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Legal requirements and recommendations to prescribe naloxone

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Abstract

Background: The continued toll of opioid-related overdoses has motivated efforts to expand availability of naloxone to persons at high risk of overdose, with 2016 federal guidance encouraging clinicians to co-prescribe naloxone to patients with increased overdose risk. Some states have pursued analogous or stricter legal requirements that could more heavily influence prescriber behavior.

Methods: We conducted a systematic legal review of state laws that mandate or recommend that healthcare providers prescribe naloxone to patients with indicators for opioid overdose risk. We coded relevant statutes and regulations for: applicable populations, patient criteria, educational requirements, and exemptions.

Results: As of September 2019, 17 states had enacted naloxone co-prescribing laws, the earliest of which was implemented by Louisiana in January 2016. If patient overdose risk criteria are met, over half of these states mandate that providers prescribe naloxone (7 states, 41.1 %) or offer a naloxone prescription (2 states, 11.8 %); the remainder encourage prescribers to consider prescribing naloxone (8 states). Most states (58.8 %) define patient overdose risk based on opioid dosages prescribed, although the threshold varies substantially; other common overdose risk criteria include concomitant opioid and benzodiazepine prescriptions and patient history of substance use disorder or mental illness.

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Contributors

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Declaration of Competing Interest

None.

Conclusions: A growing minority of states has adopted a naloxone prescribing law, although these policies remain less prevalent than other naloxone access laws. By targeting higher-risk patients during clinical encounters, naloxone prescribing requirements could increase naloxone prescribed, destigmatize naloxone use, and reduce overdose harms. Further investigation into policy effectiveness, unintended consequences, and appropriate parameters is warranted.

Keywords

Naloxone; Opioid policy; Co-prescription; Overdose; Harm reduction

1. Introduction

As fatal opioid overdose rates have skyrocketed over the past decade, there has been rapid growth in state laws that expand naloxone access and use in the community setting (Davis and Carr, 2017). Pharmacists can now dispense naloxone through non-patient-specific prescription models or prescriptive authority in all states; these laws have shown potential to increase distribution of naloxone (Abouk et al., 2019; Gertner et al., 2018; Xu et al., 2018) and reduce opioid-related overdose mortality (Abouk et al., 2019; McClellan et al., 2018; Rees et al., 2019). However, a wealth of studies suggest that naloxone laws that intervene through the pharmacy dispensation channel may be inadequate to promote sufficient naloxone access in many states, due to concerns over dispensing logistics, inadequate knowledge about the legislation, discomfort among pharmacists about dispensing naloxone through non-patient-specific prescription models, reimbursement issues, and low demand among pharmacy patrons (Evoy et al., 2018; Freeman et al., 2017; Green et al., 2017; Meyerson et al., 2018; Puzantian and Gasper, 2018; Thompson et al., 2019; Thornton et al., 2017; Zaller et al., 2013).

As a complementary effort to encourage greater naloxone access, the March 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain recommended the co-prescription of naloxone for patients with a history of overdose or substance use disorder, prescribed opioid dosages of 50 morphine milligram equivalents (MMEs) or more, or with concurrent benzodiazepine and opioid use (CDC, 2016). Other federal agencies and national medical organizations, like the U.S. Surgeon General's Office and the American Medical Association, have also strongly supported this practice (Adams, 2018; AMA, 2017; SAMHSA, 2018).

More recently, numerous states have adopted some form of naloxone prescribing requirement or recommendation ("naloxone prescription laws"). Naloxone prescription laws follow a trend of states adapting CDC Guidelines into law, as has occurred with opioid prescription days' supply and dosage limitations (Davis et al., 2019). Although evidence suggests that certain CDC guidelines modestly change opioid prescribing behavior (Bohnert et al., 2018), they are not legally binding. State naloxone prescription laws have the potential to more dramatically affect prescribers, in part due to higher salience to providers who may be legally obligated to comply with their provisions and who may exhibit greater compliance with regulations administered by professional licensing bodies. Because the laws encourage intervention among potentially higher-risk patients when engaging with a trusted medical

professional, naloxone prescription laws could increase naloxone prescribed and dispensed, destigmatize naloxone use, offer information about insurance coverage, and reduce overdose harms more effectively than pharmacy naloxone access laws, at least among certain populations.

