Opioid Safety: Focus on Furnishing Naloxone

A GUIDE FOR CALIFORNIA COMMUNITY PHARMACISTS
Purpose of this guide

Community pharmacists are uniquely poised to engage in efforts to reduce opioid misuse and opioid related overdose. Pharmacists are often in the difficult position of distinguishing between patients in dire need of pain relief and patients struggling with addiction to opioids.

Pharmacists can effectively address and significantly impact our current epidemic of opioid misuse and overdose because they are trusted, knowledgeable, and accessible members of our communities.

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Epidemiologic trends in opioid use and overdose

Since 1999, sales of prescription opioids in the U.S. have quadrupled.¹

In 2014, 10.3 million persons reported using prescription opioids non-medically.²

71% of people who abuse prescription opioids get them from a friend or relative.³

71% obtained from friend or relative

29% other

~55% got them for free

~16% bought or stole them
Overdose deaths

DRUG OVERDOSE IS THE LEADING CAUSE OF INJURY-RELATED DEATH IN THE U.S.⁴

OPIOID OVERDOSE

DRUG OVERDOSE DEATH RATES, INCLUDING THOSE INVOLVING PRESCRIPTION OPIOIDS AND HEROIN, CONTINUE TO INCREASE IN THE U.S.⁷

OPIOID SAFETY: FOCUS ON FURNISHING NALOXONE

91 AMERICANS die every day from an opioid overdose (that includes prescription opioids and heroin)⁸
Overview and background

Opioid overdose deaths in California

AGE-ADJUSTED RATE PER 100,000 RESIDENTS BY COUNTY, 2012-2016*

>25
20-24.9
15-19.9
10-14.9
5-9.9
0-4.9

The community pharmacist’s role in opioid safety

It is clear we are midst an epidemic. To halt the epidemic, new cases of opioid addiction must be prevented and access to treatment for those who have already developed a substance use disorder must be expanded.
Make a positive impact

• **Ensure the appropriate use of opioids.** Be well-versed in pain management and work with prescribers and patients to appropriately manage pain.

• **Read the CDC Guideline for Prescribing Opioids for Chronic Pain,** which addresses how to optimally manage pain while preventing opioid use disorder (dependence, addiction, abuse) and overdose. The guideline was developed to:
  — Improve communication between providers and patients about risks and benefits of opioids
  — Improve safety and effectiveness of pain treatment
  — Reduce risks associated with long-term opioid therapy, including opioid use disorder and overdose

• **Recognize legitimate uses for opioids,** including short-term treatment of acute pain, cancer pain, or end-of-life care.

• **Limit access to opioids for illegitimate use.** For red flags, refer to California’s Prescription Drug Monitoring Program (PDMP): Controlled Substances Utilization Review and Evaluation System (CURES).

• **Become aware of treatment resources** in your community and refer patients for medication-assisted treatment (MAT) with methadone or buprenorphine.

• **Provide opportunities for drug destruction and take-back** for individuals in the community to dispose of controlled substances safely: tinyurl.com/3ogb85c.

• **Educate individuals at risk for overdose about, and expand access to,** life-saving naloxone.
Evaluate opioid prescriptions

Validity:

- Has prescription been forged or altered?
- Has prescriber’s DEA number been verified?
- Is prescription within the prescriber’s scope of practice?
- Has patient’s identity been verified?
- Has CURES been checked?

Appropriateness:

- Is opioid indicated for patient’s pain?
- Have other agents been tried?
- Is current regimen meeting treatment goals?
- Can opioids be reduced to a lower dosage or discontinued?

Safety:

- Are there any medications that may interact (e.g., benzodiazepines)?
- Is patient using alcohol or illicit substances?
Look for red flags

Look for signs of opioid use disorder or diversion of prescription opioids. CURES will help identify some of these red flags.

