle*, 387 U.S. 541, 545 (1967) (finding the fire inspection of a business to be unconstitutional without a warrant or consent).

180. GOSTIN, *supra* note 101, at 403–04, 468–69. If obtaining a warrant is impractical, the courts will conduct an individualized assessment using reasonableness standards—probing the importance of the state interest, the degree of privacy invasion, and whether the state had a reasonable suspicion or special need. *Id.* at 403–04. *See* *Bd. of Educ. v. Earls*, 536 U.S. 822, 829 (2002) (holding that drug testing high school students participating in extracurricular activities is reasonable given the important state interests in protecting children’s health, the minimal intrusion associated with urine testing, and the reduced expectation of privacy that schoolchildren possess). A special need must be something aside from merely enforcing laws, although this standard has been interpreted more generously over time. *See, e.g.,* *Ferguson v. City of Charleston*, 532 U.S. 67 (2001) (finding that state hospital performance of urine tests on pregnant women without their consent to obtain evidence for law enforcement purposes constituted an unconstitutional search under the Fourth Amendment. No special need was recognized given that the testing was linked to the state’s general interest in law enforcement.); *Loder v. City of Glendale*, 927 P. 2d 1200, 1230 (1997) (striking down mandatory drug tests for all city employees seeking promotions because they had already been tested, whereas drug tests for new applicants were permissible given the lack of prior knowledge of their drug use).

181. The Fifth Amendment to the U.S. Constitution states: “No person shall . . . be deprived of life, liberty, or property, without due process of law.” U.S. CONST. amend. V. The Fifth Amendment has been extended to the states under the Fourteenth Amendment to the U.S. Constitution.

182. *See, e.g.,* *Greene v. Edwards*, 263 S.E.2d 661, 663 (1980) (holding that people with communicable tuberculosis must be afforded counsel, written notice, and the right to confront the witnesses against them).

183. GOSTIN, *supra* note 101, at 132.

184. *See, e.g.,* *Lawrence v. Texas*, 539 U.S. 558, 562 (2003) (finding a liberty right to engage in private acts, particularly intimate acts in nonpublic locations, such as the home).

between persons of different races and ethnicities¹⁸⁵—requires justification based on equal protection principles.¹⁸⁶ The level of scrutiny applied by courts in considering substantive due process and equal protection claims varies depending on the nature of the burdened right or interest.¹⁸⁷

Although not raised in *Jacobson* or yet in the context of PDMPs, freedom of speech is relevant to the evaluative framework and policymaking calculus in other public health law contexts, such as regulating the advertising of tobacco products. State regulators should be mindful that courts afford exceptional protection to speech, and the trend has been toward increasing protection of commercial speech, in particular.¹⁸⁸ Indeed, the First Amendment is, of late, arguably the most significant constitutional barrier to state and federal public health regulation in the contexts of both compelled speech and speech restrictions.¹⁸⁹

4. *Liberty Issues Raised by PDMPs*

Although states are generally within the purview of their police powers in creating PDMPs, certain features of these heterogeneous programs have the potential to infringe upon individual rights and freedoms and may, therefore, be subject to legal challenge. PDMPs, as typically implemented, meet the extraterritoriality and necessity

185. See, e.g., *Yick Wo v. Hopkins*, 118 U.S. 356, 372 (1886) (striking down a facially neutral ordinance restricting the washing of clothes in public laundromats after 10:00 p.m. on the basis that it was being enforced with discriminatory intent—only against Chinese owners); *Jew Ho v. Williamson*, 103 F. 10, 26 (N.D. Cal. 1900) (finding that the quarantine of an entire district in San Francisco in order to contain a bubonic plague epidemic was used as a guise to discriminate against Chinese people who populated most of the area, the health of whom was actually placed at greater risk by the quarantine).

186. The Fourteenth Amendment also provides that no state shall “deny to any person within its jurisdiction the equal protection of the laws.” U.S. CONST. amdt. XIV.

187. For further discussion of substantive due process, equal protection, and levels of constitutional review, see GOSTIN, *supra* note 101, at 135–42.

188. *Id.*; see, e.g., *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 554–55 (2011) (finding that a Vermont state statute banning the sale, use, or transmission of prescriber-identifiable data (absent prescriber consent) violated data miner free speech rights); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 376–77 (2002) (holding that a provision of the FDA Modernization Act, which exempts certain compounded drugs from having to satisfy drug approval requirements if the drug is not advertised or promoted, unconstitutionally restricts pharmacists’ commercial speech); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555–56 (2001) (holding that Massachusetts’ outdoor and point-of-sale advertising restrictions targeting smokeless tobacco and cigars violated the First Amendment); *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1221–22 (D.C. Cir. 2012) (holding that the FDA rule requiring graphic warning images on cigarette packages and advertisements violates the First Amendment).

189. For academic discussion of this evolving and expansive body of law, see David Orentlicher, *The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm*, 37 AM. J.L. & MED. 299 (2011); Micah L. Berman, *Manipulative Marketing and the First Amendment*, 103 GEO. L.J. 497 (2015).

requirements for public health laws originally articulated in *Jacobson*.¹⁹⁰ Each program operates within its state's borders, collecting data on controlled substances dispensed within the state and permitting prescriber, pharmacist, and sometimes regulator use of that data.¹⁹¹ Some interstate sharing of information to authorized users (typically, prescribers or pharmacists) or PDMPs in other states occurs,¹⁹² but any information transmitted across state boundaries is usually shared reciprocally, subject to the originating state's requirements for authorized use, and intended to complement public health efforts in both states. Furthermore, sharing of data across state lines can be justified given the sometimes interstate nature of prescribing, drug fills, and diversion.¹⁹³ With regard to necessity, there is little debate that the exercise of police power is necessary to address opioid misuse and overdose, a public health threat of significant and increasing magnitude.¹⁹⁴

Further, the programs appear reasonable in the *Jacobson* sense of the term.¹⁹⁵ PDMPs bear a real and substantial relation to the protection of public health and safety: They aim to inform optimal prescribing as well as to address patients and prescribers with outlier fill and prescribing patterns, respectively. Given that the vast majority of drugs misused originate from prescribers, either directly or indirectly,¹⁹⁶ prescribing is a reasonable level at which to intervene to address the epidemic. Also, because a small percentage of prescribers source the majority of opioids, and because a small percentage of patients receive disproportionately large amounts of opioids,¹⁹⁷ outliers in each of these categories are reasonable targets for intervention. If challenged, a court would likely view a state's decision to implement a PDMP in lieu of or in addition to other available interventions that target prescription drug misuse (such as pain clinic laws¹⁹⁸) with deference, finding it neither arbitrary nor totally unreasonable.

190. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) for a definition of states' "police power." See *supra* note 175 of this Article for such a definition.

191. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 4.

192. *Interstate Sharing of Prescription Monitoring Database Information*, NAT'L ALL. FOR MODEL STATE DRUG LAWS (2014), <http://www.namsdl.org/library/BCC76DA9-E7E5-7D40-AE816BB3141687D7/> (last visited Aug. 5, 2016).

193. *Id.*

194. See GOSTIN, *supra* note 101, and text accompanying note 176; *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); see also Part I, *supra* for a discussion of the public health significance of opioid misuse.

195. See *supra* note 175 and accompanying text.

196. See *supra* notes 11–12 and accompanying text.

197. U.S. DEP'T OF HEALTH & HUMAN SERVS., ADDRESSING PRESCRIPTION DRUG ABUSE IN THE UNITED STATES: CURRENT ACTIVITIES AND FUTURE OPPORTUNITIES 15–17 (2013).

198. Laws that regulate "pill mills," or pain management clinics that source large quantities of prescriptions, aim to prevent these facilities from inappropriately prescribing controlled substances. Such laws typically provide for state oversight of pill mills and contain other requirements pertaining to ownership and operation of the facility. For instance, a law may set forth personnel and operational requirements,

The heart of challenges to PDMPs revolves around informational privacy rights. These rights can be located in the Fourth and Fourteenth Amendments, as well as in federal and state confidentiality laws. Because statewide prescription dispensing data is aggregated in a database that can be widely accessed by many types of authorized users, PDMPs present new possibilities for security breaches in which private information is disclosed to the general public, as well as for law enforcement and licensing body use of the data. The potential for broad data access raises privacy concerns among patients and prescribers and could reduce their drug seeking and prescribing behaviors, respectively. Some such behavior changes may be desirable, given that a central purpose of PDMPs is to have a deterrent effect on over-prescribing, doctor shopping, and diversion. But other behavioral changes may be unintended¹⁹⁹ and undesirable, such as the chilling of appropriate prescribing or patient access to legitimately needed painkillers. Courts seek to balance the competing state and individual privacy interests in determining the legality of PDMPs and access to prescription information contained therein.

The Supreme Court addressed the right to informational privacy in prescription records under the Due Process Clause of the Fourteenth Amendment in *Whalen v. Roe*.²⁰⁰ In *Whalen*, the Court considered whether New York's paper prescription monitoring program (which also collected the prescription information in a computerized database) violated individual interests in (1) avoiding disclosure of personal matters, and/or (2) independence in important decisionmaking.²⁰¹ The Court admitted that the monitoring program could have a chilling effect on opioid prescribing and use. Nonetheless, it found that the program adequately safeguarded physicians' and patients' right to informational privacy, emphasizing the extensive security protections in place to keep private information from being disclosed and the fact that the decision whether to prescribe or use a drug is still left to patients and doctors.²⁰² Subsequent state courts have considered the right to informational privacy in prescription records housed in individual pharmacies, rather than statewide databases, and relied on the *Whalen* precedent to find no

inspection and licensure procedures, standards of care, and/or patient billing procedures. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 66.

199. See *infra* Parts II.B–C for additional consideration of unintended consequences of PDMPs under the evaluative framework.

200. *Whalen v. Roe*, 429 U.S. 589 (1977).

201. *Id.* at 591, 599–600.

202. *Id.* at 600–02, 604 (noting protections, including a receiving room protected by a locked wire fence and alarm system, limited access to a small number of people, and serious penalties for unlawful release). The Court also found that any physician claim regarding potential disclosure of patient information was “derivative from, and therefore no stronger than, the patients’”—in other words, rejecting physician privacy rights violations in this context. *Id.* at 604.

constitutional violations.²⁰³ Although not yet squarely addressed by any court, it seems unlikely an electronic PDMP would infringe upon Fourteenth Amendment privacy rights if adequate safeguards were in place to protect the data from public disclosure.²⁰⁴

Patient (and prescriber) Fourth Amendment privacy rights are also implicated by warrantless searches of PDMP data by law enforcement officials and other regulators. In almost all states, professional licensing bodies and law enforcement officials can access PDMP data for the respective purpose of conducting administrative searches and pursuing criminal investigations against patients, prescribers, or pharmacists.²⁰⁵ What differs from state to state is whether these officials can access the data simply pursuant to an active investigation, or whether they need to satisfy the more stringent standards of accessing the information only with a court-issued search warrant, subpoena, or order.²⁰⁶ While the stated goals of PDMPs vary—and many programs explicitly do aim to prevent criminal activities such as diversion and doctor shopping²⁰⁷—a common primary goal is to improve health care by reducing drug misuse and facilitating appropriate prescribing.²⁰⁸ If law enforcement and licensing officials are given access to the files absent any probable cause or reasonable restrictions around terms of access, PDMPs could easily turn into tools primarily used to troll for criminal or medical misconduct. This shift in emphasis could induce a chilling effect on prescribing and prescription drug use in ways that actually interfere with optimal medical care.

The *Whalen* Court did not decide whether a centralized state database housing prescription records implicates the Fourth Amendment

203. See, e.g., *State v. Wiedeman*, 835 N.W.2d 698, 714 (Neb. 2013) (finding no violation of the Fourteenth Amendment after “weighing the State’s significant interest in the regulation of potentially dangerous and addictive narcotic drugs against the minimal interference with one’s ability to make medical decisions and the protections from broader dissemination to the general public”); *Stone v. City of Snow*, 593 N.E.2d 294, 301 (Ohio 1992) (holding that the Ohio statutes permitting warrantless inspection of prescriptions, orders, and records to law enforcement officials and regulators did not violate doctor, patient, or pharmacist rights to privacy as they did not allow disclosure to the general public and included adequate safeguards).

204. In a *Whalen v. Roe* concurrence, Justice Brennan did express concerns with the computerized storage of sensitive information, leaving open the possibility that the Court would view electronic PDMPs, whereby data are shared across a wide network of authorized users, as a heightened invasion of privacy. David B. Brushwood, *Maximizing the Value of Electronic Prescription Monitoring Programs*, 31 J.L. MED. & ETHICS 41, 43 (2003). But see Dilcher, *supra* note 40 (suggesting it is unlikely that the Supreme Court will invalidate electronic PDMPs on general privacy grounds).

