

Rapid Expansion of the Opioid Ecosystem: National
Implications for Prescriber–Pharmacist
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INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC), approximately 46 people died each day in 2016 from prescription opioid–related poisoning.¹ Opioid prescribing volume per capita, which directly correlates with mortality, has declined but remains three times higher than in the late 1990s.² The lifesaving drug naloxone is being rapidly deployed as a stopgap measure to prevent deaths.³ However, multifaceted strategies for preventing and treating opioid use disorders, such as increased access to evidence-based treatment (e.g., medication-assisted treatment), are urgently needed.

STATE AND FEDERAL STRATEGIES

Current public health strategies for primary prevention rely, in part, on decreasing supply (e.g., exposure-avoidance techniques, such as limiting an initial opioid prescription for acute pain). For acute opioid exposures, each additional day of opioid supplied increases the probability of long-term use and, by extension, the risks that accrue from long-term exposure.⁴ This strategy is promulgated in the CDC's opioid prescribing guideline (from March 2016): "Clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed."⁵

Public policy is rapidly evolving to adopt opioid prescribing limits (or caps) as a legislative course of action. As of April 2018, at least 32 states have legislated limits on initial opioid prescriptions for acute pain, ranging from 3 to 14 days, with the majority (Delaware, Louisiana, Maine, Michigan, Nebraska, New Hampshire, Ohio, Utah, Vermont, Virginia, and Washington) enacting 7-day limits.⁶ Figure 1 shows states that have enacted

opioid prescribing limits and those with mandatory prescription drug monitoring program (PDMP) use.

In 2018, Florida, one of at least eight states that has declared a state-level public health emergency because of the opioid crisis, followed suit in passing a bill that limits new opioid prescriptions to a 7-day supply.⁷ Private industry is moving in the same direction. In September 2017, CVS Caremark announced an enhanced opioid utilization management plan for all commercial, health plan, employer, and Medicaid clients that includes a 7-day limit on the supply of opioids dispensed to opioid-naïve individuals for certain acute pain indications, unless clients opt-out.⁸ Additional opioid utilization management criteria in the plan include a requirement to initiate an immediate-release opioid prior to prescribing a long-acting opioid and a dispensing limit on morphine milligram equivalents. As CVS Caremark is one of the nation's largest pharmacy benefits managers, whose programs serve nearly 90 million members,⁹ these new opioid policy impacts could be extensive. The White House has publicly supported the CVS Caremark initiative.¹⁰ The Centers for Medicare and Medicaid Services announced in March 2018 that it was considering prescribing limits for Medicare recipients.¹¹ With such sweeping private, state, and federal changes, the populations impacted by prescription opioid monitoring

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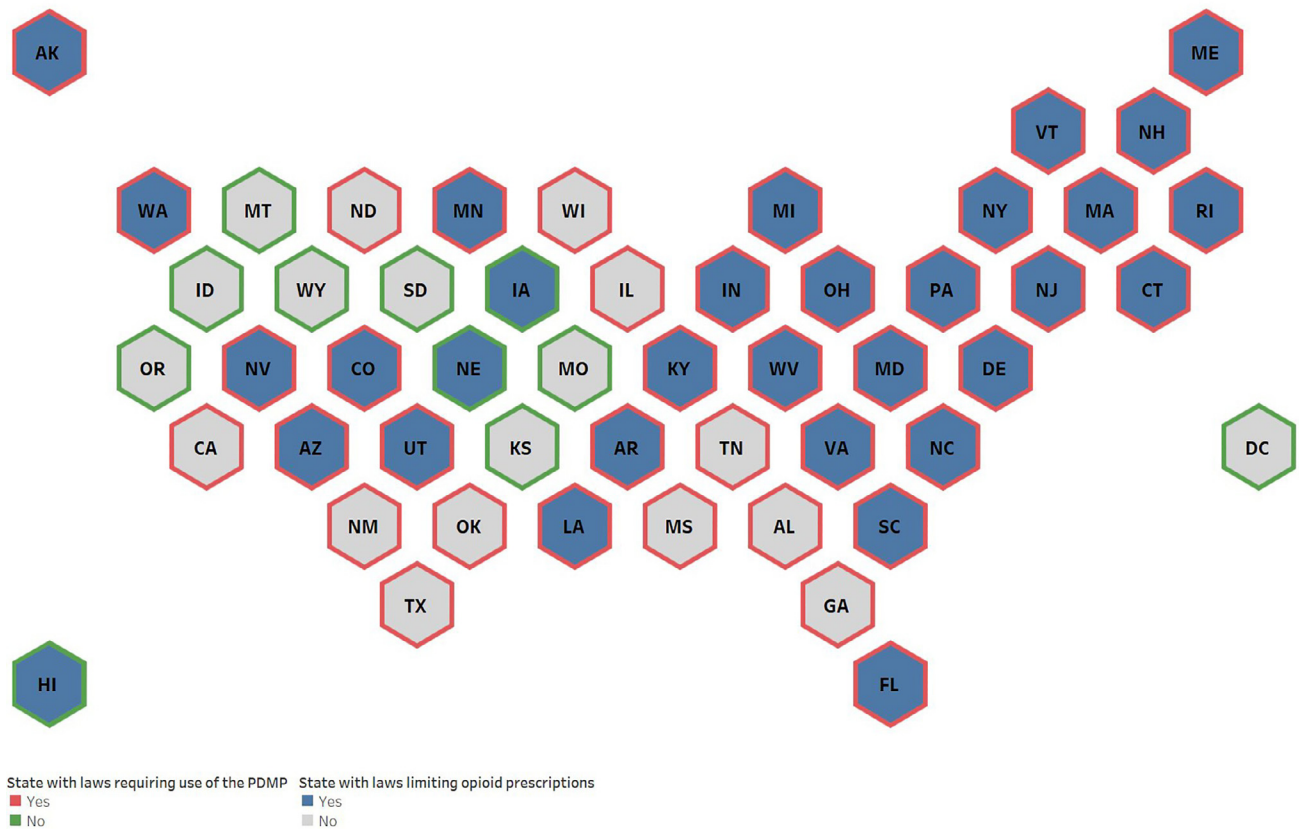


