

# Drug Topics®

Voice of the Pharmacist

## Controlling Prescription Drug Abuse [THE PHARMACIST'S ROLE]



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# Naloxone and the Pharmacist's Role in Reducing Opioid Overdose Harm

By Fred Gebhart

**N**aloxone may be the single most effective tool to counteract opioid overdose that can quickly lead to death. New formulations, new laws, and new attitudes are making it easier for more pharmacists to get this life-saving tool into more households and community locations to save more lives.

"Instead of running out of naloxone, which was the case a couple of years ago, we now have two branded products—a self-injector and an intranasal—and generics," said Jeffrey Bratberg, PharmD, BCPS, Clinical Professor of Clinical Practice at the University of Rhode Island College of Pharmacy and naloxone expert. "And because there is an overdose risk at any dose of opioid, every pharmacist has patients at risk. Carrying naloxone, encouraging prescribers to write for naloxone, and encouraging patients to take naloxone home is taking an active role in managing the risks inherent in opioid use."

Drug overdose deaths, driven largely by prescription drug overdose, surpassed motor vehicle accidents as the leading cause of injury-related death in the United States in 2013. More than 47,000 individuals died from Rx drug overdose in 2014, Dr. Bratberg noted. Opioid overdoses led the toll.

"Naloxone has the unique ability to reverse acute opioid toxicity and save lives," noted Ryan Oftebro, PharmD, President and Principal of Kelley-Ross & Assoc, Inc, which owns five pharmacies in Seattle, Wash. "Every community pharmacy that serves a population at risk of opioid overdose should stock and distribute naloxone. Given the broad use of prescription opioids, that is just about every community pharmacy in the country."

Naloxone was approved by the Food and Drug Administration in 1971 and has long been available as a generic for intravenous, intramuscular, and intranasal delivery.

FDA approved a self-injector, Evzio (Kaléo Pharma) in 2014 and a nasal spray, Narcan (Adapt Pharma) in 2015. Generic formulations continue to be available. Most states allow some form of pharmacist prescribing for naloxone, and most large drug chains provide pharmacist training in its use.

## Naloxone pilot program

Dr. Bratberg helped create a naloxone pilot program with Walgreens in 2013. Two years later, every Walgreens and CVS store

in the state was stocking naloxone and pharmacists were prescribing it under collaborative practice agreements (CPAs) with local physicians.

New Hampshire now has a standing order for naloxone dispensing at all pharmacies in the state. In October, 2015, CVS announced that it will allow pharmacists in an additional 20 states to dispense naloxone under CPAs. Rite Aid announced plans to train 6,000 pharmacists on naloxone use. The National Association of Chain Drug Stores, National Community Pharmacists Association, American Pharmacists Association, and American Society of Health-System Pharmacists all announced plans to expand naloxone education and training.

The growing attention to naloxone should help focus payer attention on the potential to reduce the risks of opioid use by increasing distribution of naloxone through improved reimbursement, said Bethany DiPaula, PharmD, BCPP, Director of Pharmacy at Springfield Hospital Center and Associate Professor at the University of Maryland School of Pharmacy. Dr. DiPaula headed a College of Psychiatric and Neurologic Pharmacists task force that published *Naloxone Access: A Practical Guideline for Pharmacists* in 2015.

## A leading role for pharmacists

"We are paving the way for pharmacists to take a leading role in the management and reduction of opioid overdose," Dr. DiPaula said. "Pharmacists should be playing a larger role by making naloxone readily available."

Pharmacists can also play a larger role in reducing the stigma that can be attached to naloxone. While naloxone is highly effective at reversing acute opioid toxicity, it is most often referenced in the context of heroin overdose.

"We need to change the way naloxone is marketed in the community," Dr. Bratberg said. "It is marketed as an anti-heroin drug, which only increases the stigma. But we know that patients on chronic prescription opioids don't associate these drugs as being as powerful as heroin or recognize that they carry the same risk or even higher of overdose. That can be a barrier to recommending naloxone for someone in hospice care or a chronic pain patient. Naloxone should become the standard of care for every patient on any dose of any opioid."

Contributing Editor Fred Gebhart is a freelance writer based in Oregon.

