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Implementation and Enforcement of State Opioid Prescribing Laws

Elizabeth M. Stone, MSPH,
Johns Hopkins Bloomberg School of Public Health, Department of Health Policy and Management , 624, N. Broadway, Room 509, Baltimore, MD 21205

Lainie Rutkow, PhD, JD,
Johns Hopkins Bloomberg School of Public Health, Department of Health Policy and Management , 624 N. Broadway, Room 592, Baltimore, MD 21205

Mark C. Bicket, MD, PhD,
Johns Hopkins School of Medicine, Department of Anesthesiology and Critical Care Medicine , 600 N. Wolfe Street, Baltimore, MD 21205

Colleen L. Barry, PhD, MPP,
Johns Hopkins Bloomberg School of Public Health, Department of Health Policy and Management , 624 N. Broadway, Room 482, Baltimore, MD 21205

G. Caleb Alexander, MD,
Johns Hopkins Bloomberg School of Public Health, Department of Epidemiology , 615 N. Wolfe Street, Room W6035, Baltimore, Maryland 21205

Emma E. McGinty, PhD, MS
Johns Hopkins Bloomberg School of Public Health, Department of Health Policy and Management , 624 N. Broadway, Room 359, Baltimore, MD 21205

Abstract

Background: In response to the role overprescribing has played in the U.S. opioid crisis, in the past decade states have enacted four main types of laws to curb opioid prescribing: mandatory prescription drug monitoring program (PDMP) enrollment laws requiring clinicians to register with a PDMP; mandatory PDMP query laws requiring clinicians to check a PDMP prior to

(corresponding author): estone@jhu.edu, Phone: (618) 541-0522.

Contributors

All authors made substantial contributions to conceptualization or design of the manuscript.

Conflict of Interest

Dr. Bicket reports Axial Healthcare (past served on an advisory board, stock options) and Alosa Health (advisory board). These arrangements have been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr. Alexander previously served as Chair of FDA's Peripheral and Central Nervous System Advisory Committee; has served as a paid advisor to IQVIA; and is a consultant and holds equity in Monument Analytics, a health care consultancy whose clients include the life sciences industry as well as plaintiffs in opioid litigation; and is a member of OptumRx's National P&T Committee. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. The other co-authors have no conflicts of interest to disclose.

prescribing opioids; pill mill laws regulating pain management clinics; and opioid prescribing cap laws limiting the dose/duration of opioid prescriptions. While 47 states now have one or more of these laws in place, little is known about implementation and enforcement strategies, facilitators, and barriers.

Methods: From November 2017 to February 2019, we interviewed 114 professionals involved in state opioid prescribing law implementation and enforcement in 20 states and identified common themes.

Results: Implementation efforts focused on awareness campaigns and targeted training of key front-line implementers. Enforcement strategies included active, complaint-based, and automated strategies. Collaboration across agencies and stakeholders, particularly health agencies and law enforcement, was identified as an important facilitator of implementation and enforcement. Two key interrelated barriers were identified: the complexity of state opioid prescribing laws in terms of which providers, patients, and prescriptions they applied to, and IT infrastructure.

Conclusion: Despite differing approaches, our findings suggest similar barriers to implementation and enforcement across state opioid prescribing laws. Strategies are needed to ease implementation and enforcement of laws that apply only to specific sub-sets of providers, patients, or prescriptions and address issues of access and data utilization of the PDMP.

1. Introduction

High volume opioid prescribing has been a key driver of the U.S. opioid crisis,[1–4] peaking in 2010 at 81.2 prescriptions per 100 persons. Today, prescribing rates remain about three times higher than in 1999.[5] Deaths from heroin and illicit synthetic opioids like fentanyl surpassed prescription opioid overdose deaths in 2014,[6] but prescription opioids continue to play a significant role in opioid-related morbidity and mortality: in 2017 prescription opioids were involved in 40% of opioid overdose deaths,[6] and about 70% of individuals who use illicit opioids initiated their opioid use with prescription opioids.[7]

Many states have enacted laws designed to curb opioid prescribing.[4] In the past decade, the four primary types of state opioid prescribing laws included: 1) mandatory prescription drug monitoring program (PDMP) enrollment laws, which require prescribers to enroll in a state's online prescription database tracking patients' receipt of controlled substances including opioids; 2) mandatory PDMP query laws, which mandate prescribers to query the state's PDMP in certain scenarios, for example, before writing an initial opioid prescription; 3) "pill mill" laws requiring pain management clinics to register with the state and meet administrative and patient care requirements; and 4) prescribing cap laws limiting the dosage and/or days' supply of opioid prescriptions. In 2019, 22 states had mandatory PDMP enrollment laws, 33 had mandatory PDMP query laws, 11 had pill mill laws, and 35 had prescribing cap laws. These laws followed an earlier generation of laws that established state PDMPs but did not require prescribers to enroll in or check their state's PDMP prior to prescribing an opioid (i.e., voluntary PDMP laws).