- Forged prescriptions presented with unusual wording or abbreviations, absence of typical abbreviations, overly meticulous writing, or an unusual signature
- Altered prescriptions presented with multiple colors, ink types, or handwriting styles on one prescription
- Patients or prescriptions originating from outside the local geographic area
- Prescribers practicing outside their scope of practice
- Prescriptions for high dosages or high quantities
- Patients appearing intoxicated
- Patients who pay with cash only
- Patients who ask for early refills
- Patients with multiple prescribers or multiple pharmacies

If prescription opioid misuse is suspected:

- Consider pharmacists’ corresponding responsibility in ensuring prescriptions are legal and not for purposes of abuse: tinyurl.com/mqmxlpb.
- When misuse is suspected, a pharmacist should contact the prescriber to obtain more information. If a pharmacist cannot determine validity of a prescription, the prescription should be refused until validity can be determined.
Assess for risk of overdose

Patients at highest risk of overdose include:

- Those who have had a prior overdose
- Those taking higher doses of opioids (≥50 morphine milligram equivalents or MME/day; resource for calculating MME: tinyurl.com/lvfdksv)
- Those who use opioids while they are alone (not at greater risk for overdose, but at greater risk for fatal overdose)
- Those with reduced tolerance, e.g., period of abstinence (including incarceration or rehab) or a change in dose
- Those using other substances concomitantly, particularly alcohol, benzodiazepines, or cocaine
- Those with chronic medical illnesses that impact lung, liver, and kidney functions
How to talk about opioids

Communicating with patients

General tips:
- Be empathic. Don’t be judgmental.
- Ask open-ended questions.
- Use active listening techniques.
- Use clear words. Avoid technical verbiage.
- The approach should be “risky medicines” not “risky patients.”
- The term “overdose” carries stigma especially to prescription opioid users. Use terms such as “toxicity,” “bad reaction,” and “antidote.”
- Direct patients to additional resources.

Questions you might ask to engage patients:
- What medications are you currently taking?
- What pain medications have you taken and how have they worked for you?
- How well is your medication working to relieve your pain?
- What other ways do you have to help manage your pain?
- Are you experiencing any side effects from your medications?
- Do you know which medications you should avoid taking with your opioid medication?
- Do you have any questions for me about any of your medications?

Provide education about:
- Pain management
- Proper use of opioids, including dosing and refill expectations
- Avoiding alcohol, benzodiazepines, and other CNS depressants when taking opioids
- Safe and secure storage which restricts access to others, and safe disposal of unused medication
- Opioid use disorder (provide resources and referral to treatment)
- Risks and signs of opioid overdose (provide resource such as “Opioid safety and how to use naloxone” trifold)
- Use of naloxone to reverse overdose
Communicating with prescribers

When to call prescribers:
- Fraudulent prescription presented
- Patient appears intoxicated
- CURES elicits concern (e.g., multiple prescribers)
- Patient taking other CNS depressants (e.g., benzodiazepines)
- Patient presenting early for refill

Benefits of communicating with prescribers:
- Collaborate with prescribers to optimize pain management for patients.
- Reduce potential for misuse or diversion by communicating about any red flags.
- Reduce potential for overdose by discussing concerns about concurrent medication or substance use.
- Provide recommendations to prescribers when medication assisted treatment (MAT) for opioid use disorder is indicated.
- Identify prescribers in your community who are pain management specialists.
- Identify prescribers in your community who provide MAT.
Treating opioid use disorder: medication-assisted treatment

Use of medication-assisted treatment (MAT) has been shown to increase recovery rates, decrease overdose deaths, decrease criminal activity, and lower the risk of infections such as HIV and hepatitis C.
Overview

Medication-assisted treatment (MAT) is the use of medications such as buprenorphine, methadone, and extended release naltrexone, often in combination with counseling and behavioral therapies, to treat opioid use disorder.

- Barriers to MAT include stigma of addiction (substance use disorder), not recognizing opioid use disorder, a lack of awareness of treatments available, lack of physician training, and limited access to treatments and treatment providers.

