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Reviewing state-mandated training requirements for naloxone-dispensing pharmacists

Andrew W. Roberts, PharmD, PhD,

Assistant Professor, Department of Preventive Medicine and Public Health, University of Kansas Medical Center, 3901 Rainbow Blvd, Mailstop 1008, Kansas City, KS 66160

Delesha M. Carpenter, PhD,

Assistant Professor, Division of Pharmaceutical Outcomes and Policy, University of North Carolina Eshelman School of Pharmacy

Austin Smith, and

PharmD Candidate, Creighton University School of Pharmacy and Health Professions

Kevin A. Look, PharmD, PhD

Assistant Professor, Division of Social and Administrative Sciences, University of Wisconsin-Madison School of Pharmacy

Abstract

Background—Expanding access to naloxone is crucial for mitigating the public health epidemic of opioid overdose deaths in America. Pharmacists now have greater independent authority to dispense naloxone to the public due to a wave of enhanced pharmacy naloxone access laws. It is unknown to what extent pharmacists are required to receive specialized training to serve in this capacity.

Objectives—The goal of this study was to review naloxone training mandates from states with enhanced pharmacy naloxone access laws.

Methods—Structured internet searches were completed using publicly available legislative, regulatory, and administrative records to identify the type of enhanced pharmacy naloxone access law and the presence and characteristics of a pharmacist naloxone training mandate in each state.

Results—As of November 22, 2017, all 50 states have implemented an enhanced pharmacy naloxone access law. Only 19 states mandated targeted naloxone education before pharmacists engaged in independent naloxone dispensing/prescribing activities.

Conclusions—A lack of standardized naloxone training requirements for naloxone-dispensing pharmacists may affect the rate of adoption of enhanced pharmacy naloxone dispensing practices

Corresponding author: Andrew W. Roberts, PharmD, PhD, aroberts9@kumc.edu, Phone: 913-588-2382.

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CONFLICTS

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at community pharmacies and suboptimal education of patients at risk of opioid overdose. Ensuring pharmacists' preparedness to serve as naloxone providers is necessary to meaningfully prevent opioid overdose deaths in their communities.

Keywords

Naloxone; pharmaceutical policy; opioids; continuing education; community pharmacy; overdose

INTRODUCTION

The Centers for Disease Control and Prevention estimate that over 42,000 Americans died from a prescription or illicit opioid overdose in 2016.^{1,2} New evidence suggests this figure may drastically underestimate the true burden of opioid overdose mortality.³ Expanding access to naloxone, an opioid overdose antidote, has become a leading policy strategy for preventing overdose deaths nationwide.

Naloxone is a mu-opioid receptor antagonist that temporarily reverses the effects of opioids, including the potentially fatal respiratory depression that occurs during an opioid overdose event.⁴ Naloxone is available in multiple generic and branded FDA-approved products and can be administered to individuals experiencing an overdose via injection or intranasal spray. It takes effect within minutes and can be repeatedly administered as necessary until the individual can receive emergency medical services. Naloxone is an overwhelmingly safe and effective method for treating opioid overdoses in community settings.⁵

Policymakers are taking steps to increase the availability and use of naloxone among individuals at risk of experiencing an opioid overdose as well as those who are in a position to help individuals at risk of overdose. For example, law enforcement agencies and first responders are increasingly carrying naloxone rescue kits.⁶ A majority of states allow prescribers to write naloxone prescriptions for third parties and confer legal immunity to providers and individuals who give naloxone to patients.⁷ Most widespread, though, are state policies granting enhanced authority to pharmacists to dispense—and in some states, prescribe—naloxone directly to members of the public.