Research on these laws' effects on opioid prescribing patterns and overdose deaths is growing, though many studies are limited by their inability to disentangle the effects of multiple laws implemented at or around the same time.[8] The largest body of research has

focused on PDMP laws, with mixed results.[9–19] Recent studies suggest that while voluntary PDMP laws have minimal effects on opioid prescribing, morbidity, or mortality, mandatory PDMP query laws may have protective effects.[11,14–19] One of these studies also found that mandatory PDMP enrollment was associated with reductions in opioid prescribing.[19] Several studies suggest that pill mill laws are associated with reductions in high-risk opioid prescribing,[20–22] though research on the effects of these laws on opioid overdose deaths is mixed.[23,24] There is limited evidence surrounding opioid prescribing cap laws, the first of which was implemented in Massachusetts in 2016. Two early studies suggest that prescribing cap laws were associated with reduced opioid prescribing, though neither used rigorous nonexperimental methods for causal inference.[25,26]

A key gap in the research on state opioid prescribing laws is the lack of understanding of implementation and enforcement. Such research can yield insight into whether and how implementation and enforcement influence laws' effects on outcomes. This information is particularly important given that 47 of 50 of U.S. states currently have one or more of the four opioid prescribing laws of interest in place. Whereas in the past decade decisionmakers were focused on whether to enact opioid prescribing laws, they are now increasingly focused on implementation and enforcement.

2. Methods

To characterize the implementation and enforcement of mandatory PDMP enrollment, mandatory PDMP query, pill mill, and opioid prescribing cap laws, we conducted semi-structured interviews with stakeholders in 20 states representing 22 state laws of interest (two states, New York and Ohio, implemented two different laws), including regulatory agency employees, PDMP staff, professional organization staff, and law enforcement officials.

To characterize implementation and enforcement of each specific type of law and minimize confounding with other laws, we identified states where one opioid prescribing law of interest could be isolated. Selected states implemented only one opioid prescribing law of interest during a two-year period, with at least one year pre-and one year post-implementation as of September 2017. States that implemented multiple opioid prescribing or related laws (e.g., voluntary PDMP laws) during the two-year period were not eligible. To determine laws' effective dates, our team used standard legal research and legislative history techniques,[27] including full-text searches of the Westlaw legal database and identification of state session laws and regulatory materials.

Within each state, potential interviewees were identified using a combination of purposive and snowball sampling. First, the person or state agency with primary responsibility for implementation and enforcement of the law of interest as defined by statute was contacted. Then, additional interviewees with knowledge of implementation/enforcement were identified using snowball sampling. All interviewees were sent an initial e-mail introducing the study and inviting them to participate. Nonresponders were sent two follow-up e-mails, each one week apart, following the initial e-mail.

A common interview guide was used for all interviews. The guide was drafted based on a review of the literature, experience among members of the study team, and our research questions. The interview guide focused on the following domains: the problem of prescription opioid use in the state; goals of the state opioid prescribing law of interest; implementation of the law of interest; and enforcement of the law of interest (see Appendix).

Semi-structured interviews were conducted from November 2017 to February 2019. All interviews were completed by one member of the study team. An oral consent process was completed at the beginning of each interview. Interviews were conducted over the phone, audio-recorded, and transcribed. Median interview time was 16 minutes. Three interviewees chose to submit written responses to questions in lieu of a phone interview. All transcripts were reviewed and validated using the audio recording and personally identifying information was removed from the transcript. Interviews were conducted until data saturation[28] was reached within each state.

Interview transcripts were analyzed using a hybrid inductive/deductive approach. The development of an initial codebook was informed by summary memos created by the interviewer after completion of each interview, previous literature, and the study team's a priori knowledge. This codebook was pilot tested by two members of the study team on one transcript for each of the four laws of interest. Further refinement of the codebook was completed using an iterative process with study team members reviewing development and organization of themes. Coding and identification of key themes and sub-themes was completed using NVivo 11. This research was reviewed and approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.

