

National Perspective on Opioids and Substance Use Disorders

June 27, 2017

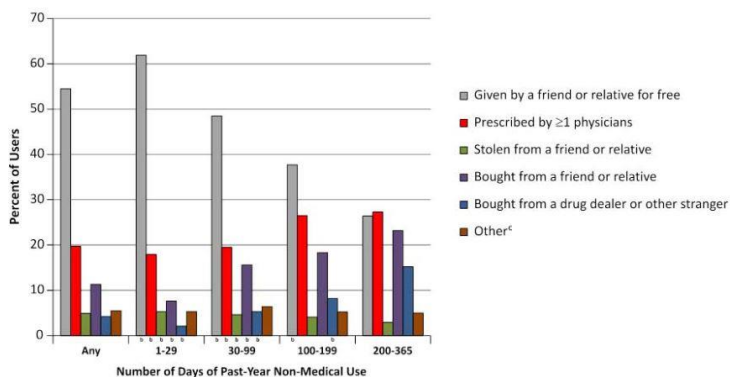
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The Problem

- 33,091 opioid deaths in 2015 (including prescription opioids and heroin)¹
 - Nearly half due to prescription opioids
 - Quadrupled since 1999

Sources of Prescription Opioids Among Past-Year Non-Medical Users^a



^a Obtained from the US National Survey on Drug Use and Health, 2008 through 2011.⁵

^b Estimate is statistically significantly different from that for highest-frequency users (200-365 days) (P<.05).

^c Includes written fake prescriptions and those opioids stolen from a physician's office, clinic, hospital, or pharmacy; purchases on the internet; and obtained some other way.

SOURCE: Jones C, Paulozzi L, Mack K. Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008–2011. JAMA Int Med 2014; 174(5):802-803.

Chronic Pain and Opioids

\$560 - \$635
billion/year.

- 116 million people in U.S. with chronic pain
- 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings²
 - Primary care providers account for half of opioids prescribed
- Risks associated with opioids resulting in new approaches to chronic pain management
 - Integrative approach to care
 - Nonopioid pharmacologic therapies
 - Nonpharmacologic therapies
 - Multiple strategies at federal and state level to restrict opioid use

www.painmed.org/patient/facts.html#incidence

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Federal Government Response to the Opioid Crisis

- White House
 - Commission on Combating Drug Addiction and the Opioid Crisis (Gov. Chris Christie – Chair)
- Congress
 - Multiple bills to address opioid access, PDMPs, substance use disorder, etc.
- HHS
 - Opioid crisis is one of top 3 priorities for HHS Secretary Price

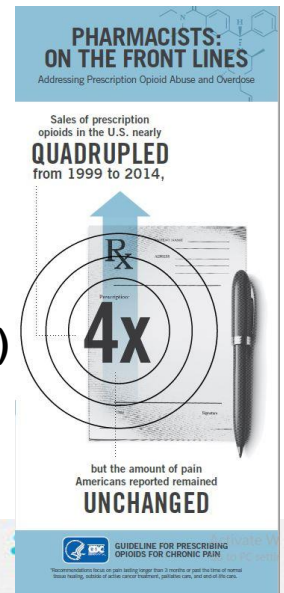


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Federal Government Response to the Opioid Crisis

- CDC
 - Prescribing guidelines
 - Resources for providers and patients
- FDA – “More Forceful Steps”
 - FDA Opioids Action Plan
 - New actions to highlight risks of opioids (black box warnings, update REMS program?)
 - Proposed mandatory education (prescribers, others?)
 - Abuse deterrent formulations

<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>
https://www.cdc.gov/drugoverdose/pdf/Pharmacists_Brochure-a.pdf
<https://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm>



Federal Government Response to the Opioid Crisis

- National Institutes on Health (NIH)
 - Research in multiple areas (pain, addiction)
- National Institute on Drug Abuse (NIDA)
 - Research on substance use disorder – pharmacy pilot
 - Clinical Trials Network – community pharmacy group
- Substance Abuse and Mental Health Services Administration (SAMHSA)
 - Behavior health and substance use disorder
- DEA
 - Diversion control

The Pharmacist's Role in Chronic Pain Management and Substance Use Disorder

Enforcement:
Prevent diversion

DEA
enforcement
of federal laws
and
regulations

**Corresponding
Responsibility:** Patient
legitimate
need/access



**Finding an
appropriate balance**

Patient Care:
Pain management

Treatment for
Substance Use
Disorder Treatment

Collaboration
with other
health care
professionals

The Pharmacist's Role

- Understand and apply changes in treatment approaches for chronic pain management
- Understand and apply treatment approaches for opioid use disorder
- Educate patients about safe and effective use of opioids
 - Risks, overdose/misuse, and proper storage and disposal
- Develop treatment plans in coordination with health care team
- Review and monitor patient's medications in collaboration with prescribers
- Provide naloxone for opioid overdose reversal

The Pharmacist's Role

- Consult prescription drug monitoring programs (PDMPs) and input applicable data
- Initiate, modify, and discontinue therapy in collaboration, as authorized
- Provide drug information and medication recommendations to the health care team
- Participate in community outreach and prevention activities
- Referral for treatment?