Figure 1. States with laws limiting opioid prescriptions and requiring the use of prescription drug monitoring programs (as of April 2018). Consult your state’s physician and pharmacist licensing boards for details regarding exemptions.

Source: The National Conference of State Legislatures (as of April 5, 2018) and the Prescription Drug Monitoring Program Training and Technical Assistance Center (as of March 19, 2018).

may significantly expand from those in the crosshairs of “red-flag” pharmacosurveillance—the “doctor shoppers,” “pill mill” operators, and criminal prescribers—into the vastly larger pool of patients who are opioid naïve.

THE OPIOID ECOSYSTEM FROM A LARGE STATE PERSPECTIVE

To understand the potential patient pool size and the associated healthcare professional network in Florida, according to data from the Florida PDMP, an estimated 78% of individuals (3.5 million) who were prescribed opioids in 2016 were opioid naïve. The analysis included the numbers of patients receiving opioid prescriptions in 2016 who had not received another opioid prescription within the previous 6 months. Approximately 39% of these patients received an opioid prescription for 7 or more days, which would potentially trigger dispensing-level oversight for approximately 1.4 million people. These Florida patients were associated with an estimated

71,505 prescribers and 5,884 pharmacies. One can imagine the vast number of new medical decision-making points and interprofessional interactions needed to ensure the appropriate prescribing of opioids nationwide. It is hypothesized that these legislative and opioid utilization management policy changes will have substantial impact on interprofessional communication between prescribers and pharmacists in the new “opioid ecosystem,” defined herein as the network of opioid-treated patients, their healthcare providers, and their payers. Consider for example CVS Caremark’s opioid utilization management policies that will reject, at the point of care, opioid prescriptions that do not meet their utilization criteria. Recent guidance issued by CVS Caremark specifically directs pharmacists to “reach out by phone to communicate the rejection and understand whether the quantity can be reduced . . .”¹²

How have prescribers and pharmacists dealt with this type of interaction in the past, what does the research on interprofessional communication show, and how can PDMPs potentially mediate these relationships?

OPIOID-RELATED COMMUNICATION CHALLENGES FOR PRESCRIBERS AND PHARMACISTS

Recent history from the pill mill era and the Drug Enforcement Administration's action against chain pharmacies in Florida is illustrative. In 2013, the Drug Enforcement Administration charged Walgreens Corporation, one of the nation's largest drug store chains, with administrative violations that resulted in a record \$80 million settlement for civil penalties under the federal Controlled Substances Act. The settlement resolved allegations that Walgreens committed vast controlled substance dispensing and recordkeeping violations at one of its distribution centers and at six retail pharmacies, allowing the shipment, receipt, and dispensing of more than three times the mean quantity of oxycodone per pharmacy in Florida.¹³ As part of the settlement, Walgreens implemented a good faith dispensing policy that included a validation checklist for pharmacists' use when reviewing select Schedule II opioid prescriptions prior to dispensing.¹⁴ As part of the validation procedure, pharmacists were encouraged to call prescribers to verify diagnosis, previous trials of non-opioid alternative treatments, and conformity with the standards of care.¹⁵ Prescriber reaction to these calls manifested nationally as a series of high-profile, formal resolutions from the American Medical Association warning against the practice of "routine pharmacist prescription diagnosis verification."¹⁶ Not surprisingly, professional pharmacy organizations responded, calling for more effective communication and collaboration between pharmacists and physicians.¹⁷