205. NAT’L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 5, 25–26. In a handful of states, the PDMP is actually housed within a law enforcement or professional licensing agency, as opposed to a health agency, thereby giving these regulators and officials’ unfettered access to the records. *Id.* at 25–26.

206. *Id.*

207. Corey S. Davis et al., *Overdose Epidemic, Prescription Monitoring Programs, and Public Health: A Review of State Laws*, 105 AM. J. PUB. HEALTH e9, e9–e10 (2015).

208. *Id.*

right to privacy.²⁰⁹ However, other state and federal courts have addressed this right in the context of pharmacy-housed prescription records, generally finding that although patients have a subjective expectation of privacy in their prescription records, they do not have a privacy right that society is prepared to recognize as objectively reasonable²¹⁰—as is also required to invoke Fourth Amendment protections.²¹¹ Some courts have justified patients' (and prescribers') reduced expectation of privacy in pharmacy records on the basis that most states have laws that explicitly allow certain officials access to these records without a warrant.²¹² Other courts have recognized pharmaceuticals as a pervasively regulated industry²¹³ and thus applied the three-pronged test set out in *New York v. Burger* to determine whether a warrantless search is reasonable.²¹⁴ In applying the *Burger* test, courts have typically found that allowing searches of prescription data furthers substantial and well-established government interests in regulating prescription drugs, and that notice requirements are met if these searches are conducted during reasonable hours.²¹⁵ Most courts have found the warrant exception applies to administrative inspections of pharmacy records, such as those conducted by pharmacy boards, though some also have applied it to searches conducted pursuant to criminal investigations.²¹⁶

209. The Court declined to address the Fourth Amendment arguments brought by physician and patient plaintiffs because the case did not “involve affirmative, unannounced, narrowly focused intrusions into individual privacy during the course of criminal investigations.” *Whalen v. Roe*, 429 U.S. 589, 604 n.32 (1977).

210. *See, e.g.*, *State v. Wiedeman*, 835 N.W.2d 698, 710–11 (Neb. 2013); *State v. Russo*, 790 A.2d 1132, 1152 (Conn. 2002); *Stone v. City of Snow*, 593 N.E.2d 294, 300–01 (Ohio 1992).

211. *Katz v. United States*, 389 U.S. 347, 361 (1967) (Harlan, J., concurring).

212. *See Douglas v. Dobbs*, 419 F.3d 1097, 1102 (10th Cir. 2005); *Murphy v. State*, 62 P.3d 533, 536 (Wash. Ct. App. 2003); *State v. Underwood*, No. K2/98-0485A, 1999 WL 47159, at *5 (R.I. Super. Ct. Jan. 20, 1999); *Gettel v. State*, 449 So.2d 413, 414 (Fla. Dist. Ct. App. 1984). *See Russo*, 790 A.2d at 1141. *See NAT'L ALL. FOR MODEL STATE DRUG LAWS, PRESCRIPTION MONITORING PROGRAMS, PHARMACY RECORDS AND THE RIGHT TO PRIVACY* 21–37 (2014) (providing a catalogue of these pharmacy records access laws).

213. In its close level of regulation, the pharmaceutical industry is distinguishable from certain other areas of health. *See, e.g.*, *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 551 (9th Cir. 2004) (holding that an Arizona regulation that required abortion clinics to submit to warrantless inspections by the Arizona Department of Human Services violated the Fourth Amendment. The Ninth Circuit determined that the administrative search exception was inapplicable because abortion services are not a closely regulated business).

214. *New York v. Burger*, 482 U.S. 691 (1987). To determine whether a warrantless search is reasonable, three criteria must be met: (1) there must be a substantial government interest in regulating this area; (2) the regulatory scheme must further that government interest; and (3) the regulation must provide a constitutionally adequate substitute for a warrant—in other words, it must provide comprehensive notice to the target of the search and appropriately limit the time, place, and scope of the search. *Id.* at 702.

215. *See Terraciano v. Montanye*, 493 F.2d 682, 683–85 (2d Cir. 1974); *State v. Welch*, 624 A.2d 1105, 1110–12 (Vt. 1992); *Stone*, 593 N.E.2d at 300–01.

216. *State v. Jarvis*, No. 16388, 1998 WL 57342, at *4–5 (Ohio Ct. App. Feb. 13, 1998) (finding that inspectors were not required to ignore evidence of criminality discovered during a warrantless

PDMPs, however, raise unique issues with respect to unfettered searches, particularly when conducted by law enforcement or licensing officials, which justify different data access standards from those applied to pharmacy-housed records. PDMPs centralize *all* dispensing data generated within a state (and sometimes across states), rather than that from a single pharmacy. Most are fully electronic and searchable, for instance by prescriber, pharmacy, or patient name—or conceivably by controlled substance or prescribing volume. Under the mosaic theory, the aggregation of prescription information in PDMPs should be covered by a reasonable expectation of privacy under the Fourth Amendment, even if each individual pharmacy-housed record may not be.²¹⁷ Moreover, although the third-party doctrine suggests that when certain records are turned over and maintained by third-parties, they are no longer private and not protected by the Fourth Amendment when exposed to others, significant support for patients' expectation of privacy in *medical* records exists.²¹⁸ Because PDMP data, by virtue of their comprehensive nature, are akin to medical records, there is a strong argument that such records are entitled to some measure of protection from unfettered access by government officials.

Indeed, the heightened Fourth Amendment privacy concerns associated with PDMPs were recognized in *Oregon Prescription Drug Monitoring*. In this leading case in the area, the American Civil Liberties Union (“ACLU”) intervened on behalf of the PDMP to raise arguments about individual physician and patient Fourth Amendment privacy rights

administrative search conducted with independent administrative justification); *Welch*, 624 A.2d at 1112; *Stone*, 593 N.E.2d at 300–01. *See* *State v. Desper*, 783 N.E.2d 939 (Ohio Ct. App. 2002) (finding that once a search ceases to be administrative in nature and a criminal investigation commenced, a warrant was required); *State v. Penn*, 576 N.E.2d 790 (Ohio 1991) (upholding lower court's grant of a motion to suppress evidence uncovered during a joint inspection by the state pharmacy board and the police, given that the search was undertaken for general criminal purposes, stating that, the “board cannot act as a surrogate for the police to obviate the constitutional duty of obtaining a search warrant.”). *But see Penn*, 576 N.E.2d at 723; *Commonwealth v. Frodyma*, 436 N.E.2d 925 (Mass. 1982) (refusing to extend the warrant exception to criminal investigations).

217. *See* Benjamin J. Priester, *Five Answers and Three Questions After United States v. Jones (2012), the Fourth Amendment “GPS Case”*, 19–28 (Mar. 28, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2030390 (noting five Justices' express support for the “mosaic theory” in *U.S. v. Jones*, or the idea that the aggregation of information may be covered by a reasonable expectation of privacy, even though each discrete piece of information standing alone would not. The mosaic theory, which suggests the Fourth Amendment protection can be triggered when the sheer quantity of information becomes great, applies both to information presented to the public and that turned over to a third-party, like PDMP data. However, the precise parameters of how this theory will be applied by the Court remain uncertain). For additional arguments in favor of the mosaic theory, see Wayne A. Logan, “*Mosaic Theory*” and *Megan's Laws*, 2011 CARDOZO L. REV. DE NOVO 95 (2011).

218. *See, e.g., State v. Skinner*, 10 So. 3d 1212, 1218 (La. 2009) (finding that the Fourth Amendment requires a search warrant before a search of medical or prescription records for criminal investigative purposes can be undertaken); *Doe v. Broderick*, 225 F.3d 440, 451 (4th Cir. 2000) (holding that a patient at a methadone clinic had a legitimate expectation of privacy in the records on file there, given their intimate and private nature).

in their PDMP information. Notwithstanding federalism issues discussed above in Part II.A.2, the federal district court decided in favor of the ACLU and held that the Fourth Amendment was violated by the DEA's use of administrative subpoenas (rather than a court-issued warrant) to obtain PDMP records for an individual patient's prescriptions and for all drugs prescribed by two physicians.²¹⁹ The court found that both patients and physicians have subjective *and* objective expectations of privacy in PDMP records for the Schedule II through IV drugs at issue.²²⁰ The court found that although patients must expect that medical personnel will access their prescription files, it is reasonable for patients to expect that law enforcement will not have access to the PDMP records—given the intensely personal nature of the data (often revealing a person's medical condition and treatment patterns) and information on the PDMP's website that emphasized the protection of confidential information.²²¹ Although the district court's decision is not binding in other jurisdictions and a few state courts have held alternately,²²² PDMPs are beginning to follow *Oregon Prescription Drug Monitoring* guidance by increasingly requiring

219. *Or. Prescription Drug Monitoring Program v. United States Drug Enf't Admin.*, 998 F. Supp. 2d 957, 960, 967(D. Or. 2014).

220. *Id.* at 964–67.

221. *Id.* at 966–67. The district court found it “difficult to conceive of information that is more private or more deserving of Fourth Amendment protection” than prescription drug information that would reveal if a patient is being treated for gender identity disorder—as would be captured by PDMP records. Prescribing records of this kind are protected against government intrusion by a “heightened privacy interest rendering the use of administrative subpoenas unreasonable.” *Id.* The court also dispensed with the DEA's assertion that the “third-party doctrine” undermines the patient/prescriber expectations of privacy because (1) PDMP records are inherently personal and private; and (2) doctors and patients do not voluntarily convey the information to the PDMP—rather it is required by law that all dispensing information be included. *Id.*

222. *Williams v. Commonwealth*, 213 S.W.3d 671, 676–78 (Ky. 2006) (finding that the Kentucky statute authorizing warrantless searches of PDMP data is facially constitutional and does not amount to a “search,” because only limited data of Schedules II–V controlled substances that did not reveal a patient's medical condition or treatment were conveyed); *Lambert v. Larizza*, Case No. 13-314-2-CICI (Fla. Cir. Ct. Feb. 13, 2014) (holding that the production of PDMP prescription records for 3300 patients to state and federal law enforcement officials pursuant to a warrantless request did not violate Florida's constitution because there is a reduced expectation of privacy in prescription records); *Florida Judge Rules Government Can Search Prescription Drug Monitoring Database*, THOMSON REUTERS (Feb. 21, 2014), <http://blog.legalsolutions.thomsonreuters.com/practice-of-law/florida-judge-rules-government-can-search-prescription-drugmonitoring-database/> (discussing the ruling in *Lambert v. Larizza*). See Jodie Tillman, *California High Court to Consider Limits on Regulators' Access to Prescription Database*, L.A. DAILY NEWS (Apr. 26, 2015), <http://www.dailynews.com/general-news/20150426/california-high-court-to-consider-limits-on-regulators-access-to-prescription-database> (last visited Aug. 5, 2016) (describing the decision of a California state appeals court that found medical board use of PDMP data to identify a physician with outlier prescribing trends that led to his administrative probation does not violate the patients' rights to privacy under the state constitution. The court found that medical records are not comparable to prescription records from a privacy standpoint, as the latter are subject to regular scrutiny by law enforcement and regulatory agencies).

a search warrant or a court-issued subpoena for law enforcement officials to access PDMP data.²²³

Privacy protections for PDMP data can also be located in non-constitutional sources, such as the Health Insurance Portability and Accountability Act (“HIPAA”) and state privacy laws.²²⁴ The HIPAA “Privacy Rule” creates a national standard for the protection of individually identifiable health care information from disclosure by “covered entities” (or health care providers), with limited exceptions that may apply to PDMP data.²²⁵ For example, a covered entity may disclose health information that identifies a patient without receiving permission from that individual for enumerated exceptions germane to PDMPs, including: disclosures required by law; public health activities; health oversight activities; law enforcement purposes; and for treatment, payments, and health care operations.²²⁶ Moreover, HIPAA does not preempt state law (including state privacy and PDMP laws) if the Secretary of Health and Human Services determines that the state provision serves a compelling public health need or has as its principal purpose the regulation of any controlled substance, among other aims.²²⁷ All of this suggests that HIPAA should not prevent the sharing of information via PDMPs—either by dispensers when initially logged into the PDMP or to authorized users of PDMPs—so long as the information shared is limited to the minimum necessary to achieve the intended purpose.²²⁸

223. NAT’L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 2; Devon T. Unger, *Minding Your Meds: Balancing the Needs for Patient Privacy and Law Enforcement in Prescription Drug Monitoring Programs*, 117 W. VA. L. REV. 345, 386 (2014) (arguing that patients have a legitimate interest in personally identifiable PDMP data and that the Fourth Amendment requires law enforcement to obtain a warrant before accessing such data). Still, thirty states allow law enforcement to conduct searches of PDMP data merely pursuant to an active investigation, and many allow licensing boards to do the same. NAT’L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 25–26.