State Policies to Address Opioids and Substance Use Disorder

Becky Snead, NASPA



State Approaches - monitoring

- Prescription drug monitoring programs
 - Frequency of data reporting
 - Ranges from monthly (Alaska) to real-time (Oklahoma)
 - Majority of states are daily
 - Alaska will change to weekly on 7/17/17
 - Required registration for prescribers/dispensers
 - Required PDMP check for prescribers/dispensers
 - Data sharing (clinicians vs. law enforcement)
 - Data sharing across state lines



State Approaches - prescribers

- Pain management clinics (“pill mills”)
 - State oversight of pain management clinic operations
 - Regulations to prevent inappropriate prescribing
 - Encourage partnerships with health departments, law enforcement and other stakeholders
- Prescribing limitations
 - Days supply limits
 - Emergency room limitations
 - Naloxone co-prescribing requirements
 - *What is the pharmacists’ corresponding responsibility?*



State Approaches – patients

- Lock-in programs
 - Limit state program beneficiaries suspected of misusing controls to a single prescriber or pharmacy
- Partial-fills
 - State policies to align with CARA
 - Allows patients to pick up a partial amount of a controlled prescription without forgoing the remainder



State Approaches – harm reduction

- Drug treatment
 - Funding
- 911 Good Samaritan
 - Protects those that call for help when someone overdoses
- Syringe Access
 - Needle exchange
 - Reduce exposure to blood-borne disease
- Replacement therapy
 - Methadone
 - Buprenorphine



State Approaches - naloxone

- Naloxone prescriber immunity
 - Civil, criminal, professional liability protections
- Third-party prescriptions
 - Prescribing to someone who is not an end user
- Training
 - Patient, recipient of third-party prescription, prescriber, dispenser
- Emergency medical responders
 - Allow first responders to possess and administer opioid antagonists
- Access from Pharmacists



Naloxone Access from Pharmacists *Standing Orders (23)*

- Allows a non-patient specific prescription to be written for naloxone
- Similar to a CPA
- Authorizing prescriber is the prescriber of record
- Pharmacy responsible for finding an authorizing prescriber
- Anecdotally reported to have low uptake
 - Prescriber liability concerns, despite state laws protecting liability
 - Logistically challenging for the pharmacy
- County-wide standing orders could be issued by the health department



Naloxone Access from Pharmacists *Dispense without a Prescription (5)*

- Some state policies authorize pharmacists to dispense naloxone without a prescription
- Issues with insurance
 - Will the PBM allow it to be covered?
 - What about on audit?
- How is it documented?
 - If documented in pharmacy system, who is the prescriber of record?



Naloxone Access from Pharmacists *Statewide Standing Order (11)*

- State official with prescribing authority issues a standing order for the entire state
- State official is the prescriber of record
- What happens when that state official leaves office?
- Will insurance cover it?
 - Some fears from pharmacies that it won't be covered upon audit
 - State official may not be a practicing provider
- Pharmacy may need to opt in to access the standing order



Naloxone Access from Pharmacists *Statewide Protocol/Prescriptive Authority (10)*

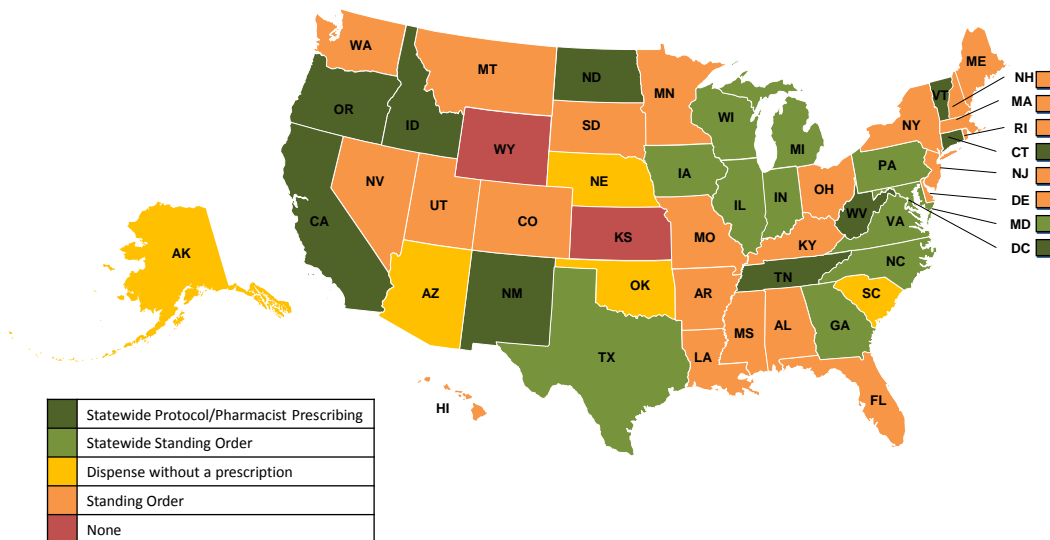
- States may empower pharmacists to prescribe naloxone
 - Prescriptive authority (often “prescribe and dispense”)
 - Under a statewide protocol
- Pharmacist is the prescriber of record
- Insurance problems
 - Pharmacist should update their NPI taxonomy to “clinical pharmacist”
 - May not ensure coverage but could remove one barrier



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Naloxone Access in Community Pharmacies

Based on data collected by NASPA (updated June 2017)



Questions/Discussion