3. Results

We conducted 98 interviews with 114 interviewees in 20 states (see Appendix Table 1). We interviewed 25 individuals in four mandatory PDMP enrollment law states (Colorado, Idaho, Illinois, and New Mexico); 32 individuals in six mandatory PDMP query law states (Arkansas, New York, Oklahoma, Pennsylvania, South Carolina, and Virginia); 25 individuals in four pill mill law states (Mississippi, Ohio, Tennessee, and Texas); and 32 individuals in eight prescribing cap law states (Connecticut, Delaware, Kentucky, Massachusetts, New Jersey, New York, Ohio, and Rhode Island). A mean of 5 individuals were interviewed from each state (range: 2–10). Forty-two percent of interviewees were female. Nearly half of interviewees were representatives of a health-related state agency (e.g., Department of Health, Board of Medicine) followed by representatives of a state medical professional association, other professional association (e.g., hospital association, chronic pain society), or other entity with knowledge of the law (e.g., research organization, state opioid taskforce) (Table 1).

3.1 Variation in key themes by state opioid prescribing law

Key themes were categorized as relating to implementation strategies, enforcement strategies, or crosscutting both implementation and enforcement. For the purposes of this study, we defined "implementation" as activities designed to support providers' ability to adhere to the law, for example information dissemination and education activities. We

defined “enforcement” as activities focused on tracking law compliance and penalizing those who did not comply.

Interviewees described dissemination of information about the law as the primary strategy for state opioid prescribing law implementation across all four laws of interest (Table 2). Awareness building efforts, focused on making clinicians and the general public aware of a law’s existence and requirements, were the most frequently cited dissemination strategy for all four types of laws. Targeted education efforts, involving proactive outreach to the front-line clinicians responsible for implementing and complying with the law, were also described by interviewees in states representing all four laws of interest, but were most frequently mentioned in relation to PDMP query and prescribing cap laws.

Three primary strategies for enforcing state opioid prescribing laws were identified across all four laws of interest (Table 2). Active enforcement actions including prescription auditing and inspections were described across all four state opioid policy laws. Prescription auditing, such as the use PDMP data as a tool for examining opioid prescribing patterns and determining whether prescribing practices adhered to the law, was the most frequently mentioned active enforcement action overall and was more frequently mentioned as pertaining to mandatory PDMP enrollment and query laws relative to pill mill and prescribing cap laws. Inspections, the other active enforcement action discussed by interviewees, were primarily utilized for pill mill laws. The second type of enforcement strategy described was reactive complaint-based actions, or actions prompted by receipt of complaints about a prescriber or clinic. Reactive, complaint-based actions were also mentioned by states with all four types of laws though were less likely to be mentioned for mandatory PDMP enrollment laws relative to other law types. Finally, automated enforcement strategies, which tied opioid prescribing law compliance to other activities not directly related to the law, were mentioned only in relation to PDMP enrollment laws.

Three cross-cutting themes related to both implementation and enforcement of state opioid prescribing laws arose in the interviews: coordination across agencies and stakeholder groups, law complexity, and information technology (IT) infrastructure (Table 2). All three of these themes were mentioned across all four opioid prescribing laws of interest. Coordination across agencies and stakeholder groups included two subthemes. Coordination with law enforcement was most frequently mentioned in the context of pill mill laws. Stakeholder involvement in the design of the law itself and implementation enforcement processes, was mentioned most frequently in opioid prescribing cap law states. Law complexity included three subthemes. All three subthemes, lack of prescriber understanding of the law, difficulty operationalizing law criteria, and exemptions in the law, were mentioned most frequently in states with prescribing cap laws relative to states with the other three laws of interest. Finally, IT infrastructure, identified primarily as a barrier to implementation and enforcement for both individual prescribers and the state agencies overseeing implementation/enforcement, was most commonly mentioned by interviewees discussing one of the two types of PDMP laws.

3.2 Key themes related to implementation strategies for state opioid prescribing laws

Sixty-one interviewees mentioned dissemination of information as a key implementation strategy in relation to 22 state laws (Table 3). Passive awareness-building efforts included posting resources online, for example a handout providing an overview of the state pill mill law created by the Ohio Department of Health. States also engaged in more active awareness-building efforts, including email blasts and press conferences. For example, in Illinois the PDMP administrator sent email blasts to all controlled-substance prescribers in the state alerting them to the effective date and key provisions of the mandatory PDMP enrollment law. In Ohio, the Governor's office held two press conferences regarding the opioid prescribing law, one when the law was first passed and a second following the release of the final rules detailing which providers, patients, and types of prescriptions were subject to the law.