224. Unger, *supra* note 223, at 362–64.

225. 45 C.F.R. §§ 160, 164 (2012). “Covered entities” include medical or health care service providers, such as physicians and pharmacists, who electronically transmit individually identifiable information in connection with financial or administrative activities related to health care. *Id.* §§ 164.501, 164.506, 164.512.

226. 45 C.F.R. §§ 164.501, 164.506, 164.512 (2012).

227. HIPAA does not preempt state law (including a PDMP law) if the Secretary of Health and Human Services determines that the provision serves a compelling public health need, or has “as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substance;” or “provides for the reporting of disease or injury . . . or for the conduct of public health surveillance, investigation, or intervention.” 45 C.F.R. §§ 160.203(a)(1)–(2), 160.203(c). See *Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and Prescription Drug Monitoring Programs (PMPs)*, NAT’L ALL. FOR MODEL STATE DRUG LAWS (2010), <http://www.namsdl.org/library/BB52D3BB-1372-636CDD90AC3AAB8D724F/> (last visited Aug. 5, 2016).

228. 45 C.F.R. § 164.502(b)(1). At least one federal lawsuit charges that access by a local police department of a man’s prescription history without probable cause, a subpoena, or court order is a violation of HIPAA. Mollie Bryant, *Brandon Denies Police Violated HIPAA*, THE CLARION-LEDGER (Jan. 25, 2016),

Moreover, some states include explicit privacy protections in their PDMP laws. These steps are advisable for all programs and include: exempting PDMP data from public records requests;²²⁹ imposing criminal or civil penalties for unauthorized disclosure of PDMP data;²³⁰ limiting authorized users of the data to a select set of professionals; and explicitly requiring that the housing entity comply with all relevant state and federal privacy and confidentiality laws.²³¹ States should also put in place substantial data security protections to avoid disclosure of PDMP information, especially if data is shared across state lines. These measures include password-protected access (and careful authentication of all users), data encryption software, preventing unauthorized downloads of the data, and monitoring for potential security breaches.

While some states set forth stricter conditions for law enforcement and licensing official access PDMP files, as compared to pharmacy-housed files, the majority still allow warrantless searches.²³² The *Oregon Prescription Drug Monitoring* decision to require law enforcement officials to obtain a warrant based on probable cause strikes a reasonable balance between facilitating federal and state law enforcement drug investigations and protecting physician-patient interests and medical privacy. These data access requirements should also be extended to licensing bodies given their analogous role to law enforcement and ability to sanction medical professionals by revoking or suspending medical licenses. Otherwise, unfettered access to prescription records by law enforcement and licensing officials runs a higher risk of hampering prescribing and/or opioid use to an extent that compromises legitimate pain management. State rules that require the data be housed within a health agency and limit PDMP authorized users to those who use the data for clinical purposes—and provide the data (absent a warrant) to others (such as researchers, law enforcement, or licensing bodies) only on a de-identified basis—run the least risk of running afoul of privacy laws or interfering with the doctor-patient relationship. Moreover, requiring law enforcement and licensing bodies to obtain a warrant does not substantially interfere with their duties and is therefore reasonable.²³³

<http://www.clarionledger.com/story/news/2016/01/25/brandon-denies-bpd-violated-hipaa/79313188/> (last visited Aug. 5, 2016).

229. Thirty-one states currently exempt PDMP data from public records laws. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 41.

230. Thirty-eight states currently have such penalties for disclosing or obtaining PDMP data without authorization. *Id.* at 42. However, enforcement of these penalties is not well-documented.

231. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68; Unger, *supra* note 223, at 379–82 (proposing that all data be personally de-identified before disclosure to law enforcement officials).

232. See NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 22–37; NAT'L ALL. FOR MODEL STATE DRUG LAWS, TYPES OF AUTHORIZED RECIPIENTS—PROFESSIONAL LICENSING OR REGULATORY BOARDS (2014).

233. See *People v. Curco Drugs, Inc.*, 350 N.Y.S.2D 74, 84 (N.Y. Crim. Ct. 1973) (“[O]btaining of a warrant would not have seriously undermined the [statute allowing administrative inspections of

In summary, states seem to be the appropriate level for PDMP implementation and a federal PDMP is neither a realistic option on the horizon nor a necessary one. However, certain features of state PDMPs can infringe upon protected individual rights and should be carefully considered going forward. Given the potential for broad PDMP data access that could hinder optimal medical care by affecting doctor and patient behavior around opioid prescribing and drug seeking, PDMPs should be guarded carefully by the housing entity and available to a limited subset of users under select circumstances. Most notably, law enforcement and licensing officials should only obtain the data pursuant to a warrant based on probable cause. Penalties for unauthorized data disclosure should be clear, strong, and enforced.

B. EFFECTIVENESS OF REGULATION

Even if a PDMP seems likely to withstand privacy challenges, policymakers must further inquire into the effectiveness of a particular approach. This second consideration with respect to public health laws is empirical in nature: Will (or does) the regulation in question—either proposed or already implemented—effectively address the immediate public health threat? State regulators should specifically ask: (1) what are the public health outcomes this law seeks to impact?; (2) do these outcomes align with pre-defined primary and secondary health outcomes we seek to target?; (3) does sufficient, credible evidence exist to suggest that the law will achieve (or has achieved) intended public health outcomes when applied to the context and environment at hand?; and (4) Is the predicted or actual ratio of intended to unintended consequences high enough to warrant implementation?

This Article considers public health laws that are “interventional” in nature, meaning those that are intended to either directly affect health outcomes, or to impact health via mediating factors (such as health behaviors or environments) in the causal chain between laws and health outcomes.²³⁴ Interventional laws are central to answering the question at the core of public health lawmaking: “What are the best legal tools to use to promote health?”²³⁵ Nevertheless, many other types of public health laws, such as those of infrastructural and incidental natures, are critical to

pharmacy premises without a warrant]’s purpose of deterring violations. Clearly, it would have been only a minimal interference with their duties to obtain a warrant.”).

234. Anthony D. Moulton et al., *The Scientific Basis for Law as a Public Health Tool*, 99 AM. J. PUB. HEALTH 17, 17 (2009) (distinguishing “interventional” public health laws, or those designed to address specific health conditions or risk factors, from “infrastructural” public health laws, or those that empower public health agencies and jurisdictions); Burris et al., *supra* note 109, at 175 (further delineating further a third category, “incidental public health law,” as comprised of those policies that impact population health although they are not on their face oriented toward health).

235. Burris et al., *supra* note 109, at 186.

effective policymaking,²³⁶ and this framework could be adapted to measure the success of those laws as well.

With respect to interventional laws, the level of certainty required to deem a regulation effective can vary. As a general matter, policymakers should aim to identify robust evidence, generated using optimal designs for establishing causality, to support a particular regulatory approach. In other words, does the law itself *cause* intended changes in targeted health outcomes? This question can and should be assessed at different stages.²³⁷ If a policy is being newly considered for implementation, regulators can consider evidence generated from comparable contexts to support law initiation.²³⁸ Alternatively, if the law is already implemented, regulators can focus on retrospective evaluations of the specific law as well as literature reviewing similar policies to determine whether the law should be retained, revised, or abandoned in favor of other policy options (FIGURE 1). Policymakers might also consider a package of laws or a law intervention paired with a different type of policy, such as a PDMP combined with prescriber education initiatives, in which case they should seek evidence to support the interactive effects of these multiple interventions.²³⁹

Fortunately, in contemporary times, research on the effectiveness of public health law is increasingly available.²⁴⁰ Public health law research (“PHLR”) may be generated from within the legal academy, where there has been an explosion of empirical work in recent years, or from researchers in other social science fields (such as economics, health services research, political science, or public policy) that “use systematic methods within an explicit theoretical framework to collect and analyze data.”²⁴¹ The translation of available scientific evidence (research) into

236. *Id.* at 175, 186; Burris & Anderson, *supra* note 101, at 109.

237. See J. Frank Wharam & Norman Daniels, *Toward Evidence-Based Policy Making and Standardized Assessment of Health Policy Reform*, 298 JAMA 676, 677 (2007) (identifying the need for systematic and ongoing evaluations of new health policies, the lack of which has led to the discovery of unintended consequences years after policy implementation, and presenting a framework for maximizing the effectiveness and ethical characteristics of health policy. The four essential elements identified in the framework include: “(1) [r]eview to ensure that the policy’s fundamental precepts are ethical... (2) [t]argeted pilot projects or timely retrospective assessments to address benefits and harms for stakeholders... (3) [s]tudies to determine if unintended consequences can be satisfactorily minimized... [and] (4) [f]eedback systems to maintain acceptable outcomes after policy implementation.”).

238. Burris et al., *supra* note 109, at 187.

239. See Nancy E. Kass, *An Ethics Framework for Public Health*, 91 AM. J. PUB. HEALTH 1776, 1778 (2001) (observing that if a law is one of multiple and varied interventions that together are designed to reduce health risks and poor health, then interventions and studies must be designed with the awareness of the relationship between this program of interventions and ultimate reduction in morbidity and mortality).

240. For example, the Robert Wood Johnson Foundation funded a large Public Health Law Research initiative starting in 2008, to promote the scientific study of the relationship between laws and legal practices, and population health. Burris et al., *supra* note 109, at 171.

241. *Id.* at 172. In other words, they engage in “research.” *Id.*

public health policy and law, though a critical step, has historically been under-emphasized and constitutes a key criterion in the framework for evaluating the success of public health law (FIGURE 1).²⁴² Moreover, evidence included for this translation should be selected with care, based on some hierarchy of rigor and robustness, to avoid regrettable health policy decisions based on inadequate or misleading research.²⁴³

I. Outcome Variables of Interest

Intended outcomes that signify improved public health should be pre-defined by policymakers based on policy needs and targeted health risks. Public health targets of interventional laws can be categorized as primary and secondary outcomes, as described below. Other non-health-related or process-oriented benefits of legal interventions may accrue and are important, such as increased employment or community building in the process of carrying out the law, but these benefits are ancillary to the main goals of public health regulation.²⁴⁴ At the forefront of policymakers' minds when considering public health regulation should be stated goals of improving population health.²⁴⁵

242. See Jonathan E. Fielding et al., *How Do We Translate Science into Public Health Policy and Law?*, 30 J.L. MED. & ETHICS 22 (2002); see also Kass, *supra* note 239, at 1780 (noting that due to the all-too-common situation in which PHLR findings are not translated into policy, benefits can fail to accrue from the research. Institutional review boards allow research to proceed with the expectation that a benefit to research subjects or communities will emerge. Without translation into policy, the risk-to-benefit ratio of the research will rarely weigh in favor of research proceeding). *But see* Burris & Anderson, *supra* note 101, at 107–08 (discussing the influential nature of PHLR on policymaking, in both a top-down and bottom-up fashion. Research funding so crucial to creating a robust PHLR base, however, has been disproportionately light in comparison to its wide use and impact). Some of this policy translation has failed to occur for reasons outside of the effectiveness evidence, such as budget constraints and public support. See *infra* Part II.C.; see also Stephanie Zaza et al., *Using Science-Based Guidelines to Shape Public Health Law*, 31 J.L. MED. & ETHICS (SPECIAL SUPP.) 65, 66 (2003) (observing that legislators often shy away from evidence-based decisionmaking simply because they lack the knowledge to understand the science or because they lack confidence in the actual health benefits and effectiveness of a proposed intervention); Beverly Gard et al., *Connecting Public Health Law with Science*, 32 J.L. MED. & ETHICS (SPECIAL SUPP.) 100, 100 (2004).

243. See Sumit R. Majumdar & Stephen B. Soumerai, “*The Unhealthy State of Health Policy Research*,” 28 HEALTH AFF. w900 (2002) (discussing examples where researchers failed to adopt core principles of study design prerequisite to producing valid evidence, such as in the field of health information technology, which arguably led to the adoption of ineffective interventions. Worse, such an evidence-base could lead to the unintended consequence of population harm); see also Stephen B. Soumerai et al., *How Do You Know Which Health Care Effectiveness Research You Can Trust? A Guide to Study Design for the Perplexed*, 12 PREVENTING CHRONIC DISEASE: PUB. HEALTH RESEARCH, PRACTICE & POL’Y 1 (2015).

244. Kass, *supra* note 239, at 1778. These incidental benefits may play a role in balancing of benefits and harms when considering whether regulation should be undertaken.

245. *Id.* (“[A] reduction in morbidity and mortality need not and could not be the goal of every individual public health intervention or program; however, individual public health programs should not be undertaken that are not part of a larger package of programs whose combined goal is the reduction of morbidity and mortality.”).

Population health improvements can be measured in terms of primary outcomes or secondary outcomes. Primary outcomes are ideal measures of public health law effectiveness, as these directly reflect population health sought to be addressed by the law. Those considered of value to state policymakers include population-level morbidity and mortality measures.²⁴⁶ Pre-defined and “clinically significant” improvements in primary outcomes typically include reductions in diagnosed illnesses or deaths. In the PDMP context, primary targeted outcomes that signify improved health include reduced opioid-related overdoses, substance abuse treatment admissions, emergency department visits, and rates of addiction.