There is no quantitative data available indicating how frequently professional conflicts arise between prescribers and pharmacists when prescription opioids are involved. However, recent qualitative research suggests that many pharmacists recognize and resent their gatekeeper role, sometimes feeling like "opioid police," while also blaming prescribers for opioid abuse among patients.^{18,19} Similar research focusing on prescribers was not identified, but as the American Medical Association resolution made clear, the reaction to real or perceived encroachments on professional autonomy was swift. And, although the term *policing* may seem out of place in the context of medical decision making, it may be appropriate, given the corresponding responsibility of pharmacists, defined by law in 21 C.F.R. § 1306.04, which outlines how they can be held liable for controlled substance prescribing decisions made by prescribers. (See Norwood and Wright²⁰ for a summary of corresponding responsibility from pharmacists' perspective.)

As has been demonstrated, simple mathematics suggests that prescription opioid-related communications

will evolve in the coming years. Furthermore, empirical evidence suggests that expanding state PDMP utilization mandates will add another dimension to the communication path between prescribers and pharmacists. To gain insight into the frequency and nature of this communication, the authors examined a 2016 survey of Florida PDMP users. The findings are described below; the methodology has been published previously.²¹

STATE PRESCRIPTION DRUG MONITORING PROGRAMS ARE CRITICAL POINTS OF OPIOID-RELATED COMMUNICATION

Overall, prescribers and dispensers increased communication with each other as a result of using the Florida PDMP. A larger majority of pharmacists ($n=1,294$, 68%) reported increased communications with physicians than did physicians with pharmacists ($n=753$, 54%). Among several specialties examined, pain management specialists increased their communication with pharmacists the most ($n=68$, 74%). This is unsurprising, as a greater percentage of their patient encounters involve opioid analgesics and recent research suggests that these specialists may face greater challenges in earning the trust of pharmacists.²² Communication increased with the frequency of PDMP use (Table 1) and the communication points for both groups were largely focused on doctor shopping and pain management (Table 2). Following examination of PDMP data, psychiatrists, more than other specialists, tend to include substance abuse treatment in their communication with colleagues.

The frequency and quality of this interprofessional communication may be state specific. In the Florida sample of PDMP users, taken several years after PDMP implementation and arguably influenced by prescribers' voluntary use of the database, more than half of prescribers and pharmacists report an increase in communication with each other after using the PDMP. Pharmacists seem to communicate more with prescribers than prescribers do with pharmacists. This finding is consistent with that of Hagemeyer et al.,¹⁹ showing that pharmacists in an Appalachian region tended to initiate prescription opioid-related communication. The same research, however, reported decreases in interprofessional communication when PDMP use was mandated. In Florida, mandatory PDMP use takes effect in July 2018 and may provide another opportunity to examine this finding. A survey similar to the Florida survey, administered to Kentucky PDMP users, showed that approximately 60% of pharmacists sometimes or frequently initiated a discussion of PDMP findings with prescribers, whereas only 26% of prescribers initiated such discussions.²³ With 40

Table 1. Communication Between Medical Doctors and Pharmacists, by Self-reported PDMP Use Frequency^a

Clinician type	"Yes" communicate more		
	Frequent PDMP users	Moderate PDMP users	Minimal PDMP users
As a result of using the PDMP, do you communicate more with pharmacists?			
All medical doctors	307 (61)	289 (57)	155 (41)
Family medicine	90 (64)	106 (69)	58 (51)
Pain management	52 (77)	14 (82)	2 (33)
Psychiatry	49 (67)	36 (60)	24 (55)
As a result of using the PDMP, do you communicate more with prescribers?			
All pharmacists	731 (72)	445 (67)	114 (54)

Note: Values are *n* (%).

^aPDMP user frequency was defined using the question, Relative to peers in your specialty, how would you characterize your use of the PDMP? Data were collected in Florida, 2016.

PDMP, Prescription Drug Monitoring Program.