Targeted education strategies included trainings for front-line implementers on how to comply with state opioid prescribing laws, often run by state professional societies. In Arkansas, the Board of Nursing ran a series of workshops to train nurses across the state in implementation of the mandatory PDMP query law. In Rhode Island, the Board of Medicine conducted in-person continuing medical education (CME) for physicians in multiple locations around the state on the prescribing cap law.

3.3 Key themes related to enforcement strategies for state opioid prescribing laws

Forty-four interviewees in relation to 20 state laws described active enforcement strategies, which were concentrated in two sub-categories: prescription auditing (mentioned by 37 interviewees in relation to 18 state laws) and inspections (mentioned by 11 interviewees in relation to 5 state laws) (Table 4). The degree to which auditing led to enforcement actions, such as reporting non-complying physicians to the state's medical licensing board, varied across states. Some states reported using auditing primarily as a tool to educate prescribers. In Arkansas, as part of implementation of the mandatory PDMP query law, the Medical Board used PDMP data to produce opioid prescribing report cards showing individual prescribers how their opioid prescribing patterns compared to clinical guidelines and other physicians in the state. The report cards did not track law compliance (i.e., the requirement that prescribers check the PDMP before prescribing an opioid) per se, but instead were designed to help prescribers self-correct the types of high-risk prescribing practices (e.g., prescribing high-dose or long-term opioids, prescribing opioids in combination with benzodiazepines[4]) that PDMP usage is intended to prevent. In contrast, New York used audits of its PDMP system to determine whether prescribers were checking the database as required by the mandatory PDMP query law. Inspections were also used as a proactive enforcement strategy. In Ohio, the Board of Pharmacy conducted an in-person inspection of every pain clinic applying for state licensure as required by the state's pill mill law.

Twenty-five interviewees in relation to 14 state laws described reactive complaint-based strategies for enforcing state opioid prescribing laws. For example, in Arkansas, the Medical Licensure Board only investigated physicians' compliance with the mandatory PDMP query law if the board received a complaint, from a patient or another clinician, about the physician's opioid prescribing practices. To enforce Mississippi's pill mill law, the State

Medical Board investigated pain clinics only when alerted by external parties about signals of potential non-compliance, such as issuance of opioid prescriptions without a medical exam.

Automated strategies tying opioid prescribing law compliance to other activities not related to the law and thereby "automating" enforcement were mentioned by 12 interviewees in relation to the 4 PDMP enrollment laws. Automated strategies required opioid prescribing law compliance as a condition of a prescriber's state controlled substance registration or state medical licensure. For example, Idaho required physicians to demonstrate PDMP enrollment (in compliance with the state's PDMP enrollment law) to renew their state controlled substance registration.

3.4 Crosscutting themes related to both implementation and enforcement of state opioid prescribing laws

Of the crosscutting themes, the importance of coordination across agencies and stakeholder groups was mentioned by 51 interviewees in relation to 18 state laws (Table 5). In some states, separate agencies were tasked with implementation and enforcement, e.g. New Mexico's PDMP enrollment law, where the Board of Pharmacy was responsible for implementation and the Board of Medicine was responsible for enforcement. Even when one agency was responsible for both implementation and enforcement, interviewees reported the need for cross-agency collaboration, particularly with law enforcement.

Nineteen interviewees in relation to 9 state laws mentioned the importance of coordination between the health agency housing the PDMP and law enforcement, which needs access to PDMP data to investigate potential violations. Eleven interviewees in relation to 8 state laws mentioned the importance of involving representatives from multiple agencies and other key stakeholder groups in the design of state opioid prescribing laws and implementation and enforcement processes. Examples included Tennessee's use of a task force–involving representatives from the Board of Medical Examiners, Board of Nursing, State Medical Association, pain clinics, and others–to draft the regulations for the state's pill mill law and collaboration between the Colorado Board of Pharmacy and Board of Medicine to design the implementation process for that state's mandatory PDMP enrollment law.

Thirty-six interviewees in relation to 18 state laws described a law's complexity as a barrier to implementation and enforcement. Complexity contributed to lack of prescriber understanding of a given law, which was described as impeding implementation (mentioned by 21 interviewees in relation to 12 state laws). For example, Ohio's pill mill law defined pain clinics as any provider prescribing opioids to over 50% of their patients. However, many such providers did not self-identify as running pain clinics and did not understand that they needed to register as a pain clinic to comply with the law.