Secondary outcomes considered in public health law evaluations include proximal or intermediate outcomes that lie along the pathways of effect. Such proxy outcome variables include changes to environments and behaviors that expose individuals to health risks.²⁴⁷ PDMP proximal outcomes include changed prescriber and patient behavior, reduced controlled substance supply, and enhanced law enforcement or other surveillance activity. Changes in prescribing behavior indicative of reduced opioid misuse and overdose risk include, for example, lower rates of prescribing of high-morphine-equivalent dosages²⁴⁸ or less co-prescribing of opioids and benzodiazepines.²⁴⁹ Reduced rates of doctor shopping²⁵⁰ and drug diversion reflect changes in patient behaviors and/or law enforcement activity, from which lowered opioid adverse health effects theoretically follow.

While primary outcome measures are the ultimate measure of public health law effectiveness, a focus on intermediate (or secondary) outcomes is often necessary or reasonable for several reasons.²⁵¹ First, the time horizon required to detect changes in population health often can be lengthy,²⁵² because reduced morbidity and mortality attributable to a policy take time to manifest and measure. Take opioid misuse, for instance: Even if a PDMP reduces incident opioid addiction by erecting appropriate barriers to individuals obtaining prescriptions, reductions in population-level overdoses and mortality will take some time to manifest

246. Burris et al., *supra* note 109, at 177–78; Kass, *supra* note 239, at 1777.

247. *Id.*

248. Jane A. Baumblatt et al., *High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths*, 174 JAMA 796 (2014); Nathaniel Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance—Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996–2006*, 19 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 115 (2010); Logan et al., *supra* note 52; Wilsey et al., *supra* note 53.

249. Logan et al., *supra* note 52; Wilsey et al., *supra* note 53; Dunn et al., *supra* note 53.

250. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 67, for a definition of “doctor shopping.”

251. Burris et al., *supra* note 109, at 177–79.

252. *Id.*

because an already-addicted population will continue to experience these adverse health outcomes in the short-term. Also, ultimate health outcomes like opioid-related overdoses and hospitalizations are so rare that they must be observed over some time to detect policy-attributable changes, if there are any. It is thus more practicable and still telling to measure changes in prescribing patterns as a proxy for changes in the environment that ultimately would contribute to reduced opioid-related adverse health outcomes. Second, because ultimate health outcomes are often attenuated from laws or policies, understanding mechanisms that may lead to changes in these outcomes increases confidence that any effects observed are indeed attributable to a particular intervention. Access to and measurement of intermediary variables along the causal pathway avoids exclusive use of sometimes unpersuasive ecological studies, not uncommon to the PHLR literature.²⁵³

2. *Assessing the Evidence*

Policymakers and researchers should explicitly identify the intended and/or anticipated pathways of effect from law to health outcomes. Research supporting or refuting aspects of this pathway can be located within a causal model,²⁵⁴ while gaps in the research base may also become apparent. But how can regulators identify empirical research worth including in the evidence base to either support or call into question public health laws? PHLR can be good science, but this is not true across the field. Furthermore, some laws lend themselves to evaluation better than others.²⁵⁵ Principles of research design can be used to guide policymakers—even those with limited empirical training—in identifying scientific evidence worth incorporating into policy.²⁵⁶

A wide array of research methods are available for studying the effects of public health laws,²⁵⁷ ranging from qualitative research,²⁵⁸ to observational studies,²⁵⁹ to quasi-experiments,²⁶⁰ to randomized controlled

253. Burris & Anderson, *supra* note 101, at 108.

254. See Jeffrey Swanson & Jennifer Ibrahim, *Picturing Public Health Law Research: Using Causal Diagrams to Model and Test Theory*, in PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS 217–36 (eds. Alexander C. Wagenaar & Scott Burris, 1st ed. 2013).

255. Burris & Anderson, *supra* note 101, at 107–08.

256. Soumerai et al., *supra* note 243, at 14–15.

257. See generally Swanson & Ibrahim, *supra* note 254 (discussing the mechanisms, theories, and models central to public health law research).

258. Robert Drislane & Gary Parkinson, *Qualitative Research*, ONLINE DICTIONARY OF THE SOC. SCI. (2011), <http://bitbucket.icaap.org/dict.pl> (defining “qualitative research” as “[r]esearch using methods such as participant observation or case studies which result in a narrative, descriptive account of a setting or practice”).

259. WILLIAM R. SHADISH ET AL., EXPERIMENTAL AND QUASI-EXPERIMENTAL DESIGNS FOR GENERALIZED CAUSAL INFERENCE 12 (2002) (providing that, synonymous with a correlational study, an observational study is one “that simply observes the size and direction of a relationship among variables”).

260. *Id.* (“An experiment in which units are not assigned to conditions randomly.”).

experiments.²⁶¹ Study design types within these broad categories of research can be characterized by the inter-related concepts of rigor, suitability for causal inference, and capacity to control for common biases.²⁶²

A simplified hierarchy of designs can assist policymakers (ideally in coordination with researchers) in organizing PHLR to assess whether sufficient evidence exists to support law adoption or continued existence. The quantity of evidence is important here,²⁶³ although less so than the quality of evidence used to determine policy effectiveness and the generalizability of the evidence to the context in question. TABLE 2 suggests a way to organize studies, generally arranged from the strongest to weakest designs for causal inference (that is, to demonstrate that effects were *caused* by the policy studied). Randomized controlled experiments, the “gold-standard” for inferring a causal relationship between the law and an outcome,²⁶⁴ are quite rare in PHLR.²⁶⁵ Thus, natural experiments, or those where the intervention is not randomly assigned, are important to consider.²⁶⁶ The hierarchy presented is by no means exhaustive of the different types of studies that policymakers may encounter. Rather, it is intended as a starting point to assist in assessing the value of PHLR for policy incorporation.

261. *Id.* (“An experiment in which units are assigned to receive the treatment or an alternative condition by a random process such as the toss of a coin or a table of random numbers.”).

262. *See, e.g.*, Mello & Zeiler, *supra* note 102, at 657–62 (providing a helpful catalogue of methodological approaches to the empirical study of health laws, from strongest to weakest designs, and also displaying the rating system used by the U.S. Preventive Services Task Force in considering whether sufficient evidence exists to support a preventive health measure); Soumerai et al., *supra* note 243, at 15.

263. Kass, *supra* note 239, at 1778–79 (suggesting that the greater the burdens posed by a program, the stronger the evidence base must be to support that a program will achieve its stated goals).

264. Because the law is “randomly assigned” to an intervention group and not the comparison group, the two groups theoretically are comparable on every other dimension. Therefore, the effects found can be attributed to the intervention rather than confounding variables. Confounding variables are those that could be related to both the intervention and the outcome variable, and could thus explain any changes in outcomes observed.

265. Mello & Zeiler, *supra* note 102, at 660. *But see* Alan S. Gerber et al., *Evaluating Public Health Law Using Randomized Experiments*, in PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS, *supra* note 254, at 283–306.

265. SHADISH ET AL., *supra* note 259, at 171–206.

266. *See* Alexander C. Wagenaar & Kelli A. Komro, *Natural Experiments: Research Design Elements for Optimal Causal Inference Without Randomization*, in PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS, *supra* note 254, at 307–24.

TABLE 2. HIERARCHY OF PUBLIC HEALTH LAW RESEARCH DESIGNS

Category	Design Type	Brief Description	Strengths	Validity Threats ²⁶⁷
Experimental	Randomized controlled trial	Experiment in which units are assigned to receive a legal intervention or no intervention by a random process (e.g., toss of a coin or lottery). ²⁶⁸	<ul style="list-style-type: none"> • “Gold standard” of evidence for identifying causal relationships. • If randomization is successful, the risk of unmeasured confounding variables is minimized. 	<ul style="list-style-type: none"> • External validity (i.e. generalizability to other contexts, populations) is limited. • Quite rare in PHLR.
Quasi-Experimental	Interrupted time series	Study that specifies a time at which an intervention occurred to “interrupt” the prior situation (e.g., time at which a law is effective) and observes outcomes over multiple time points pre- and post-interruption. ²⁶⁹ Stronger design if it includes a comparison group or outcome not exposed to interruption.	<ul style="list-style-type: none"> • Displays graphically baseline trends and any changes in level or trend of the outcome variable at the time of interruption in the intervention group. 	<ul style="list-style-type: none"> • Co-occurring interventions or indeterminate intervention time periods threaten validity. • Requires adequate observations pre- and post-interruption to establish seasonality or secular trends.

267. Study validity can be characterized in a number of ways. This table and accompanying discussion focus on internal validity and external validity. “Internal validity” refers to the validity of inferences about whether observed covariance between treatment (intervention) and outcome variables reflects a causal relationship. “External validity” refers to the validity of inferences about whether the cause-effect relationship holds over variation in persons, settings, treatment variables, and measurement variables. SHADISH ET AL., *supra* note 259.

268. *Id.* at 12–13.

269. *Id.* at 171–206.

Category	Design Type	Brief Description	Strengths	Validity Threats ²⁶⁷
	Regression discontinuity	Study participants are assigned to a condition (e.g., health insurance coverage) on the basis of a cutoff score (e.g., income). Outcome variable is measured before and after assignment. ²⁷⁰	<ul style="list-style-type: none"> Minimizes differences (i.e., confounders) between groups, but for the cutoff score. 	<ul style="list-style-type: none"> Possible manipulation of the cutoff criteria (e.g., lying about income). Generalizable only to populations close to the cutoff.
	Difference-in-differences (or) controlled pre-post	Study that compares outcomes before and after the intervention in a group exposed to an intervention compared to a group not exposed.	<ul style="list-style-type: none"> Minimizes concern that effects merely reflect secular trends. 	<ul style="list-style-type: none"> Not accounting for differing baseline trends of groups.²⁷¹
Observational	Uncontrolled pre-post	Study measures outcome variable before and after the intervention, but without a comparison group. Stronger design adjusts for potential confounding variables (i.e., uses multivariate regression). ²⁷²	<ul style="list-style-type: none"> Can rule out that effects are caused by other confounding variables rather than the law of interest by including these variables in the model. 	<ul style="list-style-type: none"> Cannot rule out that secular changes in the environment may introduce confounding variables responsible for effects.

270. *Id.* at 207–43.

271. Soumerai et al., *supra* note 243, at 15.

272. Mello & Zeiler, *supra* note 102, at 659–60; Soumerai et al., *supra* note 243, at 15.

Category	Design Type	Brief Description	Strengths	Validity Threats ²⁶⁷
	Cross-sectional designs	Study is descriptive only, measuring outcome variable at one point in time after the intervention (i.e., no baseline measure). Stronger designs adjust for confounding variables (i.e., use multivariate, instead of univariate or bivariate regression). ²⁷³	<ul style="list-style-type: none"> • Can describe the relationship between two variables. Precision in the measure of this relationship is enhanced if other variables that relate to both (i.e., confounders) are included in the model. 	<ul style="list-style-type: none"> • No baseline measure(s) to provide a basis for comparison to outcome measures after the intervention, so no cause-effect relationship can be identified.
Qualitative	Surveys, interviews, focus groups	Systematic content analysis (and sometimes quantitative analysis) of questions answered by multiple study participants.	<ul style="list-style-type: none"> • Can provide rich context to the factors affecting policy effectiveness. 	<ul style="list-style-type: none"> • Subjective and susceptible to response bias.²⁷⁴ • Not generalizable given typically small sample sizes.
	Case studies	Description of policy intervention experience using a particular example or set of examples.	<ul style="list-style-type: none"> • Can provide rich information about particular example(s) of policy effectiveness.²⁷⁵ 	<ul style="list-style-type: none"> • Example(s) selected may be unique and not generalizable to other contexts.²⁷⁶

In addition to the above categories of designs for individual studies, other types of research aim to aggregate the findings of multiple primary studies and may be very valuable to policymakers. Systematic reviews use explicit methods to identify and critically review research relating to a particular outcome or set of outcomes and evaluate the strength of their findings to arrive at a general conclusion about the literature.²⁷⁷ Meta-analyses apply quantitative statistical analyses to pool and analyze findings from different studies to arrive at effect estimates of similar interventions across the literature.²⁷⁸ There are certain collaborative entities, such as the Cochrane Collaboration, Campbell Collaboration, and The Community Guide (of the Centers for Disease Control and Prevention) pioneering the work in these areas, although relatively few systematic-type

273. Mello & Zeiler, *supra* note 102, at 658–60.
 274. *Id.* at 658.
 275. *Id.*
 276. *Id.*
 277. *Id.* at 661; Moulton et al., *supra* note 234, at 17.
 278. *Id.*

reviews are available relative to the numerous and varied types of public health laws in existence.²⁷⁹ Finally, “comparative effectiveness” studies do not necessarily encompass a specific study design type, but are defined as those that compare methods to “prevent, treat, and monitor a clinical condition or to improve the delivery of care,” and to inform decisionmaking by policymakers, among others.²⁸⁰ This definition can potentially include head-to-head comparisons of community- and population-level interventions to improve health conditions, such public health law approaches to treating prescription opioid misuse.²⁸¹ Comparative effectiveness research, although in its infancy in the United States, is enjoying substantial federal funding²⁸² and may be increasingly available and relevant to public health policymaking in the future.