# THE PHARMACIST'S ROLE IN Controlling Prescription Drug Abuse

**THE UNITED STATES CONTINUES** to face an epidemic of prescription drug abuse. While representing only 5 percent of the world's population, Americans consume 75 percent of the world's prescription drugs.<sup>1</sup>

Enough prescription painkillers were prescribed in 2010 to medicate every American adult every 4 hours for one month. Most strikingly, the number of deaths due to drug overdose in the United States increased from 4000 in 1999 to 16,600 in 2010.<sup>2</sup> The chronic use of prescription drugs continues with an estimated 1.9 million people in the United States who suffered from substance use disorders relating to prescription opioid pain medicines in 2013.<sup>3</sup>

Pharmacists are on the frontlines in the war against prescription drug abuse. Not only do they have an ethical duty, backed by federal and state laws, to ensure a prescription for a controlled substance is appropriate, they must also determine that the prescription is legitimate, match the prescription to the condition, and take proactive steps to prevent drug misuse. Pharmacists must exercise sound professional judgment when determining whether a prescription for a controlled substance is legitimate.

## Code of Federal Regulations

### Section 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a **legitimate medical purpose** by an individual practitioner acting in the **usual course** of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests with the pharmacist who fills the prescription.**

## Prescription Drug Monitoring Programs (PDMPs)

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track

the prescribing and dispensing of controlled prescription drugs to patients. There are 51 PDMPs, in all states except Missouri, plus the District of Columbia and Territory of Guam.

Reporting requirements of PDMPs vary state by state. Typically, pharmacists must report the following: name of prescriber; medication dispensed; date prescription was filled; quantity dispensed; name and national drug code (NDC) of controlled substance; name, address, and date of birth of person for whom the prescription was written; and more. Pharmacists must adhere to various regulations on what prescriptions to report, how to report them and how to protect the privacy of reported information.

Penalties vary for noncompliance, can be taken against a pharmacy that does not report this information properly, and pharmacists can be prosecuted for filling a prescription that they know, or should have known, was not for a legitimate purpose.

Pharmacists do more with PDMPs beyond their requirement to report data. Pharmacists can proactively use the information contained within PDMPs, which are designed to help both pharmacists and providers monitor for suspected medication abuse or diversion. PDMPs can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history—and thus the means to identify high-risk patients who may benefit from early interventions or the data can be used to pinpoint possible doctor or pharmacy shopping.

## Navigating PDMPs and State and Federal Regulations

State-run PDMPs are vital tools in combating the epidemic of controlled substance abuse. However, keeping up with state and federal guidelines can be a daunting task. Reporting requirements vary by state. For instance, all state programs require reporting for Schedule II drugs. Most, but not all, states require reporting for Schedule III and IV drugs. Some states require reporting of Schedule V drugs.

Pharmacists rely on the Gold Standard Drug Database State and Federal module to comply with state PDMPs and federal controlled substances regulations. The module provides current, easily

accessible data on medication-related guidelines and mandates; and it supplies data for states whose controlled substances classifications are more restrictive than federal requirements. This includes drug schedule classification by NDC, State, Classification ID, and start/end date.

PDMPs are important tools in the fight to control prescription drug abuse, and the pharmacist's role is important. Elsevier's Gold Standard Drug Database provides timely and accurate drug information with TRUE Daily Updates.™ Every day, including weekends and holidays, Elsevier updates its drug information. Pharmacists rely on Elsevier's database to help reduce the manual effort associated with maintaining required PDMP data and can rest assured that proper data are reported per state requirements.

In response to the high number of fatalities resulting from prescription opioid overdose, President Obama issued a memorandum directing federal departments and agencies to provide opioid prescriber training to federal healthcare providers who prescribe controlled substances as part of their responsibilities.

In addition, states have made a commitment to ensure more healthcare providers complete opioid prescriber training, and to double the number of healthcare providers registered with their PDMP programs. Further, 30 states are actively sharing PDMP data through a secure communications exchange platform across state lines.

The burden of prescription drug abuse remains enormous. Even though 2012 saw the first national drop in prescription overdose deaths since the 1990s, more than 16,000 people lost their lives to prescription drug abuse in 2013. This decrease in fatal overdoses mirrors a similar decline in painkiller prescribing rates across the country...and gives promise to continued progress in reversing this epidemic.<sup>4</sup>

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1 World Drug Report, 2011. [http://www.unodc.org/documents/data-and-analysis/WDR2011/World\\_Drug\\_Report\\_2011\\_ebook.pdf](http://www.unodc.org/documents/data-and-analysis/WDR2011/World_Drug_Report_2011_ebook.pdf)

2 Prescription Drug Abuse: Top 10 Things CDC Says You Should Know, April 30, 2013. <http://www.pbs.org/newshour/rundown/prescription-drug-abuse-top-10-things-cdc-says-you-should-know/>.

3 What is the Federal Government Doing to Combat the Opioid Abuse Epidemic? May 2015. <http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/what-federal-government-doing-to-combat-opioid-abuse-epidemic>

4 Centers for Disease Control & Prevention, Injury Prevention & Control: Prescription & Control: Prescription Drug Overdose, <http://www.cdc.gov/drugoverdose/data/>

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