These innovative pharmacy naloxone access laws include allowing individual pharmacies to establish naloxone standing orders with individual physician partners, blanket statewide protocols or standing orders allowing all pharmacists in a state to dispense naloxone without a prescription, and granting pharmacists the independent authority to prescribe naloxone or dispense it without a prescription (Table 1). Under each of these circumstances, the clinical decision to engage in enhanced naloxone dispensing activities requires pharmacists to understand how to appropriately screen prospective naloxone recipients, counsel patients and third-party caregivers on recognizing and treating opioid overdose with specific naloxone delivery devices, and both immediate and long-term patient care management after naloxone administration.⁸ Additional education may also be required to inform pharmacists about their liability protections when engaging in enhanced naloxone dispensing activities and address misconceptions about naloxone, such as the belief that its use encourages high-risk opioid use behaviors.⁹

The purpose of this paper is to review each state's current legislatively-mandated training requirements that pharmacists must complete prior to engaging in enhanced naloxone dispensing activities. This knowledge is necessary to understand community pharmacists' readiness and capability to serve as independent naloxone providers and to shed light on implications for expanding naloxone access through community pharmacists, who are among the most trusted and accessible healthcare providers in the community setting.

METHODS/SEARCH STRATEGY

For each state, we performed a structured internet search to determine the presence of an enhanced pharmacy naloxone access policy and state-mandated naloxone-related training requirements for pharmacists. Enhanced pharmacy naloxone access policies included standing orders, statewide standing order/protocol, authority to dispense without a prescription, and pharmacist prescriptive authority. We used key search terms and phrases in a popular search engine to identify primary legislative and regulatory sources of the desired information: "[state name] AND pharmacist AND naloxone"; "[state name] AND pharmacies AND naloxone"; [state name] AND pharmacist AND (training OR "continuing education")." Two researchers identified and reviewed primary data sources reporting the presence/type of enhanced pharmacy naloxone access laws and state-mandated naloxone training requirements. Data sources included legislative and regulatory code text, naloxone standing order/protocol documents available on official state government websites, and/or official communications from state departments of health and boards of medicine or pharmacy. From these sources, we recorded the presence and type of enhanced pharmacy naloxone access law or regulation, the existence of a pharmacist training requirement to engage in enhanced naloxone dispensing activities, and specifications of a mandated training program, including duration and frequency.

RESULTS

All 50 states have implemented an enhanced community pharmacy naloxone access policy as of November 20, 2017 (Table 2). Forty-two states have enacted policies effectively granting practicing pharmacists independent authority to dispense naloxone at their discretion (31 states implemented a statewide standing order/protocol, 4 states allow pharmacists to dispense naloxone without a prescription, and 7 states conveyed naloxone prescriptive authority to pharmacists). The remaining 8 states allow individual pharmacies to establish a naloxone standing order with a licensed physician.

Only 19 states (38%) mandate that pharmacists complete naloxone training prior to engaging in enhanced naloxone dispensing practices. Explicit instructions on the duration and frequency of required naloxone training were found for 12 of these states. The most common mandatory training requirement was the completion of a single 1 to 2 hour continuing education program (AL, CA, CT, IA, ME, ND, TN, TX, WA, WI). Two states require continuous naloxone training for pharmacists—New Mexico mandates a 2-hour continuing education course every other year, while Nevada requires completion of a 1-hour continuing education course annually. The remaining 7 states (AZ, IL, IN, KY, MA, MI, MS) direct pharmacists to receive mandatory naloxone training but do not provide details on

duration or frequency. Illinois also requires naloxone-dispensing pharmacists to also be CPR certified.

Naloxone training requirements were most common in states granting naloxone prescriptive authority to pharmacists (4 out of 7 states = 57%) (Table 3). In contrast, only about one-third of the 31 states with a statewide standing order/protocol and one out of 4 states that allow pharmacists to dispense naloxone without a prescription require that pharmacists complete naloxone training.

Some states do not explicitly mandate required pharmacist naloxone training programs but instead expect pharmacists to have sufficient prerequisite knowledge on the proper use of the naloxone products they will dispense. For example, the Missouri Board of Pharmacy recommends that pharmacists include a required training component in the naloxone standing orders they create. South Carolina also does not explicitly prescribe a naloxone training program for pharmacists but states, “Pharmacists should be sufficiently educated regarding the naloxone HCL product(s) being dispensed to provide appropriate counseling to the persons receiving the medication...”

It should be noted that a small number of states including Oregon and Vermont require people who purchase naloxone from community pharmacies to verify that they have completed naloxone education (data not shown). Others like Louisiana, Virginia, West Virginia, and Wyoming explicitly mandate pharmacists counsel recipients of naloxone on its use but do not require pharmacists to receive training before engaging in enhanced naloxone dispensing.