3. PDMP Effectiveness

The body of research investigating PDMP effectiveness is beginning to generate information about whether these policies impact opioid-related primary health outcomes or proximal outcomes. Although the literature is growing and of a respectable size, many studies are not rigorous enough to warrant policy incorporation or replication, when compared against the hierarchy of research designs presented in Table 2. Several more recent studies, though, use long-term data from multiple states and assess specific PDMP features to draw conclusions about PDMP impacts. As these kinds of stronger studies proliferate, a clearer sense of PDMP effectiveness will emerge.

The APPENDIX TABLE catalogs key studies of PDMPs that shed light on identified primary and secondary outcomes.²⁸³ The TABLE summarizes the results of a search of social science and medical peer-reviewed literature²⁸⁴ for studies that measure the effects of state-based, electronic

279. See Moulton et al., *supra* note 234, at 17, for a detailed discussion and catalogue of systematic reviews available for interventional public health laws, as well as identification of notable gaps in the field; see also Mello & Zeiler, *supra* note 102, at 661.

280. Jane Hyatt Thorpe, *Comparative Effectiveness Research and Health Reform: Implications for Public Health Policy and Practice*, 125 PUB. HEALTH REP. 909, 909 (2010) (quoting the Institute of Medicine’s definition of comparative effectiveness research).

281. *Id.*

282. *Id.* at 909–10.

283. See *supra* Part II.B.1 for identification of these outcomes.

284. The helpfulness of unpublished PDMP evaluations, such as those conducted internally by states, for informing policy is limited by the widespread use of uncontrolled designs (that is, the studies fail to include a comparison group for reference when evaluating a particular PDMP) and contexts which are difficult to generalize across states. Further, these evaluations are not subject to the peer-review process. Also, evaluations of PDMPs in other countries, most notably Canada, are not included in the literature presented. Extrapolating results from these studies presents numerous challenges given differing health care systems, prescribing norms, patient behaviors, and PDMP features. See Yoko Murphy et al., *Prescription Opioid Use, Harms and Interventions in Canada: A Review Update of New Developments and Findings Since 2010*, 18 PAIN PHYSICIAN E605, E610–E611 (2015).

PDMPs.²⁸⁵ Included in the TABLE are the published analyses that employ quasi-experimental and observational designs (*see* Table 2). Although this review does not focus on them, qualitative studies can offer further insights into the relationship between PDMPs and health outcomes, and should supplement policymaker considerations. The APPENDIX TABLE should not be considered exhaustive of research bearing on PDMPs, but it includes the best candidate studies currently available for drawing causal inferences about the public health effects of PDMPs.

Although some have interpreted the PDMP literature as providing strong evidence of program effectiveness,²⁸⁶ the story is far from clear.²⁸⁷ We still lack a robust understanding of whether PDMPs reduce opioid-related overdose deaths, the ultimate health outcome of interest. The best available study uses national mortality data from the Centers for Disease Control and Prevention to find no association between PDMPs and overdose mortality.²⁸⁸ However, the data used is somewhat outdated (1999–2005) and spans over a period when PDMPs were not very robust.²⁸⁹ On the other hand, states with PDMPs do seem to experience fewer opioid-related treatment admissions and poisonings, based on two strong quasi-experimental studies.²⁹⁰ These analyses used national poisoning and treatment admission data cumulatively spanning from 1997 through 2009 and characterized states of study based on the

285. There is a decent-sized body of literature on paper PDMPs, particularly focusing on their impact on benzodiazepine prescribing. However, this literature is not included in Appendix Table because paper PDMPs were a substantially different intervention from electronic PDMPs and were implemented during a different prescribing era. This literature thus may have limited generalizability to electronic PDMPs. *See* Tamara M. Haegerich et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose*, 145 *DRUG & ALCOHOL DEPENDENCE* 34, 37–38 (2014), for a summary of these paper PDMP studies.

286. *See, e.g.* PRESCRIPTION DRUG MONITORING PROGRAM CTR. OF EXCELLENCE AT BRANDEIS, *supra* note 69, at 3; Julie Worley, *Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research*, 33 *ISSUES IN MENTAL HEALTH NURSING* 319, 326 (2012).

287. *See* Haegerich et al., *supra* note 285, at 37–38 (presenting an astute but limited review of the PDMP evaluation literature from 1946–2014. The authors conclude that “later studies . . . have not clearly established significant effects on total opioid prescribing or health outcomes with PDMPs. The largest limitation is the lack of detailed data on prescribing volume and patterns prior to PDMP implementation, which forced the use of cross-section, observational study designs. The effect sizes in the most recent studies have been small, making it conceivable that the differences are due to unaddressed confounding variables. There is yet little data to settle the question of whether specific actions of PDMPs (e.g., proactive reporting) add to their effectiveness.”). No rigorous systematic reviews study PDMP effects.

288. *See* Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs and Death Rates from Drug Overdose*, 12 *PAIN MED.* 747 (2011).

289. *Id.*

290. Liza M. Reifler et al., *Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?*, 13 *PAIN MED.* 434 (2012); Richard M. Reisman et al., *Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 *SUBSTANCE ABUSE: RES. & TREATMENT* 41 (2009).

presence or absence of a PDMP.²⁹¹ Reifler et al. went a step further and conducted sub-analyses of “superior” PDMP features—for example, program was in effect for a long time, sent unsolicited reports, and monitored comprehensive drug schedules—to find consistent results.²⁹² Although further study of all primary health outcomes is warranted, these studies suggest that PDMPs are at least associated with decreased poisonings and admissions.

However, the mechanism of effect (or secondary outcomes) to explain reduced treatment admissions and poisonings is uncertain. The literature findings are mixed as to whether state PDMPs reduce opioid supply or prescribing. Several quasi-experimental studies use national opioid supply data spanning 1997 through 2008 to draw different conclusions regarding whether PDMPs are associated with reduced supply. Another quasi-experimental study conducted by Rutkow et al. found that Florida’s (voluntary) PDMP and pill mill law combined to drive modest decreases in total opioid fills and morphine concentration per dose (but not days’ supply of drugs) among the highest baseline users and prescribers, respectively.²⁹³ This strong analysis nevertheless suffers from an imperfect comparison state—Georgia, which had much lower prescribing at baseline—and an inability to isolate PDMP effects from those of another intervention.²⁹⁴ Weaker observational studies have drawn mixed conclusions about the effect of PDMPs on prescribing behavior and typically include small sample sizes, which limit their generalizability.²⁹⁵ Finally, there is very little evidence to suggest that PDMPs reduce doctor shopping or diversion, given that the few studies available on these outcomes do not lend themselves to causal inference.²⁹⁶

Although the evidence base in support of PDMPs is growing, it requires significant further exploration and rigor. Weaknesses in the

291. *Id.*

292. Reifler et al., *supra* note 290.

293. See Rutkow et al., *supra* note 167.

294. *Id.*

295. See David F. Baehren et al., *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors*, 56 ANNALS EMERGENCY MED. 19 (2010); Chris Ringwalt et al., *The Effects of North Carolina’s Prescription Drug Monitoring Program on the Prescribing Behaviors of the State’s Providers*, 36 J. PRIMARY PREVENTION 131 (2015); Matthew W. McAllister et al., *Impact of Prescription Drug-Monitoring Program on Controlled Substance Prescribing in the ED*, 33 AM. J. EMERGENCY MED. 781 (2015); Scott G. Weiner et al., *Clinician Impression Versus Prescription Drug Monitoring Program Criteria in the Assessment of Drug-Seeking Behavior in the Emergency Department*, 62 ANNALS EMERGENCY MED. 281 (2013).

296. See, e.g., Linda Simoni-Wastila & Jingjing Qian, *Influence of Prescription Monitoring Programs on Analgesic Utilization by an Insured Retiree Population*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1261 (2012); Hilary L. Surratt et al., *Reductions in Prescription Opioid Diversion Following Recent Legislative Interventions in Florida*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 314 (2014).

literature are numerous. First, many of the more rigorous studies were conducted during a period when PDMPs were much weaker policies—for instance, through the early 2000s, programs typically monitored only Schedule II substances and were seldom queried—and thus need updating. Second, most studies are not rigorous, with no randomized controlled trials and few quasi-experimental studies available. Many studies also lack a comparison group, fail to measure outcomes before a policy went into effect, or include small sample sizes. Third, studies typically do not adequately account for many other, co-occurring prescription drug misuse policy interventions (such as pill mill laws, or opioid drug reformulations), and thus could falsely attribute effects to PDMPs instead of to these policies. Finally, mixed results could be attributable to divergent PDMP policies, which are typically not carefully characterized in studies. Studies could do a much better job of differentiating the PDMP interventions based on policy strength.

A major drawback in PDMP studies, moreover, is the typical failure to account for actual levels of PDMP *use* by prescribers, which is still thought to be quite low.²⁹⁷ The median PDMP *registration* rate among providers who issued at least one controlled substance prescription was thirty-five percent from 2009–2012,²⁹⁸ and not all enrolled prescribers regularly query PDMPs. A recent national study found that only fifty-three percent of primary care physicians reportedly use their state's PDMP.²⁹⁹ Although studies do suggest that PDMP awareness is high and that use is increasing over time,³⁰⁰ database queries are still sufficiently low that not incorporating this measure into studies may dilute any potential findings of effect. Also, further investigation is required into whether targeting increased use among a subset of high-volume

297. *But see* Ringwalt et al., *supra* note 295; Chris Delcher et al., *Abrupt Decline in Oxycodone-Caused Mortality After Implementation of Florida's Prescription Drug Monitoring Program*, 150 *DRUG & ALCOHOL DEPENDENCE* 63 (2015) (incorporating a measure of PDMP queries into the intervention variable).

298. PETER KREINER ET AL., BUREAU OF JUSTICE ASSISTANCE PRESCRIPTION DRUG MONITORING PROGRAM PERFORMANCE MEASURES REPORT: JANUARY 2009 THROUGH JUNE 2012 (2013). The percentage of prescribers who registered with the program (among prescribers who issued at least one controlled substance prescription in the prior three months) from 2009–2012 ranged from one to eighty-two percent based on the state. *Id.* at 15–16.

299. Lainie Rutkow et al., *Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, But Many Find the Data Difficult to Access*, 34 *HEALTH AFF.* 484, 487 (2015).

300. *See, e.g.*, Jeanmarie Perrone et al., *Prescribing Practices, Knowledge, and Use of Prescription Drug Monitoring Programs (PDMP) by a National Sample of Medical Toxicologists*, 8 *J. MED. TOXICOLOGY* 341 (2012); Lance Feldman et al., *Awareness and Utilization of a Prescription Monitoring Program Among Physicians*, 13 *J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY* 908 (2011); Lance Feldman et al., *Influencing Controlled Substance Prescribing: Attending and Resident Physician Use of a State Prescription Monitoring Program*, 13 *J. PAIN MED.* 908 (2012); Kirstin Barrett & Ashby Watson, *Physician Perspectives on a Pilot Prescription Monitoring Program*, 19 *J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY* 5 (2005).

prescribers, rather than all physicians or controlled substance prescribers, is warranted.

Because so many varied PDMPs have been implemented, policymakers and researchers should now look to evidence from multi-state, retrospective, comparative evaluations of their effectiveness.³⁰¹ This evidence base needs to be updated, using longer-term data from before and after program implementation, now that sufficient time has passed since electronic PDMPs were implemented in many jurisdictions. Identifying appropriate comparison jurisdictions to enable quasi-experimental designs is somewhat of a challenge, given that forty-nine states have adopted their own PDMPs. Thus, time variation in PDMP adoption or implementation of certain features offers opportunities for comparative studies. For instance, the impact of relatively recent “strong” PDMP mandates on reduced opioid prescribing (requiring that prescribers check the systems regularly) shows promise in the handful of states that have adopted this policy lever,³⁰² but requires additional empirical support. Also, comparison outcomes offer new avenues. For example, researchers can compare opioid prescribing for acute pain or headaches (indications where opioids have been shown to have limited utility) versus that for cancer (where opioid prescribing receives little scrutiny). One would hypothesize that PDMPs would reduce opioid prescribing in the former case, but not the latter.