Indeed, early indications suggest that two of the first naloxone prescription laws, in Virginia and Vermont, were associated with dramatic increases in naloxone prescriptions (Sohn et al., 2019), although these effects may have been short-lived. As more states consider enacting these laws, it will be critical to understand variation across states in the prescriber and patient populations to which they apply. To better inform the current policy landscape and ongoing evaluation efforts, we provide the first systematic review of these rapidly emerging laws to elucidate state practices, facilitate policy evaluation, and prompt consideration of best practices.

2. Methods

Two trained legal researchers (R.L.H and S.C.) systematically reviewed the Westlaw and Nexis Uni databases for all statutes and regulations in each of the 50 states and the District of Columbia that require or recommend naloxone prescribing under specified circumstances. Each state's statutes and regulations were independently searched for laws enacted by September 30, 2019 that included the terms (“antagonist! or naloxone or reversal”) and (“co-prescri! or co-prescri! or benzo! or prescr!”). We also conducted internet searches for these terms, and we reviewed state legislative and regulatory websites for relevant documentation.

Each legal researcher made a determination as to whether each identified law met the pre-specified study inclusion criteria. We excluded laws that more generally relate to naloxone access—such as laws relating to distribution and possession by laypeople, third party or standing order authorizations, laws generally encouraging naloxone prescribing (absent specific patient risk factors), and laws providing immunity for naloxone prescribers, dispensers, administrators—as these have been characterized elsewhere (Davis and Carr, 2017). We identified features that emerged in the laws, including: applicable prescriber and patient populations, nature of the co-prescribing requirement or recommendation, antagonist specified, patient triggering criteria (i.e., opioid prescribing characteristics, polypharmacy, patient medical history or condition), exemptions, and prescriber penalty for violation. Each researcher then coded these features for each law included. We collaboratively reconciled minor differences in laws identified and features characterized.

3. Results

As of September 30, 2019, 17 states had enacted laws requiring or recommending naloxone be prescribed, the first of which was Louisiana in January 2016 (Fig. 1). Seven states (AZ, FL, NM, RI, VA, VT, WA) mandate that providers prescribe naloxone to patients meeting specified criteria for opioid overdose risk. Two states (CA, OH) require providers to *offer* a prescription for naloxone to patients meeting overdose risk criteria. Eight additional states (AL, CO, LA, ME, MD, NC, TX, UT) encourage providers to consider prescribing naloxone to certain patients. In contrast to the regional concentration documented for laws limiting

opioid prescriptions for acute pain (Davis et al., 2019), naloxone prescription laws exhibit substantial geographic variation (Fig. 1).

Most naloxone prescription laws apply to all prescribing health professionals, although some specifically apply to prescribers of controlled substances (FL, UT), prescribers of opioid analgesics (NM), specific types of clinicians (OH, VA, WA), or clinicians in select practice settings (two NM laws). Most laws also exclusively name naloxone as the antagonist to be co-prescribed, although several (AZ, CA, FL, NM, MD) referred more broadly to opioid antagonists “approved by the Food and Drug Administration”.

3.1. Patients warranting a naloxone prescription

As shown in Table 1, ten states (58.8 %) define patient overdose risk warranting a naloxone prescription based on opioid dosages prescribed, although the threshold varies from 50 to 120 MMEs per day. Only four states (26.7 %) follow the CDC-recommended 50 MME threshold. Other common overdose risk criteria include patient concomitant opioid and benzodiazepine prescriptions (n = 9), history of substance use disorder or opioid use disorder (n = 12), history of overdose (n = 7), or history of mental illness (n = 5). Less common overdose risk criteria include patient respiratory disease (n = 3), opioid tolerance or chronic pain (n = 3), and risk of returning to a high opioid dose to which patient is no longer tolerant (n = 3).

Naloxone prescription laws generally apply to all patients meeting at least one of the aforementioned criteria, with select exceptions. California and Ohio specify exemptions from the mandated prescription offer for terminally ill patients and opioid administration in an inpatient setting. Colorado and North Carolina established the guidelines only for the workers’ compensation context. New Mexico’s earlier laws applied only to patients treated in opioid treatment programs or to inmates discharged from corrections facilities with a diagnosis of OUD.