DISCUSSION

Community pharmacists in every state now have the opportunity to independently provide naloxone to individuals at risk of experiencing an opioid overdose as well as third-party caregivers. This presents an invaluable opportunity for pharmacists to lead community-level efforts to combat the public health epidemic of opioid overdose deaths. However, only 19 states—which are home to just over 40% of practicing pharmacists in the United States¹⁰—require pharmacists to complete mandatory training on the appropriate use of naloxone before engaging in enhanced naloxone dispensing activities.

Targeted education for pharmacists about when and how to use naloxone, as well as recommended medical care in the wake of an overdose, is important for multiple reasons. First, and most obvious, pharmacists with naloxone training are better equipped to deliver more accurate and comprehensive patient counseling than pharmacists without this training. A study of over 1,000 Kentucky pharmacists who completed a comprehensive 90-minute naloxone training program developed by the Advancing Pharmacy Practice in Kentucky Coalition reported that it was overwhelmingly helpful for educating their patients about naloxone.¹¹ A recent content analysis of available online naloxone continuing education training programs for pharmacists demonstrated that comprehensive naloxone knowledge is multifaceted and requires understanding of the dosage, formulation, storage, administration, and adverse effects of naloxone, as well as recognizing risk factors, signs, and follow-up

treatment for opioid overdose and addiction.⁸ Pharmacists must also understand, from a pharmacy operations standpoint, how to order and bill for naloxone.

Mandated naloxone education also appears to increase a pharmacist's willingness to engage in enhanced naloxone dispensing activities. A recent survey of 1,282 Kentucky pharmacists found that pharmacists who were confident in their ability to educate patients about naloxone use for opioid overdose were 60% more likely to say they were willing to dispense naloxone in their practice compared to pharmacists with low confidence in their overdose counseling abilities.¹² A similar relationship between naloxone training and dispensing was observed among a cohort of West Virginia pharmacists; three-quarters of pharmacists felt they did not receive adequate naloxone training and only 20% felt comfortable dispensing naloxone over the counter.⁹

Even though the majority of states do not legislatively mandate naloxone education for pharmacists, many pharmacists may be required to receive naloxone training by their employer, particularly if they practice in a large chain pharmacy. However, we were unable to ascertain the availability or details about potential corporate-mandated naloxone training programs. Prior to engaging in enhanced naloxone dispensing activities, pharmacists may also voluntarily seek out naloxone education available from Federal or state governments, professional pharmacy organizations, or independent pharmacist continuing education companies. Nevertheless, we do not fully understand the extent to which pharmacists are receiving naloxone education across states and pharmacy practice settings. Future work is needed to assess the preparedness of the pharmacy profession to serve as a ready and reliable provider of naloxone to treat opioid overdose. We also do not know what the appropriate scope and intensity of naloxone training should be for pharmacists and whether it should vary across states with different types of enhanced pharmacy naloxone access laws. Most importantly, future work is needed to examine the effects of mandatory naloxone training on pharmacists' ability to counsel patients and caregivers and, ultimately, improve opioid overdose outcomes.

CONCLUSIONS

The recent wave of enhanced pharmacy naloxone access laws at the state level has enabled pharmacists to prevent opioid overdose deaths through enhanced independent authority to dispense naloxone. However, there is a stark lack of standardization from state-to-state in how pharmacists are formally prepared to engage in enhanced naloxone dispensing activities. Ensuring the community pharmacist workforce is adequately trained about the management of opioid overdose with naloxone is necessary to optimally and equitably address the opioid overdose epidemic in our communities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Descriptions of enhanced community pharmacy naloxone access laws

Standing order	Formal agreements between an individual pharmacy and a prescriber in which the covered pharmacist(s) are permitted to dispense naloxone without a patient-specific prescription according to patient criteria and instructions defined by the authorizing prescriber.
Statewide protocol/standing order	Formal agreements between an individual prescriber (typically a state health official) and all licensed pharmacists in that state to authorize pharmacists to dispense naloxone under pre-defined circumstances without a patient-specific prescription
Dispense without a prescription	Select naloxone products are essentially reclassified as a “behind-the-counter” products, allowing pharmacists to independently dispense naloxone without a prescription or standing order/protocol in place
Prescriptive authority	Pharmacists may independently prescribe select naloxone products to individual patients without physician supervision