Law complexity was also identified as a barrier to operationalization of law criteria (mentioned by 19 interviewees in relation to 13 state laws). In Colorado, only prescribers with drug enforcement administration (DEA) licensure were required to enroll with the PDMP. However, there was some difficulty in determining which prescribers had active DEA licensure. Exemptions (mentioned by 8 interviewees in relation to 6 state laws) for

certain prescriptions (e.g., continuing prescriptions) or subgroups of patients (e.g., those with chronic non-cancer or post-surgical pain) were perceived by interviewees as barriers to implementation, causing confusion among prescribers about which prescriptions and patients were subject to versus exempt from a law. Exemptions were also viewed as barriers to enforcement. For example, in Kentucky the enforcement agency did not have a data system that allowed it to determine whether prescribers were violating the prescribing cap law or prescribing for patients with chronic non-cancer pain, who were exempt.

The ability to implement and enforce state opioid prescribing laws was viewed as dependent upon successful information technology (IT) infrastructure (mentioned by 32 interviewees in relation to 14 state laws). For example, lack of integration of the PDMP's platform with electronic health records (EHRs) impeded implementation of Idaho's mandatory PDMP enrollment law. In Arkansas, lack of an IT system meant the enforcement agency could not monitor whether prescribers were checking the PDMP prior to prescribing an opioid as required by that state's mandatory PDMP query law.

4. Discussion

We identified common themes related to implementation and enforcement of mandatory PDMP enrollment, mandatory PDMP query, pill mill, and opioid prescribing cap laws in 20 states. Variation in implementation and enforcement both within and across state opioid prescribing laws may lead to differential effects on prescribing, morbidity, and mortality outcomes across states;[8] evidence suggests that more intensive strategies, e.g., targeted trainings for key implementers and active enforcement, are more likely to facilitate the behavior change targeted by the law–in this case changes in opioid prescribing,.[29–31] One key difference in implementation across state laws included a lack of targeted education strategies in relation to PDMP query and pill mill laws. Enforcement strategies varied by type of law, with inspections most common in relation to pill mill laws and automated or passive enforcement exclusively described in relation to mandatory PDMP enrollment. Despite nuances in the approach and goals of the different opioid prescribing laws, many implementation and enforcement issues were similar across laws of interest. Collaboration across agencies and key stakeholders, particularly state health agencies and law enforcement, was viewed as an important facilitator. Two primary interrelated barriers to implementation and enforcement were identified by interviewees in relation to all four laws: law complexity and insufficient IT infrastructure. Interviewees' insights into these barriers may inform strategies to improve implementation and enforcement.

The complexity of state opioid prescribing laws, including which prescribers, patients, and prescriptions they apply to, was identified as a barrier to both implementation and enforcement across all four laws of interest. Interviewees perceived the laws' nuances–such as exemptions in Massachusetts' opioid prescribing cap law excluding patients with chronic non-cancer pain and other debilitating conditions from the seven-day prescription limit–as causing confusion among prescribers, impeding their ability to easily determine whether prescribing an opioid for a given patient was legal. If exemptions are too difficult to apply, these laws may have unintended consequences. For example, pain experts and advocates have raised the concern that even in cases when pain patients with chronic non-cancer pain

are meant to be exempt, state opioid prescribing laws are being applied to and adversely affecting them by limiting access to opioids without substitution of other efficacious treatment.[32–37] Our findings suggest that issues surrounding exemptions are particularly pertinent for mandatory PDMP query and prescribing cap laws.

Continuing medical education focused on law exemptions as well as more intensive implementation strategies shown to facilitate clinician behavior change such as audit-and-feedback, detailing, and coaching could help physicians implement complex prescribing laws,[30,38–42] though automated processes requiring less time from prescribers may be more effective. One promising practice identified in this study was Ohio's requirement that prescribers include the ICD-10 diagnosis code leading to the need for opioid treatment on all opioid prescriptions. Pharmacies dispensing prescriptions were then able to determine if a patient was exempt from the prescribing cap law's 7-day duration limit, which only applies to acute pain.

Insufficient IT infrastructure, particularly in relation to utilization of the PDMP was another barrier described by interviewees in relation to all four laws of interest. While this was most frequently described in reference to the two PDMP laws, PDMP data was also essential for prescription auditing which was described as enforcement strategy across all four types of laws. Lack of integration of the PDMP with EHRs or delegate access capabilities were flagged as a barrier to implementation, largely due to its disruption to clinicians' workflow. Increasing integration of PDMPs into EHRs across the U.S.[43] will likely facilitate compliance with state opioid prescribing laws, particularly those mandating PDMP enrollment and utilization.