3.2. Penalties and education requirements

The mandated naloxone prescription laws do not explicitly set forth penalties for prescriber violation, although the prescriber can or, in California, must, be referred to the appropriate licensing board for potential imposition of administrative sanctions deemed appropriate by the board. Seven states (CA, CO, ME, MD, NM, UT, WA) require or encourage the prescribing healthcare professional to provide patient education regarding opioid overdose prevention and the use of naloxone.

4. Discussion

There is a growing trend towards state enactment of naloxone prescription laws, with 17 states having implemented laws since January 2016. However, the patient criteria that trigger naloxone prescribing, and whether prescribing is required or merely recommended, differ among these laws in ways that may meaningfully influence policy impact. As more states consider these laws, it will be important to see whether laws begin to converge on a consistent determination of patient overdose risk or whether they continue to exhibit substantial variation. Furthermore, it will be critical to evaluate whether these laws are

adequately targeting those individuals who could benefit from naloxone prescribing and whether they are promoting equitable and effective naloxone access.

4.1. Potential benefits and limitations

While CDC relied upon evidence—including patient risk factors for overdose—in forming its Guideline, it recently clarified that the recommendations were not meant to be bright-line rules or to induce dramatic reductions in prescription opioid analgesic supply. Rather, CDC encouraged individualized assessments and determinations be made based upon patient factors when prescribing opioid analgesics (Dowell et al., 2019). This particular guideline regarding naloxone prescribing raises less cause for concern than others, given that naloxone is a harm reduction medication without serious adverse side effects. Nonetheless, many states go beyond what the CDC recommended to include patient risks factors such as prior opioid therapy, history of mental illness, or history of respiratory disease.

While there is strong evidence that naloxone administration is effective at reversing overdoses (Giglio et al., 2015), one may question whether naloxone prescription laws would have limited impact given the pre-existing naloxone policy environment in states that have implemented these laws. All 17 states that passed naloxone prescription requirements or recommendations had already implemented innovative pharmacy-based naloxone distribution mechanisms (Davis and Carr, 2017) and expanded naloxone administration authority to non-paramedic emergency medical personnel (Kinsman and Robinson, 2018). Furthermore, many of the states that have adopted naloxone prescription requirements (e.g., RI, NM, WA) are well-served by community-based overdose education and naloxone distribution programs (Lambdin et al., 2018), which have been shown to reduce fatal overdose rates by as much as 46 % in communities where the drug is widely accessible (McDonald and Strang, 2016).

However, recent analyses highlight that there remain missed opportunities in prescribing naloxone to patients at increased risk of overdose. For instance, in 2018 only one naloxone prescription was dispensed for every 69 high-dose opioid prescriptions (Guy et al., 2019). In addition, 98.5 % of commercially insured patients at “high-risk” of overdose did not receive naloxone, despite many interactions with the health care system (Follman et al., 2019). Encouraging increased naloxone prescribing to these populations, as the laws we characterize generally seek to do, seizes the clinical encounter setting to engage patients in overdose harm reduction. Patients may be more likely to view naloxone possession and administration as legitimate if recommended by their treating clinician. Although about half of naloxone prescription laws lack an explicit education requirement, information about naloxone and overdose risk is likely to be delivered by the clinician at the time of recommending, offering, or writing the prescription. Even if patients do not ultimately fill a naloxone prescription, they are better educated about the risks of overdose due to this co-prescription initiative. If patients do fill naloxone prescriptions, the drug is available to them or their acquaintances to potentially reverse an overdose in an informed manner. Thus, mandated naloxone prescriptions may be warranted to change prescriber behavior, destigmatize naloxone, and facilitate effective use of the medication.

Still, these laws are not without limitations. Surveys suggest that providers lack information about how to prescribe naloxone and would prescribe more if better trained (Binswanger et al., 2015; Freise et al., 2018), yet with one exception (ME), no naloxone prescription laws include a *prescriber* education component. Similarly, these laws do not directly address other prescriber-identified barriers to naloxone prescribing (e.g., time, payer logistics) (Allen et al., 2019; Behar et al., 2017; Binswanger et al., 2015; Freise et al., 2018) or the out-of-pocket cost or stigmatizing concerns of naloxone prescriptions to many patients (Allen et al., 2019). For patients of less established overdose risk, the cost of purchasing naloxone, which is of particular import for branded formulations (Gupta et al., 2016), may not outweigh potential health benefits—highlighting the need for cost/benefit evaluations. Mandating naloxone prescribing may be viewed by providers as just adding to a growing list of opioid prescribing requirements. Less severe alternatives could lend clinical support for providing the naloxone prescription and training (Freise et al., 2018) without imposing a mandate. Finally, these prescribing requirements will do little to reach high-risk patients not interfacing with the health care system, who may be using more potent illicit synthetic opioids and in greater need of robust naloxone access. In all, improving naloxone access through a variety of channels—health care, community-based programs, and pharmacies—may be necessary to ensure that more populations in need are reached.