Table 2. Topics Communicated to Other Healthcare Practitioners as a Result of Using the Florida PDMP, 2016

Variable	All medical doctors	Family medicine	Pain management	Psychiatry	All pharmacists
As a result of using the PDMP, which of the following topics do you communicate more about with other healthcare practitioners? <i>n</i> (% of total)					
Doctor shopping	880 (47)	241 (47)	63 (56)	105 (47)	1,426 (58)
Pain management	725 (39)	234 (46)	56 (50)	52 (23)	1,091 (44)
Safe use of controlled substances and indicators of abuse	551 (30)	154 (30)	48 (43)	86 (38)	1,068 (43)
Substance abuse treatment	504 (27)	131 (26)	36 (32)	92 (41)	509 (21)
Prescribing guidelines for controlled substances	456 (25)	141 (28)	39 (35)	55 (24)	810 (33)
Prescription drug diversion	365 (20)	114 (22)	44 (39)	58 (26)	724 (29)
Mental health issues	288 (15)	85 (17)	20 (18)	68 (30)	110 (4)
Drug-drug interactions	249 (13)	71 (14)	21 (19)	52 (23)	598 (24)
I don't communicate more	229 (12)	62 (12)	12 (11)	32 (14)	120 (5)
Safe disposal of controlled substances	95 (5)	36 (7)	12 (11)	14 (6)	119 (5)
Something else	24 (1)	7 (1)	0 (0)	5 (2)	36 (2)
Total <i>n</i> of respondents in profession/specialty	1,865	511	112	226	2,469

PDMP, Prescription Drug Monitoring Program.

states now requiring prescriber use of the PDMP prior to issuing controlled substance prescriptions under specific circumstances, it is unclear how prescriber–pharmacist communication will be impacted and which PDMP features may improve (or even obviate the need for) communication.²⁴ The positive and negative aspects of these interprofessional communications, in the context of PDMP design, should be the topic of future research, given the magnitude of the opioid ecosystem.

Perhaps in recognition of the communication challenges ahead, the CDC has encouraged increased prescriber–pharmacist collaboration in its opioid prescribing guideline.⁵ Similarly, a recent consensus

document prepared by the National Association of Boards of Pharmacy, on behalf of 19 stakeholder organizations representing both physicians and pharmacists, highlighted the challenges posed by the opioid abuse epidemic.²⁵ The report called for a greater understanding of healthcare practitioners' roles and emphasized the need for increased collaboration and communication among prescribers and pharmacists.

CONCLUSIONS

Although opioid prescribing by volume has begun to decline, opioid overdose deaths continue to climb.¹ The

new opioid prescribing and monitoring ecosystem will become more complex in the coming years, due in part to the rapid adoption of prescribing restrictions for opioid-naïve patients.² Admonitions by the CDC and others against the common practice of co-prescribing opioids with benzodiazepines and other central nervous system depressants will pose another major challenge. Although patient care is paramount, the authors argue that new threats to the prescriber–pharmacist relationship will emerge if not acknowledged and addressed. Conversely, new opportunities to improve the coordination of patient care will arise. One such example involves decisions regarding when and how to taper patients on high-dose, long-term opioid therapy, commensurate with CDC recommendations. Recent qualitative research suggests that prescribers view pharmacists as a valuable resource in making these and similar decisions.²⁶ This use of pharmacists as a resource for prescribers will be critical for mitigating other potential unintended consequences of PDMP-identified problematic opioid use as well, such as including the pharmacist in responsibilities for monitoring patients who are at risk for transitioning to nonmedical prescription opioid use or illicit opioid use (e.g., heroin, fentanyl). Leaders from the National Institute on Drug Abuse and HHS agree, and have identified key specific aspects of the pharmacist's role for mitigating the opioid crisis.²⁷ Like others, the authors recommend establishing stronger communication norms by clarifying the respective responsibilities for communication initiation and reciprocation between the professions.¹⁸

The authors call on professional medical and pharmacy organizations to develop specific guidance for improving communications for opioid therapy initiation and long-term management. It is hypothesized that doing so would offer collaborative benefits extending beyond opioid pharmacotherapy. Some topics include highlighting pharmacists' corresponding responsibility under the Controlled Substances Act and the potential role that pharmacists have in protecting prescribers from medicolegal liability when calling to make them aware of aberrant behaviors at the point of dispensing, unsafe medication combinations, evidence of doctor shopping, and potential standard of care infractions. Perhaps these pharmacist-initiated communications will foster prescriber-initiated conversations. PDMPs are important tools for both professions in the opioid decision-making process. Considering that most states have a PDMP governed by a Board of Pharmacy or a Department of Health, the opportunities for cross-training and collaboration are numerous. In light of the challenges posed by the unprecedented expansion of the opioid ecosystem, it is imperative that PDMPs be optimized to

support and facilitate the type of interprofessional communications that optimize clinical care.

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