For state agencies charged with enforcement, opioid prescribing laws' complexity was identified as a barrier to determining compliance due to lack of data infrastructure with the functionality to identify specific prescribers and patients subject to and exempt from the law. Pertinent examples raised by interviewees included Kentucky's inability to determine, through available data sources, when a prescription was for a chronic pain patient and therefore exempt from the state's opioid prescribing cap law and Colorado's challenges identifying which clinicians had DEA licenses making them subject to the mandatory PDMP enrollment law.

Results should be viewed considering several limitations. Interviews may have been subject to response bias due to self-selection of individuals willing to participate or social desirability bias stemming from interviewees' desire to present their state in a positive light. To minimize these concerns, the informed consent process included confidentiality assurances and, by virtue of conducting interviews with multiple people in each state, triangulated responses across interviewees. Qualitative research may also be subject to researchers' biases. To mitigate this concern, we used a common interview guide and structured coding process. We included states that implemented a law of interest prior to 2017 but did not have a start date for inclusion. Interviewees in states with a longer time since law may be subject to more recall bias as compared to those whose law implementation was more recent.

5. Conclusion

In recent years, many states have implemented mandatory PDMP enrollment, mandatory PDMP query, pill mill, and prescribing cap laws. While these four laws take different approaches, all are aimed at reducing high-risk opioid prescribing. Despite the differences in these laws, key themes related to implementation and enforcement were similar across the four types of laws. Strategies to overcome implementation and enforcement barriers related to the complexity of state laws governing opioid prescribing and IT infrastructure are needed. In particular, study findings suggest a need to ease implementation and enforcement of exemptions written into state laws that apply only to specific sub-sets of providers, patients, or prescriptions and address issues of access and data utilization of the PDMP.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Interviews with 114 professionals related to state opioid prescribing laws
- Implementation efforts included awareness campaigns and targeted trainings
- Enforcement included active, complaint-based, and automated strategies
- Collaboration across agencies and stakeholders was a key facilitator
- Complexity of the law and IT infrastructure were interrelated barriers

Table 1.

Interviewees and represented organizations by law of interest (N=114 interviewees)

	PDMP Enrollment (n=25)	PDMP Query (n=32)	Pill Mill (n=25)	Prescribing Cap (n=32)
State agency representative				
Health (e.g., Board of Medicine)	17	17	9	12
Law enforcement (e.g., State Attorney General Offices)	0	3	5	3
Other state agency (e.g., Consumer Protection Offices)	1	0	3	2
State legislator/legislative staff	0	0	0	2
State professional association representative				
Medical	3	3	3	5
Nursing	0	0	0	3
Pharmacy	0	3	1	1
Other professional association (e.g., Hospital)	0	4	2	4
Other representative (e.g., State research organization)	4	2	2	0

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Table 2.

Mention of key themes by law of interest (N=114 interviewees)

	Overall		PDMP enrollment		PDMP query		Pill mill		Prescribing cap	
	Intvws.	States	Intvws.	States	Intvws.	States	Intvws.	States	Intvws.	States
	N=114	N=22	N=25	N=4	N=32	N=6	N=25	N=4	N=32	N=8
Key themes related to implementation strategies										
Information dissemination	61 (54%)	22	12 (48%)	4	17 (53%)	6	9 (36%)	4	23 (72%)	8
Awareness-building efforts	54 (47%)	20	12 (48%)	4	15 (47%)	6	9 (36%)	4	18 (56%)	6
Targeted education	23 (20%)	15	1 (4%)	1	9 (28%)	5	3 (12%)	2	10 (31%)	7
Key themes related to enforcement strategies										
Active enforcement	44 (39%)	20	11 (44%)	4	12 (38%)	6	13 (52%)	4	8 (25%)	6
Prescription auditing	37 (32%)	18	11 (44%)	4	11 (34%)	5	7 (28%)	3	8 (25%)	6
Inspections	11 (10%)	5	0 (0%)	0	1 (3%)	1	10 (40%)	4	0 (0%)	0
Reactive complaint-based enforcement	25 (22%)	14	1 (4%)	1	11 (34%)	4	6 (24%)	4	7 (22%)	5
Automated or passive enforcement	12 (11%)	4	12 (48%)	4	0 (0%)	0	0 (0%)	0	0 (0%)	0
Crosscutting themes related to implementation and enforcement										
Coordination across agencies and stakeholder groups	51 (45%)	18	9 (36%)	4	14 (44%)	5	15 (60%)	4	13 (41%)	5
Coordination with law enforcement	19 (17%)	9	0 (0%)	0	3 (9%)	3	12 (48%)	4	4 (13%)	2
Stakeholder involvement in design of the law and implementation and enforcement processes	11 (10%)	8	2 (8%)	2	2 (6%)	2	1 (4%)	1	6 (19%)	3
Law complexity	36 (32%)	18	6 (24%)	4	8 (25%)	4	6 (24%)	3	16 (50%)	7
Lack of prescriber understanding of law	21 (18%)	12	3 (12%)	2	6 (19%)	4	1 (4%)	1	11 (34%)	5
Difficulty operationalizing law criteria	19 (17%)	13	4 (16%)	3	2 (6%)	1	5 (20%)	3	8 (25%)	6
Exemptions in the law	8 (7%)	6	1 (4%)	1	2 (6%)	1	0 (0%)	0	5 (16%)	4
IT infrastructure	32 (28%)	14	8 (32%)	4	19 (59%)	6	1 (4%)	1	4 (13%)	3