The literature would benefit from a greater interdisciplinary focus by incorporating prescribers, pharmacists, program administrators, law experts, and health services researchers into informing and designing studies. Prescribers and pharmacists can provide clinical expertise germane to generating hypotheses about which PDMP features are likely to impact prescribing behavior, and to identifying appropriate comparison outcomes (see above example). Law experts can assist in categorizing PDMPs as robust or weak for comparison purposes, based on assessment of their policy features or enforcement. Policymakers can identify key outcomes of interest with regard to PDMP effectiveness. Program administrators can provide PDMP data for study and an understanding of the operational particulars of the programs, such as user-ship. And health services researchers can help to design the best studies feasible using available data.

301. Twenty PDMPs currently require that evaluations be reported to the legislature at least annually regarding the effectiveness of the programs and how they are impacting prescribing. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 11. These types of reporting requirements would offer a prime opportunity for policymakers to work with researchers and program administrators to enhance the evidence base, particularly by conducting studies using comparison states or comparison outcomes.

302. Linda Rasubala et al., *Impact of Mandatory Prescription Drug Monitoring Program on Prescription of Opioid Analgesics by Dentists*, 10 PLOS ONE 1 (2015) (discussing a strong assessment of the New York i-STOP mandate's impact on opioid prescribing among dentists). See Haffajee et al., *supra* note 70.

Finally, comparative effectiveness studies that compare PDMPs to other state interventions targeting opioid misuse, such as pill mill laws or access to opioid antagonists, would provide timely information to regulators regarding how to best invest their limited resources to tackle prescription opioid misuse. If PDMPs are implemented concurrently with other interventions, as was the case in Florida where PDMPs and other policies were pursued in quick succession, it may be practically difficult to separate out PDMP independent effects, and thus co-effects that are less generalizable to other jurisdictions must be considered.³⁰³ Exploration into all these areas would assist policymakers to most effectively address prescription drug misuse and would serve to facilitate decisions regarding whether to retain, amend, or abandon PDMPs.

C. ETHICAL CONSIDERATIONS

A third broad inquiry for state policymakers asks whether ethical objections advise against public health law implementation or perpetuation. Even if a policy falls within the appropriate legal parameters for state action and seems likely, or is proven, to be effective in addressing the public health problem, there may be ethical objections that, if substantial, should bar its implementation or continued existence.

The community-level focus of public health calls for a set of justificatory considerations distinct from those used in clinical medical settings where the treatment and cure of individual patients are paramount.³⁰⁴ Instead, public health is primarily concerned with the well-being of populations, the broader social and environmental determinants of health, and prevention of ill societal health.³⁰⁵ Public health ethics frameworks that are practice-based emerged from an explicit recognition of these distinguishing features and unique moral considerations in public

303. See Rutkow et al., *supra* note 299 (studying the interactive effects of the Florida PDMP law and pill mill laws on opioid prescribing and total opioid volume). *But see* Delcher et al., *supra* note 297 (attempting to “control” for three co-interventions that impacted Florida—including the Florida pill mill law, DEA pill mill crackdown, and OxyContin reformulation—in the multivariate regression model).

304. Kass, *supra* note 239, at 1776 (“[C]odes of medical and research ethics generally give high priority to individual autonomy, a priority that cannot be assumed to be appropriate for public health practice. . . . A framework of ethics is needed, both to provide practical guidance for public health professionals and to highlight the defining values of public health, values that differ in morally relevant ways from values that define clinical practice and research.”). See Lisa M. Lee, *Public Health Ethics Theory: Review and Paths to Convergence*, 34 J. L. MED. & ETHICS 85, 87 (2012); James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 170 (2002); Ross E.G. Upshur, *Principles for the Justification of Public Health Intervention*, 93 CANADIAN J. PUB. HEALTH 101, 101 (2002).

305. Upshur, *supra* note 304, at 101. The Institute of Medicine has defined public health as “what we, as a society, do collectively to assure the conditions in which people can be healthy.” INST. OF MED., *THE FUTURE OF PUBLIC HEALTH* 19 (1988).

health.³⁰⁶ Rather than try to provide a comprehensive philosophical approach to public health in practice, they rely upon the foundational values of rights (positive and negative) and social justice.³⁰⁷ Specifically, a code of public health ethics should emphasize the negative rights of citizens to noninterference, affirmative societal obligations to improve the health of the overall population, and the need to fulfill these obligations with special focus on the needs of the most disadvantaged.³⁰⁸ The principles proposed provide practical guidance for practitioners faced with public health-related ethical quandaries,³⁰⁹ including policymakers implementing public health laws.³¹⁰

Public health ethics principles set forth by Kass³¹¹ and Childress³¹² provide useful guideposts for the ethical implementation of public health laws. These conditions do not explicitly include, but instead complement and assume, favorable performance under those criteria already set forth herein (that is, the legal permissibility and effectiveness of a law designed to address a significant public health threat).³¹³ Although not an exact algorithm to resolve conflicts between the goal of public health and other moral considerations, the following ethical conditions can help guide determinations about the appropriateness of public health interventions, and include: (1) proportionality; (2) minimal infringement; (3) fairness; and (4) public accountability.³¹⁴ A brief discussion of the principles follows, and each is applied to the PDMP context—although it is important to bear

306. *Id.*

307. Lee, *supra* note 304, at 87–90; Kass, *supra* note 239, at 1777.

308. Kass, *supra* note 239, at 1777; GOSTIN, *supra* note 101, at 10–11 (discussing the social justice moral impulses that animate public health: (1) to advance human well-being by improving health; and (2) to do so by particularly focusing on the needs of the most disadvantaged. To satisfy these aims succeeds in bringing the good of health to *all* members of the population).

309. Lee, *supra* note 304, at 87–88.

310. Kass, *supra* note 239, at 1777 (“Indeed, it is in great part *because* such power is vested in public health by law that a code or framework of ethics designed specifically for public health is so very important.”).

311. *See id.*

312. Childress et al., *supra* note 304.

313. Several of the justificatory conditions included in public health ethics frameworks proposed by other scholars actually overlap with legal requirements set forth in Part II.A *supra*, and the general requirement of effectiveness set forth in Part II.B *supra*. For example, James Childress et al. require that a public health policy be *necessary*, *effective*, and *minimally infringing*. Childress et al., *supra* note 304, at 173. Nancy Kass requires that a public health policy be *effective* at reducing mortality and morbidity and *minimally infringing*. Kass, *supra* note 239, at 1778–80. Richard Upshur requires that the program be minimally restrictive. Upshur, *supra* note 304, at 102. Minimal infringement is included in the present framework as an ethical principle because, depending on the type of policy, the law requires varying degrees of inquiry into the level of infringement and whether less restrictive alternatives are available. By including minimal infringement as an ethical principle, an inquiry must be made into the reasonableness of the intrusiveness of the law, not merely whether an *obviously* less restrictive means is available. *See infra* Part II.A.1.

314. Childress et al., *supra* note 304, at 173.

in mind that every state PDMP is unique and must be assessed on a case-by-case basis.

I. Proportionality

First, it is critical to demonstrate that the benefits of a public health law outweigh the costs or infringements associated with its implementation.³¹⁵ Proportionality requires the weighing of societal benefits against burdens, in order to help assess whether a particular law is the best use of available resources.³¹⁶ There are two dimensions of proportionality: one that considers societal benefits against individual burdens and another that considers societal benefits against societal burdens. Individual burdens, such as liberty and privacy, will be further addressed below in the discussion of “minimal infringement.”³¹⁷ The societal benefits of PDMPs include changes in the primary and secondary outcomes outlined above: Reducing opioid-related adverse health outcomes, improving prescribing, and reducing diversion or doctor shopping. Societal benefits also include reduced expenditures associated with prescription drug misuse, as well as more intangible but potentially substantial benefits associated with reduced unemployment, absenteeism, and family disruption. Illicit drug use (a large percentage of which involves opioids) costs our nation \$11 billion in health care costs and \$193 billion annually overall³¹⁸—some of which expenditure could be saved if PDMPs work to curb this practice.

Societal burdens considered should include government costs of implementation and enforcement, as well as the opportunity costs of expending government and private resources, including political capital, instead of pursuing other policies to achieve the same ends. PDMPs are expensive to implement and finding the money to implement them has proven a challenge. Programs are funded by a combination of federal funds, private funds, and state-raised revenues, but often operate at

315. *Id.*

316. Two tools may be useful to policymakers for comparing costs to benefits. Cost-benefit analysis quantifies the costs and benefits of a course of action, comparing them using the same metric (often monetary value). Trying to quantify the benefits of a course of action can be challenging and controversial. Thus, in health interventions, cost-effectiveness analysis is often favored. Cost-effectiveness analysis divides the impact of a program (such as the percentage reduction in new cases of opioid addiction) by the cost of the program, generating a statistic termed the “cost-effectiveness ratio” (“CER”). CERs can be compared as between different policy interventions or programs. Abdul Latif Jameel, *Introduction to Evaluations: Cost-Benefit/Effectiveness/Comparison Analyses*, J-PAL, <https://www.povertyactionlab.org/methodology/what-evaluation/cost-benefiteffectivenesscomparison-analyses> (last visited Aug. 5, 2016). For further discussion of concepts and benefits of cost-effectiveness analysis for use by policymakers, see WORLD HEALTH ORG., MAKING CHOICES IN HEALTH: WHO GUIDE TO COST-EFFECTIVENESS ANALYSIS (T. Tan-Torres Edejer et al., eds., 2003), http://www.who.int/choice/publications/p_2003_generalised_cea.pdf.

317. Individual burdens are the focus of James Childress et al.’s discussion of the proportionality principle. See Childress et al., *supra* note 304, at 173–76.

318. *The Science of Drug Abuse & Addiction: Trends and Statistics*, NAT’L INST. ON DRUG ABUSE (2015), <https://www.drugabuse.gov/related-topics/trends-statistics> (last visited Aug. 5, 2016).

impaired capacity when money issues arise.³¹⁹ The programs are complex to operate—from the technical components (software is usually proprietary and owned by contracted software vendors) to ensuring confidentiality of information, to checking the accuracy of data inputted by dispensers, to promoting or enforcing use by prescribers, to facilitating optimal law enforcement use of the data. Substantial resources are required to facilitate these tasks. In the current environment, PDMPs constitute the dominant state approach to addressing prescription drug misuse, perhaps at the opportunity cost of investing money and political capital into other opioid misuse prevention efforts. In order to justify these societal costs, the health benefits and cost savings will need to be explicitly proven.

Moreover, unintended effects—both negative and positive—of regulation on population health outcomes or on non-health outcomes should be included in the calculus. There may be substantial negative unintended effects of PDMPs on populations, the extent of which are currently unknown. Although a few studies have suggested that electronic PDMPs will not have a “chilling” effect on appropriate prescribing,³²⁰ whether PDMPs lead some prescribers to cut back on or discontinue appropriate controlled substance prescribing, thereby exacerbating the under-treatment of pain epidemic or other maladies, remains to be seen. Studies of older paper PDMPs found that prescribers did, indeed, cut back on appropriate benzodiazepine prescribing, particularly among racial minorities³²¹—albeit this was a somewhat different, more forceful intervention than most electronic PDMPs. Some studies of early electronic PDMPs detected substitution from monitored (Schedule II) to non-monitored (Schedule III) opioids,³²² which lends support to the possibility that PDMPs could change pain management treatment and possibly compromise clinical care. Differentiating between appropriate and inappropriate opioid prescribing, as well as how to best use PDMPs to identify doctor shoppers and diverters, places a substantial onus on prescribers (and pharmacists) in an area where clinical disagreements abound. Also, if opioid addicts are denied pills because prescribers check PDMPs, then they may turn in increasing numbers to heroin—a

319. PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., BRANDEIS UNIV., TECHNICAL ASSISTANCE GUIDE NO. 04-13: FUNDING OPTIONS FOR PRESCRIPTION DRUG MONITORING PROGRAMS, (2013), http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf.

320. See Baehren et al., *supra* note 295; Ringwalt et al., *supra* note 295.

321. Dennis Ross-Degnan et al., *A Controlled Study of the Effects of State Surveillance on Indicators of Problematic and Non-problematic Benzodiazepine Use in a Medicaid Population*, 34 INT'L J. PSYCHIATRY MED. 103 (2004); Sallie-Anne Pearson et al., *Racial Disparities in Access After Regulatory Surveillance of Benzodiazepines*, 166 ARCHIVES INTERNAL MED. 572 (2006).

322. See Paulozzi et al., *supra* note 288; Simoni-Wastila & Qian, *supra* note 296.

perverse, negative public health ramification.³²³ Many of these potential unintended consequences of PDMPs are substantial: Research should investigate whether they occur, and safety mechanisms should be instituted to prevent their matriculation. For instance, if opioid addicts are denied prescription drugs, addiction treatment options should be recommended and made available so that they are less likely to turn to heroin.