Table 2

State naloxone access policies and pharmacist naloxone training requirements, as of 11/28/17

STATE	NALOXONE ACCESS POLICY	PHARMACIST TRAINING REQUIREMENT	NALOXONE TRAINING DETAILS
Alabama	Statewide protocol/standing order	No	
Alaska	Dispense without a prescription	Yes	Single 1 hour CE course
Arizona	Statewide protocol/standing order	Yes	Single unspecified training course
Arkansas	Statewide protocol/standing order	No	
California	Prescriptive authority	Yes	Single 1 hour CE course
Colorado	Standing order	No	
Connecticut	Prescriptive authority	Yes	Single 2 hour certificate training program
Delaware	Statewide protocol/standing order	No	
Florida	Statewide protocol/standing order	No	
Georgia	Statewide protocol/standing order	No	
Hawaii	Statewide protocol/standing order	No	
Idaho	Prescriptive authority	No	
Illinois	Statewide protocol/standing order	Yes	Single certificate program; CPR certification
Indiana	Statewide protocol/standing order	Yes	Unspecified training program
Iowa	Statewide protocol/standing order	Yes	Single 1 hour CE course
Kansas	Statewide protocol/standing order	No	
Kentucky	Statewide protocol/standing order	Yes	Single unspecified training course
Louisiana	Statewide protocol/standing order	No	
Maine	Statewide protocol/standing order	Yes	Single 2 hour CE program
Maryland	Statewide protocol/standing order	No	
Massachusetts	Standing order	Yes	Single unspecified training course
Michigan	Statewide protocol/standing order	Yes	Unspecified prerequisite training
Minnesota	Statewide protocol/standing order	No	
Mississippi	Standing order	Yes	Unspecified training program
Missouri	Statewide protocol/standing order	No *	
Montana	Statewide standing order	No	
Nebraska	Dispense without a prescription	No	
Nevada	Statewide protocol/standing order	Yes	Annual 1 hour CE course
New Hampshire	Standing order	No	
New Jersey	Statewide protocol/standing order	No	
New Mexico	Prescriptive authority	Yes	Biennial 2 hour CE course
New York	Statewide protocol/standing order	No	
North Carolina	Statewide protocol/standing order	No	
North Dakota	Prescriptive authority	Yes	Single 1 hour CE course
Ohio	Standing order	No	

STATE	NALOXONE ACCESS POLICY	PHARMACIST TRAINING REQUIREMENT	NALOXONE TRAINING DETAILS
Oklahoma	Dispense without a prescription	No	
Oregon	Prescriptive authority	No	
Pennsylvania	Statewide protocol/standing order	No	
Rhode Island	Standing order	No	
South Carolina	Dispense without a prescription	No **	
South Dakota	Standing order	No	
Tennessee	Statewide protocol/standing order	Yes	Single 1 hour CE course
Texas	Statewide protocol/standing order	Yes	Single 1 hour CE course
Utah	Statewide protocol/standing order	No	
Vermont	Statewide protocol/standing order	No	
Virginia	Statewide protocol/standing order	No	
Washington	Standing order	Yes	Single 1.5 hour CE course
West Virginia	Statewide protocol/standing order	No	
Wisconsin	Statewide protocol/standing order	Yes	Single 1 hour CE course
Wyoming	Prescriptive authority	No	

* Missouri Board of Pharmacy recommends including pharmacist training requirement in individual standing orders

** South Carolina protocol to dispense naloxone without a prescription states “Pharmacists should be sufficiently educated regarding the naloxone HCL product(s) being dispensed to provide appropriate counseling to the persons receiving the medication...” and provides links to recommended training materials.

Table 3

Frequency of mandatory pharmacist naloxone training, by enhanced community pharmacy naloxone access law type

	States with policy	States with training requirement	%
Standing order	8	3	38%
Statewide protocol/standing order	31	11	35%
Dispense without prescription	4	1	25%
Prescriptive authority	7	4	57%