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Table 3.

Key themes related to implementation for state opioid prescribing laws (N=114 interviewees; 22 state laws)

Key themes & subthemes	Theme mentioned by:	Representative quotes
Information dissemination	61 interviewees in relation to 22 state laws	
Awareness building efforts	54 interviewees in relation to 20 state laws	"I'm actually looking at one of the handouts that the [the Department of Health] did. And so, this was available to all prescribers, and it has an overview of the [pill mill] bill." – OH-pill mill-01 "They [PDMP administrator] partnered with the [regulatory agency] in communicating with all prescribers to make them aware of the new [PDMP enrollment] law. This was primarily accomplished through emails and some targeted advertising on websites." – IL −01
Targeted education	23 interviewees in relation to 15 state laws	"We [Board of Nursing] do seminar, workshops for nurses around the state." – AR-09 "There was a series of CMEs we [Board of Medicine] did across the state … I think I went to probably 20 or 25 places, just giving CMEs about what the new regulations are, and what prescribing expectations were." – RI-01

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Table 4.

Key themes related to enforcement strategies for state opioid prescribing laws (N=114 interviewees; 22 state laws)

Key themes & subthemes	Theme mentioned by:	Representative quotes
Active enforcement	44 interviewees in relation to 20 state laws	
Prescription auditing	37 interviewees in relation to 18 state laws	"They [Medical Board] are monitoring prescribing habits and giving these providers report cards. … After a year of somebody being on the high end, they will report that issue to the regulatory agency of the prescriber." – AR-09 "We [Department of Health] also see when a practitioner accesses or their designee accesses our prescription monitoring system, so we can see those that are writing prescriptions and not checking the PDMP [and are therefore out of compliance with mandatory PDMP query law] and that's something that we've looked at … because in our bureau we also have an enforcement arm" – NY-PDMP query-01
Inspections	11 interviewees in relation to 5 state laws	"Our licensure is proactive, so it's not complaint-based, so anytime someone submits an application [for pain clinic licensure as required by pill mill law] we [Board of Pharmacy] can go in and inspect, which is different from other healthcare regulatory boards, which-- we felt because these are potentially high-risk entities that we wanted to be able to regularly and proactively inspect them." – OH-pill mill-02 "So all of the compliance is actually by the commissioner [of the Department of Health], just like the board of nursing or the board of medical examiners deal with compliance with their own licensees since it's their registry under the commissioner, so the same investigators who do the inspections for pain clinics and the investigations for various licensees that the health-related boards are the ones that will do the investigating for the commissioner and then any discipline that is assessed is assessed by one of the consultants he has working for him." – TN-01
Reactive complaint-based enforcement	25 interviewees in relation to 14 state laws	"Enforcement can only occur, primarily, through a complaint process. So unless someone files a complaint on a physician, the licensure board would have no reason just to go in and randomly see if they're checking the PDMP [as required by the state's mandatory PDMP query law]." – AR-05 "They [Medical Board] probably rely more on a complaint driven-- and then that's when they would get in and then decide if someone retroactively should have been registered [in response to the pill mill law] and they're not." – MS-03
Automated enforcement	12 interviewees in relation to 4 state laws	"We [Pharmacy Board] ask them [prescribers] to at least initiate an account with the prescription monitoring program at the same time that they're applying for their state-controlled substance registration and for their federal DEA registration. … our office will not issue to them a controlled substance registration if they have not at least initiated the PDMP account." – ID-01 "The idea would be that when a physician came up for renewal, at the time they renewed their controlled substance license, along with their physician and surgeon license, they would automatically be directed to the Department of Healthcare Services [to enroll in the PDMP]." – IL-02

Table 5.