2. *Minimal Infringement*

As a corollary to the proportionality requirement, policymakers should seek to minimally infringe upon private interests and adopt the least restrictive means available. This ethical requirement can be viewed as complementary to the legal standards described in Part II.A.1 (and in some cases, of a higher threshold). This condition recognizes that there may be a number of means to achieving a public health end, and the least restrictive one should be favored—particularly when using powerful police powers that are presumptively coercive, the unintended consequences of which may be ill understood.³²⁴ Individual burdens or harms typically will fall into three categories: (1) risks to privacy and confidentiality; (2) risks to liberty and self-determination; and (3) risks to justice (which will be further addressed as a fairness consideration below).³²⁵ Even where a public health law may appear to restrict an individual's liberty, its potential to enhance the liberty of other individuals warrants consideration, as positive externalities of public health laws abound.³²⁶

PDMPs impose serious individual burdens on prescribers and patients. PDMP infringements on prescribers in their clinical practice are not insignificant, and prescribers have shown resistance to using PDMPs. Commonly cited prescriber objections to use include concerns about compromised patient satisfaction ratings (if checking a PDMP results in delays or denial of controlled substance prescriptions), unreimbursed time associated with using the program, burdensome enrollment procedures, cumbersome systems, and the information being viewed as unnecessary, incomplete, inaccurate, and/or untimely.³²⁷ To minimally

323. See Leo Beletsky, *As Heroin Deaths Skyrocket, Prescription Monitoring Programs May Do More Harm*, HUFFINGTON POST (Mar. 18, 2015), http://www.huffingtonpost.com/leo-beletsky/as-heroin-deaths-skyrocket-prescription-monitoring-programs-may-do-more-harm_b_6883944.html.

324. Upshur, *supra* note 304, at 102.

325. Kass, *supra* note 239, at 1779 (discussing the burdens more or less likely to arise from different public health activities). Regulations and legislation rank among the most intrusive approaches to public health—they are coercive because they typically impose penalties for noncompliance. *Id.*

326. Parmet, *supra* note 109, at 405.

327. Deyo et al., *supra* note 76.

infringe upon prescribers and the physician-patient relationship,³²⁸ these barriers should be reasonably addressed, for example, by automatically enrolling prescribers,³²⁹ improving integration into clinical workflow, and making data complete through frequent updates and interstate sharing (at least among neighboring states). Physicians should not be required to log into multiple, cumbersome systems, particularly absent reimbursement for their time.³³⁰

Use mandates adopted in twenty-two states raise a particularly interesting quandary: They infringe substantially on physicians, but they seem to increase use and possibly reduce opioid prescribing volume and misuse. Robust evidence, therefore, should be generated from within states that have enacted strong mandates (such as New York and Tennessee) to justify this policy lever before it is more universally adopted given significant prescriber objections.³³¹ At the same time, PDMP features that serve to dis-incentivize prescribers from checking the systems, such as laws that explicitly provide prescriber immunity from liability for failure to check³³² or exemption from any obligation to query the systems,³³³ should be abandoned to send the message that PDMPs ought to be checked frequently when prescribing monitored substances.

Infringements on prescribers and patients can also be substantial if their private prescription data are disclosed and/or used for law enforcement or regulatory purposes. As discussed in Part II.A, allowing law enforcement and licensing boards unfettered access to PDMP data—namely, to identify high-volume prescribers, doctor shoppers, or diverters absent a court-issued warrant or subpoena—tosses the line, legally speaking. As an ethical matter, even if the law allows wide access in certain jurisdictions, patients and prescribers arguably should be afforded heightened privacy protections to allow uninhibited doctor-patient decisionmaking to occur. Also, strict data security protections, particularly when information flows across states, are necessary to minimize confidentiality concerns felt by opioid prescribers and patients. These include robust technological protections³³⁴ and penalties for disclosure by PDMP authorized users.

Effective PDMPs are likely to benefit third parties, despite other liberty infringements. Preventing addiction facilitates the enjoyment of

328. See Steven E. Weinberger et al., *Legislative Interference with the Patient-Physician Relationship*, 367 *NEW ENG. J. MED.* 1557 (2012) (citing other examples of doctor-patient interferences, such as restrictions on discussions about gun safety imposed in some states).

329. Twenty-one states currently require prescribers and dispensers to register with the PDMP. *NAT'L. ALL. FOR MODEL STATE DRUG LAWS*, *supra* note 68, at 39.

330. See Haffajee et al., *supra* note 70.

331. *Id.*

332. Twenty-five states provide such immunity. *NAT'L. ALL. FOR MODEL STATE DRUG LAWS*, *supra* note 68, at 38.

333. Sixteen states absolve prescribers from any obligation to check PDMPs. *Id.* at 37.

334. See *infra* Part II.A.4 for PDMP security recommendations.

certain liberties by others, such as avoiding the burden of being exposed to prescription opioids (which increases the likelihood of using and abusing drugs); avoiding caring for, watching suffer, or losing a family member or friend; avoiding exposure to HIV or other diseases spread by sharing infected needles;³³⁵ and avoiding increases in health insurance premiums (or taxes for public programs) generated by the costs of opioid-related hospitalizations or outpatient visits.³³⁶ These benefits suggest that a balance must be struck between making PDMPs minimally intrusive on individual liberties and making them effective—as mentioned in the mandate discussion above.

3. *Fairness*

A public health law should satisfy a basic requirement of fairness.³³⁷ Although fairness can be articulated using a number of different ethical frameworks,³³⁸ this discussion centers on the distributive justice theory originally conceived by John Rawls,³³⁹ which calls for the equitable distribution of benefits and costs among populations and communities. Kass and Gostin both ground fairness in distributive justice.³⁴⁰ According to Kass's framework, distributive justice in public health obligates the government to ensure that interventions address the health of the least advantaged; Gostin goes a step further to assert that the negative consequences of interventions do not fall disproportionately on the least advantaged.³⁴¹ Because the least advantaged are more vulnerable to public health threats as well as least likely to enjoy other social determinants of health, they arguably deserve special attention.³⁴²

In the case of prescription opioid misuse, the least advantaged in society (as measured by socioeconomic status, for example) are more likely to lack robust education about the science and risks of addiction;

335. See Abby Goodnough, *Rural Indiana Struggles to Contend with H.I.V. Outbreak*, N.Y. TIMES (May 5, 2015), http://www.nytimes.com/2015/05/06/us/rural-indiana-struggles-to-contend-with-hiv-outbreak.html?_r=0.

336. See, e.g., Dr. Holm, *Harm from Drug Abuse Extends Beyond the Illicit User*, RAPID CITY J. (Aug. 3, 2015), http://rapidcityjournal.com/harm-from-drug-abuse-extends-beyond-the-illicit-user/article_95a5e18c-fc7c-5386-a946-e74b078b82be.html (suggesting that harms extending beyond the user include “increased crime and violence, child and spouse abuse, motor vehicle accidents, sexually spread diseases, fetal malformations in children, and deaths due to accidental and intentional overdose”).

337. Some of the fairness concepts presented in this Part resemble those of equal protection required under the Constitution, briefly discussed *supra* Part II.A.3, which aims to protect those groups subjected to historical discrimination. This ethical inquiry is somewhat broader, however, and does not identify specific classes of persons particularly deserving of protection.

338. For example, prioritarian or utilitarian frameworks can also be adopted, depending on societal conceptions of fairness.

339. See JOHN RAWLS, *A THEORY OF JUSTICE* (1971).

340. Kass, *supra* note 239, at 1780–81 (noting that this requirement is particularly important if an intervention is restrictive).

341. GOSTIN, *supra* note 101, at 11.

342. *Id.*

switch to cheaper and more easily accessed heroin when prescription pills are no longer available; have limited treatment options for addiction and overdose (such as naloxone access; substance abuse treatment); and lack access to social and other support services to address addiction and its consequences (such as access to clean needles). These considerations mean that PDMPs may be necessary to reduce inequalities, but also that any unintended negative consequences should not disproportionately fall upon the less advantaged. The paper triplicate form of prescription monitoring that preceded electronic PDMPs reduced problematic, as well as *non*-problematic, benzodiazepine use,³⁴³ and had disproportionate under-prescribing impacts in minority communities.³⁴⁴ The potential for these unintended consequences of electronic PDMPs should be closely monitored, to see if, for example, certain demographic groups are targeted as potential “doctor shoppers” and prescribed to less often as a result of these programs. Education and guidelines should accompany prescriber use of the systems to promote standardized and conscientious use of the data in a way that promotes good health and does not exacerbate social inequalities.

4. *Public Accountability*

Finally, the government should strive to be accountable to the public when implementing health laws on their behalf. Any public health law will infringe on some private interests and impose some social cost, and thus should be explained and justified to parties impacted. Policymaking transparency respects stakeholders as moral equals who deserve to be involved in the decisionmaking process.³⁴⁵ It also is essential to creating and maintaining public trust, an element so crucial to the acceptability and ultimate effectiveness of public health laws as well as the general legitimacy of future policymaking.³⁴⁶ Public health policies may be particularly susceptible to backlash—in the form of lack of public support, legal challenges, noncompliance, or opposition to future laws—if they are coercive.³⁴⁷ Policymakers should appreciate that different social groups may view public health laws from different perspectives and endeavor to gain diverse support.³⁴⁸ In pluralistic societies, where there is reasonable disagreement about principles that ought to guide priority setting in meeting population health needs given limited resources, different viewpoints should be understood and

343. Ross-Degnan et al., *supra* note 321.

344. Pearson et al., *supra* note 321.

345. Upshur, *supra* note 304, at 102; Childress et al., *supra* note 304, at 173.

346. Childress et al., *supra* note 304, at 173; Parmet, *supra* note 109, at 410.

347. Parmet, *supra* note 109, at 410.

348. Parmet et al., *supra* note 133, at 654.

respected, and decisionmaking made as clear and accountable as possible.³⁴⁹

PDMP implementation and policies should thus be transparent to the public. Consideration of various features and program amendments should be made with the involvement of relevant stakeholders. The process of effectuating changes to the Massachusetts PDMP provides an example of excellent public accountability in public health lawmaking. In August 2012, Massachusetts enacted a law to automatically enroll practitioners in its existing PDMP and require that they consult the database when prescribing controlled substances to new patients. The Commonwealth solicited extensive feedback and held hearings concerning these changes. Through this process, prescriber objections to the breadth of circumstances for PDMP checks surfaced and were incorporated into the final implementation rules in the form of mandate exemptions.³⁵⁰ As a result, the cooperation and mutual respect between public health officials and Massachusetts providers was likely strengthened, which will facilitate future prescription drug misuse prevention endeavors. Prescribers will also be more willing to accept and comply with the PDMP mandate now in effect.

CONCLUSION

This Article seeks to simplify and systematize the inquiries critical for state policymakers when considering public health laws—like PDMPs—for implementation. Although various scholars have outlined factors that should guide policymaking, for instance in the public health ethics and PHLR literature, this Article is the first to synthesize the factors under three key criteria relevant to *state* regulation, suggest the policymaking junctures at which they should be applied, and apply them to PDMPs. PDMPs constitute the dominant policy adopted by states to address prescription opioid misuse—a profound public health challenge that is as complex in etiology as in the policy interventions available to combat it. PDMPs exemplify unstructured policymaking uninformed by

349. *Id.*; Upshur, *supra* note 304, at 102; Norman Daniels, *Accountability for Reasonableness: Establishing a Fair Process for Priority Setting Is Easier than Agreeing on Principles*, 321 BRITISH MED. J. 1300, 1300 (2000) (outlining key elements of a “fair process” for guiding public health decisions, including: transparency about the basis of a decision, appeals to common rationales that fair minded people can accept as relevant to meeting health needs fairly; and procedures for appealing/revising decisions).

350. *Massachusetts Prescription Monitoring Program*, MASS. EXEC. OFFICE OF HEALTH & HUMAN SERVS. (July 2016), <https://www.drugabuse.gov/related-topics/trends-http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/prescription-monitoring-program.html#statistics> (last visited Aug. 5, 2016). For example, the final rule limited mandate coverage to new patient prescriptions for Schedule II/III drugs or benzodiazepines, and included myriad exceptions, such as: prescriptions to hospice patients, inpatients, children, or in emergency situations; emergency department practitioners who do not anticipate writing a Schedule II-V prescription or who prescribe a five-day supply or less; and prescribers who face circumstances that render PDMP use impossible).

evidence or systematic guiding principles, and thus would stand to benefit from a more deliberate and organized path to success. The framework articulated herein guides PDMP recommendations, but is also generalizable to public health threats that exhibit characteristics similar to prescription drug misuse—namely, significant public health problems that can be addressed with a panoply of policy options.