- For more information and a detailed resource on MAT, go to tinyurl.com/lca54te for documents such as:
  - “Recovery Within Reach: Medication-Assisted Treatment of Opioid Addiction Comes to Primary Care”
  - “Primary Care Buprenorphine Programs: Ten Elements of Success”
  - “Buprenorphine: Everything You Need to Know”

Nearly 80% of those with an opioid use disorder don’t receive treatment.¹⁰
Buprenorphine

Formulations

STANDARD FOR OPIOID USE DISORDER:

- Coformulated buprenorphine/naloxone SL tab
- Coformulated buprenorphine/naloxone film or implant

IF PATIENT DOES NOT TOLERATE/CANNOT ACCESS COFORMULATED PRODUCTS:

- Monoformulated buprenorphine SL tablets

Clinical pearls

- Partial opioid agonist with very high affinity, blocking effects of other opioids; 36 hour half life
- “Ceiling effect” due to partial agonism; lower potential for misuse, diversion, respiratory depression, and overdose than other opioids
- Reduced potential for diversion or injection due to coformulation with naloxone; combination product favored except in pregnant women
- Separate registration with DEA to obtain waiver, or “X” number, required to prescribe buprenorphine for opioid use disorder
- Patients treated in the office or at home
- Exhibition of mild to moderate opioid withdrawal symptoms before initiation; severe withdrawal symptoms if buprenorphine started too early
- Generally prescribed in very limited quantities to ensure close follow up, particularly early in treatment; opportunities for pharmacist to actively assist patients in treatment for opioid use disorder
Buprenorphine (continued)

✔️ Patient counseling tips

• **Sublingual tablets or film should be kept under tongue and buccal film should be placed on the inside of cheek until completely dissolved.** Due to low oral bioavailability, swallowing will result in reduced effect and may induce withdrawal symptoms.

• **Tablets, sublingual film, and buccal film are not equivalent;** some patients may require a change in dose when transitioning from one product to another.

• **Avoid combining with other CNS depressants,** such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medication assisted treatment should not be withheld from patients taking other CNS depressants and buprenorphine may be a safer option than methadone.

• **Store in a safe and secure location** to prevent accidental ingestion by others.
Methadone

Clinical pearls

• Full opioid agonist
• Methadone for pain prescribed then dispensed by pharmacies, but methadone for opioid use disorder only dispensed through opioid treatment programs
• Long half life (up to 60 hours), may accumulate
• QT prolongation and increased risk for serious arrhythmias
• Potential for drug interactions
• Respiratory depression and overdose risk
• Methadone dispensed from opioid treatment programs not reported to CURES (prescriptions dispensed at pharmacies reported)

Patient counseling tips

• Many medications may interact with methadone; check with physician or pharmacist anytime you start or stop a new medicine.
• Report excessive sedation, shallow breathing, or dizziness to physician.
• Avoid combining with other CNS depressants, such as alcohol or benzodiazepine, as this can increase the risk for respiratory depression and overdose toxicity. However, while the combination may increase risk, medication assisted treatment should not be withheld from patients taking other CNS depressants.
Extended release naltrexone

Clinical pearls

• Opioid antagonist; blocks euphoric effects of opioid agonists
• No addiction potential; not a controlled substance; may be prescribed by any prescriber
• More effective than oral naltrexone for opioid use disorder but less favored by patients compared to buprenorphine or methadone
• Withdrawal may be precipitated if agonists (full or partial) are on board; must be 7-10 days without other opioids before starting naltrexone (up to 14 days after discontinuing long-acting opioids such as buprenorphine or methadone)
• Increased risk for overdose during washout period prior to starting treatment, or during treatment if large amounts of opioids used to overcome naltrexone’s opioid blockade
• Increased risk of overdose with relapse after ER naltrexone discontinuation due to loss of tolerance
• Improved adherence with monthly dosing

Patient counseling tips

• Because a patient’s tolerance to opioids may be reduced, the patient’s risk for overdose is increased during the waiting period to initiate naltrexone and after stopping naltrexone.
Providing access to naloxone

Naloxone saves lives

Naloxone is a highly specific, high-affinity opioid antagonist used to reverse the effects of opioids.

In California, a licensed pharmacist may furnish naloxone by following the California State Board of Pharmacy protocol (16 CCR §1746.3): tinyurl.com/125elze
Requirements of naloxone protocol in California

Naloxone prescriptions are treated like any other prescription. However, to furnish naloxone (dispense with the pharmacist as prescriber), pharmacist must:

- **Meet a training/CE requirement** of either one hour of approved CE specific to naloxone administration or an equivalent curriculum-based training in a board recognized school of pharmacy.