Crosscutting themes related to implementation and enforcement of state opioid prescribing laws (N=114 interviewees; 22 state laws)

Key themes & subthemes	Theme mentioned by:	Representative quotes
Coordination across agencies and stakeholder groups	51 interviewees in relation to 18 state laws	
Coordination with law enforcement	19 interviewees in relation to 9 state laws	"They [outside law enforcement] don't have direct access to patient identification in the PDMP data, but we [Department of Health] also work with other outside agencies and respond to subpoenas also, so we do work with other law enforcement agencies." – NY-PDMP query-02 "Through some of these laws, like the pill mill law, I think it's allowed for more open communication between law enforcement and the healthcare community." – TN-05
Stakeholder involvement in design of the law and implementation and enforcement strategies	11 interviewees in relation to 8 state laws	"There was a taskforce formed of members of the Board of Medical Examiners, Osteopathic Examination, Board of Nursing and Physician Assistant Committee, one member from each of those, and there is a taskforce that met and interviewed draft rules to give input from those licensing entities to the commissioner and that was a meeting that was held and open to the public here at our offices. And so there were for example, representatives of some pain clinics there as well as the Tennessee Medical Association and they were recognized to speak as they requested to put input before the taskforce" – TN-01 Then this took about six or eight months of rulemaking and having the Board of Pharmacy, that runs the PDMP, working with the Board of Medicine to regulate docs, working with them to decide how they would implement this particular provision [of the state's mandatory PDMP enrollment law]. They came up with the rules and implemented them that following January, and notified all the docs that this is what was gonna happen. – C0–02
Law complexity	36 interviewees in relation to 18 state laws	
Lack of prescriber understanding of law	21 interviewees in relation to 12 state laws	"I think there was an education period, definitely, especially for those physicians who maybe didn't see themselves as pain clinics who were prescribing over 50 percent of their patients and didn't want to be called a pain clinic and didn't understand why they had to be registered as a pain clinic [under the state's pill mill law]." – OH-pill mill-03 "Probably the same thing for every legislation piece is the educational side, trying to educate them about [the prescribing cap law], and letting them know that this is out there … you know, doctors and dentists, they don't read law … the education piece, is probably the hardest to get across." – KY-04
Difficulty operationalizing law criteria	19 interviewees in relation to 13 state laws	"There was a little bit of difficulty trying to determine who had DEA registrations and who didn't, because if you didn't have a DEA registration looking at the plain language of the bill you didn't have to create a PDMP user account, so it was just trying to work with the PDMP's vendor and with the DEA to determine who had DEA registrations and who didn't." – C0–01 "So there's a barrier to enforcing the pain management clinic registration [pill mill] law because it says the majority of your patients. Well that means at least 50 percent of them, that means you have to go through 8,000 records and count the 4,000 where it [opioid prescribing] was done, 4,001, right? So there's a barrier to enforcing that law." – TX-03
Exemptions in the law	8 interviewees in relation to 6 state laws	"We'd [State Medical Board] have people call and say, "My doctor's refusing to prescribe me opioids, and he said it's because of a new law," and so I'd have to explain the constituents, that the law doesn't say he can't prescribe opioids. It says that he can prescribe up to seven, and even within that, and hopefully you guys have the text of the actual law in Massachusetts and are looking at it, there are exceptions within the law for chronic pain, for emergencies, for debilitating conditions, and so the law was written in a way to be, to really allow for an excess of seven days if the doctor felt it was appropriate." – MA-02 "And the enforcement is difficult, because we [regulatory agency] can't from [the PDMP] see what they're prescribing, and what it's prescribing for, and there's several exemptions to when you don't have to follow this rule. Chronic pain. There's several, you know, operations, all kinds of stuff. So it's really difficult to determine unless you went out and looked at medical file." – KY-04
IT infrastructure	32 interviewees in relation to 14 state laws	"A lot of physicians are required to use electronic health records and a lot of those don't integrate seamlessly with the PDMP. So it requires a separate sign in to a separate system to use the PDMP … I would say that's the biggest barrier [to implementation of the PDMP enrollment law] for physicians, not their lack of willingness but just the lack of ease of use of accessing the PDMP." – ID-05 "There's no mechanism in the system … there's no easy way to see if they prescribe or had checked the PDMP before he or she prescribed. We

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Key themes & subthemes	Theme mentioned by:	Representative quotes
		can do it on an individual basis. If, say the medical board is investigating someone, we can look, in a very individual case, if they queried for a specific patient for a specific prescription. But there's no very efficient way, yet, to audit this." – AR-04