5. Conclusion

Given the rapid expansion in naloxone prescription laws over the past two years and new laws under consideration in a number of jurisdictions (e.g., TN, NY, DE), further quantitative and qualitative evaluation of these laws is warranted to understand the nature of any effects, including on overdose, and unintended consequences. Some work has demonstrated the acceptability of naloxone prescription requirements to primary care providers, but provider and patient concerns are relatively complex (Allen et al., 2019; Behar et al., 2017) and research should probe what additional levers could complement these laws to sustain their impacts and address persistent barriers to naloxone access in clinical settings. Furthermore, states that could benefit from naloxone prescription requirements, such as those in the Midwest where prescription opioids still account for a sizeable proportion of opioid harms (Jalal et al., 2018), may want to consider adopting these laws (Fig. 1). Although naloxone prescription laws seem well-intentioned and generally grounded in solid evidence, careful adoption and rollout may maximize their acceptability and effectiveness in reducing opioid overdose harms.

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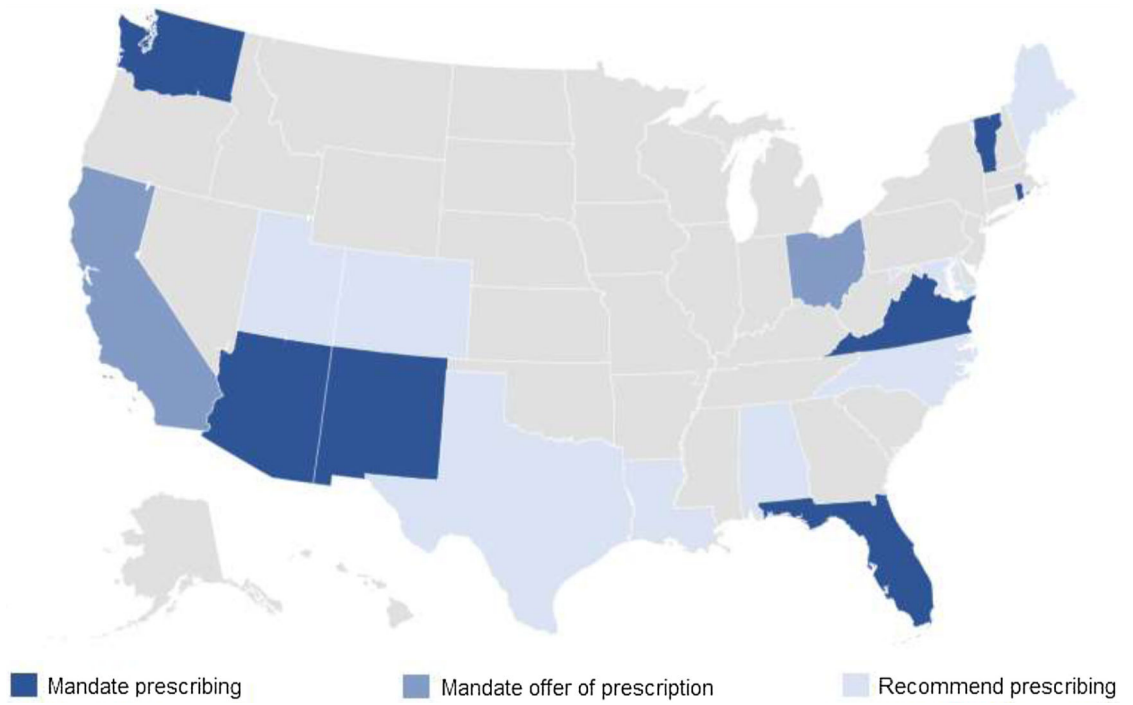


Fig. 1.
State Naloxone Prescribing Requirements and Recommendations, September 30, 2019.