To satisfy legality, effectiveness, and ethical criteria—markers of successful public health policymaking—PDMPs should follow certain guidelines. First, they should include strong confidentiality protections and be searchable by authorized health care practitioners (prescribers and dispensers) only, to comport with legal and ethical privacy requirements. Strong penalties for disclosure of information by authorized users, such as medical license suspensions for prescribers, are important to provide further confidentiality incentives. Law enforcement officials, licensing boards, and researchers³⁵¹ should be provided with the data on a de-identified basis or pursuant to a court-issued warrant or subpoena.³⁵² Second, PDMPs should be designed to infringe minimally on and assist maximally clinical practice. To this end, the data should be as close to real-time as possible, shared across neighboring states, and accurate. The databases should be easily searchable and, as soon as practicable, integrated into electronic medical records. Third, the programs ought to strongly incentivize prescriber participation, first by requiring registration and abandoning laws that provide immunity for failure to check or no obligation to query. Mandates with appropriate exceptions should be considered once further evidence of existing mandate efficacy (and possible unintended consequences) becomes available.³⁵³ Fourth, PDMPs should include user guidelines and education about how to use the data effectively.³⁵⁴ This would help to somewhat standardize opioid treatments across providers and prevent unintended consequences, such as under-prescribing for pain and burdening certain populations based on doctor shopping or diverter stereotypes. Finally, the existence and features of programs should be publicized to stakeholders, and any changes to their features going forward should incorporate diverse perspectives.

PDMPs undoubtedly show promise and should be pursued by the states, but they are still imperfect laws in need of adjustment and continued study. Effectiveness research should focus on evaluating

351. Researchers receive data on a de-identified basis in thirty-two states at present. NAT'L ALL. FOR MODEL STATE DRUG LAWS, *supra* note 68, at 22.

352. See Unger, *supra* note 223.

353. See Haffajee et al., *supra* note 70.

354. The Centers for Disease Control and Prevention has convened an expert panel to develop guidelines on opioid prescribing that will be available in 2016. These guidelines should help to develop additional clinical agreement in the clinical field and may be used to inform PDMP use, once available.

newer, strong PDMP features (such as mandates) using long-term, multi-state designs, when possible, that incorporate comparison groups or outcomes. Increased evidence linking PDMPs to improved prescribing, reduced diversion and doctor shopping, and reduced overdoses, in particular, is needed. Study of the interactive effects of PDMPs and other prescription drug misuse interventions is also desirable, as these interventions are often enacted together. Such evidence will further illuminate PDMP features appropriate for retention and replication. Incorporation of the recommendations articulated herein and ongoing re-evaluation of programs are both critical in order for PDMPs to fulfill their potential to curb the opioid misuse and overdose epidemic in the United States.

APPENDIX TABLE. LITERATURE REVIEW:
PUBLISHED STUDIES OF PDMP EFFECTIVENESS IN ADDRESSING
OPIOID MISUSE, 1990–2015

PART I. STUDY CITATIONS AND DESIGN TYPES

- STUDY No. 1. Delcher et al., *supra* note 297—Interrupted time series with comparison groups.
- STUDY No. 2. Paulozzi et al., *supra* note 288—Multiple parallel time series, comparing groups without interruption.
- STUDY No. 3. Reifler et al., *supra* note 290—Controlled pre-post.
- STUDY No. 4. Reisman et al., *supra* note 290—Multiple parallel time series display with controlled pre-post regression analysis.
- STUDY No. 5. Jane E. Brady et al., *Prescription Drug Monitoring and Dispensing of Prescription Opioids*, 129 PUB. HEALTH REPS. 139 (2014)—Controlled pre-post.
- STUDY No. 6. Paulozzi et al., *supra* note 288, and see design type above in STUDY NO. 2.
- STUDY No. 7. Reisman et al., *supra* note 290, and see design type above in STUDY NO. 4.
- STUDY No. 8. Rutkow et al., *supra* note 167—Interrupted time series with comparison group.
- STUDY No. 9. Baehren et al., *supra* note 295—Un-controlled pre-post.
- STUDY No. 10. McAllister et al., *supra* note 295—Un-controlled pre-post.
- STUDY No. 11. Rasubala et al., *supra* note 302—Un-controlled pre-post.
- STUDY No. 12. Ringwalt et al., *supra* note 295—Un-controlled post only.
- STUDY No. 13. Rutkow et al., *supra* note 167, and see design type above in STUDY NO. 8.
- STUDY No. 14. Weiner et al., *supra* note 295—Un-controlled pre-post.
- STUDY No. 15. Simoni-Wastila & Qian, *supra* note 296—Cross-sectional.
- STUDY No. 16. Surratt et al., *supra* note 296—Un-controlled pre-post.

The numbers associated with each study listed on this page can be used to locate the data source, PDMP measure, findings, and methodological comments related to that study below in Part II of this APPENDIX TABLE.

PART II. DATA SOURCES, PDMP MEASURES, FINDINGS,
AND METHODOLOGICAL COMMENTS

STUDY No.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
Primary Outcomes				
Opioid-Related Overdoses				
I	Florida Medical Examiners Commission drug-related death data (2003–2012).	Two measures of Florida PDMP: (1) binary indicator for pre- and post-PDMP; (2) continuous variable for number of health provider PDMP queries.	Significant. Oxycodone-caused mortality declined 25% in the month after PDMP.	Strengths: Control for three concurrent Florida prescription drug abuse interventions or co-interventions incorporate actual provider use of PDMP into intervention measure. Limitations: Effect observed is dramatic, particularly given that PDMP was not mandatory and use gradually increased after implementation. Ability to control for co-interventions using model chosen is unclear. Limited generalizability to other states.
2	Automation of Reports and Consolidated Orders System (“ARCOS”) data for drug distribution (1997–2005). National Center for Health Statistics & CDC drug overdose mortality data (1999–2005).	National sample that characterized states based on the presence at some time during the study period (19) or total absence (31) of a PDMP.	Not significant. PDMPs not associated with lower rates of opioid overdose mortality or lower rates of opioid consumption.	Strengths: Only national study to assess relationship between PDMPs and mortality, using supply as an intermediary mechanism. Limitations: Older study, conducted when PDMPs were not very strong. Combined all states that had PDMP at any time during study period into treatment group. Lacks before-and-after comparisons within states.

STUDY NO.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
Opioid-Related Treatment Admissions & Poisonings				
3	Research Abuse Diversion & Addiction-Related Surveillance (“RADARS”) Poison Center (2003–2009). Opioid treatment surveillance data (2003–2009).	National sample that characterized states based on the presence or absence of a PDMP, by quarter.	Significant. PDMPs were associated with lower poison center intentional exposures and lower substance abuse treatment admissions.	Strengths: Conducted sub-analyses of superior PDMP features (that is, in effect for a long time, unsolicited reports, monitor drugs through Schedule IV) with consistent results. Limitations: RADARS data are self-reported.
4	ARCOS data for opioid shipments (1997–2003). Treatment Episode Data Set (“TEDS”) data for opioid abuse admissions (1997–2003).	National sample that characterized states based on the presence (14) or absence (36) of a PDMP.	Significant. PDMPs were associated with fewer Schedule II opioid shipments and fewer opioid abuse treatment admissions.	Strengths: National sample with measures of both mechanisms (supply) and health (treatment admissions). Limitations: Outdated. Imprecise measures of PDMP laws, which were generally weak during this study period.
Secondary Outcomes				
Opioid Supply				
5	ARCOS data on opioid shipments, quarterly (1999–2008).	National sample that characterized states based on presence or absence of a PDMP, by quarter.	Not significant. State PDMPs not associated with changes in per-capita opioids dispensed.	Strengths: National sample with data over a long time period. Multivariable linear models adjust for demographics and geographic region. Limitations: Effect of PDMP varied hugely between states (66% decrease in Colorado, 61% increase in Connecticut), suggesting that measurement was imprecise.

STUDY No.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
6	(see above)	(see above)	Not significant. PDMPs not associated with lower rates of opioid consumption. States with PDMPs consumed more hydrocodone (Schedule III, less frequently monitored), suggesting substitution.	(see above)
7	(see above)	(see above)	Significant. PDMPs associated with fewer Schedule II opioid shipments.	(see above)
8	IMS Health LifeLink LRx prescription claims data (July 2010–Sept. 2012).	Florida PDMP and pill mill law concurrent implementation.	Significant. Florida PDMP and pill mill laws were associated with modest decreases in total opioid volume among highest baseline users.	Strengths: Excellent data source and robust methods used to detect multiple effects among high prescribers and users. Limitations: Comparison group, Georgia, had different levels of opioid use and prescribing at baseline. Difficult to assess whether effects are largely attributable to PDMPs or pill mill laws (or the combination). Results have limited generalizability to other states.

STUDY No.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
9	Survey of University of Toledo Medical Center Emergency Department Physicians ED, (June–July 2008).	Ohio PDMP (“OARRS”) consultation.	Significant. Prescribing was altered in 41% of cases: 60% of these cases resulted in fewer or no prescription painkiller being prescribed due to the patient’s number of previous fills; in 39% of these cases, physicians prescribed painkillers when they otherwise would not have.	Strengths: Detailed analysis demonstrates impact of PDMP information on a physician. Limitations: Small sample (n=179), limited to Ohio PDMP, so results have limited generalizability to other states. Results subject to response bias. No comparison group.
IO	PDMP prescribing data of Emergency Department physicians of an urban tertiary care, university teaching hospital (2-week period in Feb. 2014 vs. 2-week period in Dec. 2013).	Florida PDMP (“EFORCSE”) consultation.	Not significant. PDMP data was not associated with any change in average number of controlled substances prescribed per patient.	Strengths: Conducted additional survey of physician impressions of PDMP data, which suggested that they felt it altered their prescribing. Limitations: Small sample (n=710 patients), limited to Florida, so results have limited generalizability. “Historical control” not true comparison group.
II	Dental urgent care center electronic medical records (Three periods: Pre-PDMP: Dec. 2012–Feb. 2013; Post-PDMP-1: Dec. 2013–Feb. 2014; Post-PDMP-2: Mar.–May 2014).	New York PDMP (“I-STOP”) mandatory query implementation (applied to Dentists as well as other prescribers).	Significant. The odds for a patient to receive opioids decreased by 58% in Post-PDMP-1, and 72% in Post-PDMP-2, as compared to the Pre-PDMP period (when adjusting for differences in surgical volume across periods).	Strengths: First study to investigate mandates. Data consisted of close chart reviews and allowed sufficient time post-implementation to detect effects. Limitations: No comparison group. More sophisticated analytical methods preferred.

STUDY No.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
I2	North Carolina PDMP data (2009–2011, divided into 6-month blocks).	Two measures of use of North Carolina's PDMP: (1) number of providers who queried the PDMP; and (2) mean number of days on which providers queried.	(Slightly) significant. Slightly positive association between increased use of PDMP and number of opioid prescriptions filled, suggesting that the PDMP had no "chilling effect" on prescribing.	Strengths: Incorporated measures of PDMP use into intervention measures. Displays time trends. Limitations: Post-only study, after PDMP implementation (2005). No comparison group. Registration rates low (27%), so unlikely PDMP use explains overall prescribing trends.
I3	(see above)	(see above)	Significant. Florida PDMP and pill mill laws associated with modest decreases in MME per transaction and opioid prescriptions (1 year post), but not changes in mean days' supply per transaction. Reductions limited to highest baseline prescribers.	(see above)
I4	Emergency department physicians of patients presenting in two academic medical centers with chief complaint of back pain, dental pain, or headache (Jun. 2011–Jan. 2013).	Massachusetts PDMP consultation.	Significant. After PDMP exposure, emergency department physicians changed plans to prescribe opioids in 9.5% cases: 6.5% patients received opioids that were not previously planned, and 3% no longer received opioids.	Strengths: Careful survey of physician prescribing plans before and after consulting PDMP. Limitations: Small sample (n=38) of physicians, limited to Massachusetts PDMP, so results have limited generalizability. Responses subject to response bias. No comparison group.

STUDY No.	DATA SOURCE	PDMP MEASURES	FINDINGS	METHODOLOGICAL COMMENTS
Patient Behavior				
I5	Coordination of Benefits MarketScan claims data of Medicare eligible and their dependents (2007).	National sample that characterized patient exposure to PDMP or not (2007).	Significant. PDMPs were associated with decreased utilization of Schedule II opioids but an increase in Schedule III opioids, which were less frequently monitored, suggesting a substitution effect.	Strengths: Multi-variable regression analysis using large sample. Limitations: Medicare population results not generalizable to other age groups. PDMPs not characterized by the strength of features. Cross-sectional design shows association only.
I6	RADARS System (Jan. 2009–Sept. 2012, quarterly).	Florida PDMP and closely implemented prescribing laws in 2010–2011 (pill mill regulations, limitations on cash payments).	Significant. Decreases in diversion observed for three Schedule II opioid substances (methadone, morphine, and oxycodone), but not observed for a fourth Schedule II opioid (hydrocodone).	Strengths: Sophisticated multi-level models adopted. Limitations: Diversion reports could have exhibited reporting bias. Difficult to disentangle PDMP from other related laws. No comparison group.

For the strongest studies, see all studies cited in bold print.