Table 1

Characteristics of State Laws Requiring or Recommending Naloxone Prescriptions.

Law Type	Effective Date	Applicable Prescribers	Applicable Patients	Patient Criteria ^a	Polypharmacy	History or Condition
State	Citation			Opioid Supply/ Dosage		
Mandate prescribing						
AZ	ARS § 32-3248-01	All	All	> 90 MME/day	-	-
FL	FL Stat § 456.44	Schedule II prescribers	All	-	-	ISS 9 in pain treatment
NM	NMSA § 24-2D-1	OA prescribers	All	5-day supply	-	-
NM	NMSA § 24-23-3	OTP	OTP	-	-	OUD
NM	NMSA § 33-2-51	Corrections dept.	Former inmates	-	-	OUD
RI	216-RICR-20-20-4	All	All	50 MME/day	BZD & opioid	OD, OUD
VT	Vt Code R 2 3 7	All	All	90 MME/day	BZD & opioid	OD, SUD
VA	18 Va Admin Code §§ 85-21-40,70; 60-21-103	All (including dentists)	All	>120 MME/day	BZD & opioid	-
WA	WAC §§ 246-840-4980, 246-853-785, 246-922-785, 246-919-980, 246-817-977, 246-854-365, 246-918-930	Physicians, APNPs, PAs, Dentists, Podiatrists	All	50 MME/day	BZD & opioid	SUD, MI, OUD, illicit drug use
Mandate offer						
CA	CA Bus & Prof Code §§740-742	All	All	90 MME/day	BZD & opioid	OD, OUD, at-risk for returning to non-tolerant high opioid dose
OH	OAC §§ 4731-11-14, 4723-9-10	Physicians, APNPs	All	80 MME/day	Opioid & BZD/ sedative,carisprodol, tramadol, gabapentin	OD, SUD
Recommend						
AL	Ala Admin Code r. 540-X-4-.09	All	All	-	-	Opioid treatment
CO	7 CCR 1101-3 Rule 17, Ex 7, 9	All	Worker's Compensation ^c	-	Concurrent opioids	Chronic pain, MI, SUD,
LA	La Admin Code tit. 48 § 3901	All	All	> 14-day supply	-	-
ME ^b	02-396 CMR Ch 21 §§2,3	All	All	-	Opioid & BZD, tobacco, other opioids	SUD, MI, RD, falls, physical or sexual abuse, "doctor shopping" for opioids
ME ^b	Exec. Order 2	All	All	>100 MME/day	Dangerous combinations	-

Law Type	Effective Date	Applicable Prescribers	Applicable Patients	Patient Criteria ^a	History or Condition	
State	Citation			Opioid Supply/ Dosage	Polypharmacy	
MD	COMAR § 10.13.03	All	All	-	BZD & opioid	OD, opioid treatment
NC	11 NCAC § 23 M.0301	All	Worker's Compensation ^c	> 50 MME/day	BZD & CS	OD, SUD, MI, RD
TX	22 Tex Admin Code § 170.6	All	All	-	Concurrent opioids	OD, OUD, SUD, opioid or addiction treatment, recent incarceration release, resumed opioid therapy after interruption
UT	UT Admin Code r. R384-210	CS prescribers	All	50 MME/day	BZD & opioid	OD, SUD, MI, RD

Abbreviations: APNP, advanced practice nurse practitioner; PA, physician assistant; CS, controlled substance; OA, opioid analgesic; MME, morphine milligram equivalents; BZD, benzodiazepine; OD, overdose; OTP, federally certified opioid treatment program; OUD, opioid use disorder; SUD, substance use disorder; MI, mental illness; RD, respiratory disease; ISS, injury severity score.

^aPatients need only to satisfy one, rather than all, of these criteria for a given law's provisions to apply.

^bMaine has another law, 10-144 CMR Ch. 101 §80.07-12 (effective 9/1/2017) requiring MaineCare prescribers to consider offering naloxone if medically indicated and if opioid therapy is continued beyond 3 months to members with current use of benzodiazepines, a mental health or substance use disorder, or a medical condition that increases sensitivity.

^cWorker's compensation indicates that these laws apply only when an employee files a worker's compensation claim and receives medical expense benefits for harm incurred while performing work-related duties.