- **Screen the recipient of naloxone (or family member/friend)** to determine if the patient uses or has a history of using illicit or prescription opioids, or has a known hypersensitivity to naloxone. Screening questions are available in different languages from the Board of Pharmacy: tinyurl.com/l45d5c3.

- **Educate the person receiving the naloxone product regarding:**
  - Overdose prevention, recognition, and response
  - Safe administration of naloxone (dosing, effectiveness, storage conditions, shelf-life)
  - Potential side effects
  - Importance of seeking emergency medical care
  - Availability of drug treatment programs
  - Educational counseling may not be waived by the person receiving naloxone

- **Provide the naloxone fact sheet when furnishing naloxone.** This can be found in various languages on the Board of Pharmacy website: tinyurl.com/l45d5c3.

- **Notify patient’s primary care provider if the naloxone is provided** to the intended patient and consent (either verbal or written) is given by the patient.

- **Maintain records of furnishing naloxone for at least three years** (e.g., prescription in the pharmacy database with the pharmacist as the prescriber on record).

- If naloxone is furnished to a third party (not the ultimate recipient of the rescue medication), the patient on record is the third party recipient.
Identifying patients for naloxone

- Patients who have previously experienced opioid intoxication or overdose
- Patients with recent period of opioid abstinence and reinitiation of opioid
- Patients on long-term opioid therapy, on high dose opioids ($\geq 50$ morphine milligram equivalents/day), or those with recent increase in dosage
- Patients with a history of nonmedical use of opioids or other substance use disorder (including, but not limited to, alcohol, marijuana, cocaine, methamphetamines)
- Patients on long-acting opioids (e.g., methadone, fentanyl patch) or on regimens of multiple opioids
- Patients on concurrent benzodiazepine or other CNS depressant
- Patients requesting access to naloxone
- Family members or friends of any patient meeting above criteria or anyone at risk of witnessing an overdose
How to furnish, order, and bill for naloxone

- **Obtain a National Provider Identifier (NPI)** to allow you to be the prescriber on record: https://nppes.cms.hhs.gov.

- **Pharmacists who prescribe/furnish medications must enroll with Medi-Cal** for the purpose of ordering, referring, or prescribing (ORP): tinyurl.com/k88vqgz.

- **Collect resources to have on hand:**
  - Naloxone products (see formulations on pages 24-25)
    - Commercially available nasal spray
    - Auto-injector
    - Single dose vials and syringes
    - Prefilled syringes and atomizers
    - Devices for lay use (branded nasal spray and auto-injector) offer ease of use and are marketed with patient education materials. If pricing and access are issues, provide generic products with educational materials referenced below.
  - Patient education materials: tinyurl.com/k35fnch
  - Training devices for demonstration purposes (break open from stock or request placebo trainers from manufacturers)

- **Develop onsite procedures for naloxone requests** and proactive criteria for patient selection. Train pharmacy employees to ensure procedure is executed consistently.

- **Naloxone is covered by Medi-Cal as a “carve-out” medication so submit directly to Fee For Service Medi-Cal**, NOT to the Managed Care Medi-Cal plan. It is also covered by many other plans. Prices for cash payments vary widely by formulation.

- **The atomizer used with the assembly-required intranasal prefilled syringe kit (page 25) does not have an NDC** and cannot be billed through usual pharmacy billing routes. Some pharmacies are willing to cover the cost of the atomizer or patients may be requested to pay the cash price (around $5 per atomizer).
Educate patients and caregivers about preventing overdose

**How to counsel patients and caregivers**

- Only take medicine prescribed to you.
- Don’t take more than prescribed; call your doctor if pain not controlled.
- Don’t mix with alcohol or sleeping pills.
- Don’t use alone; don’t use opioids from an unknown source.
- Abstinence lowers tolerance; take less upon restart.
- Store in a secure place.
- Dispose of unused medications.
- Teach your family and friends how to respond to an overdose and how to use naloxone.
- If you are having difficulty taking opioids safely, I can refer you to help.
How to respond to an overdose

1 Recognize the signs of an overdose
   - Slow or shallow breathing; gasping for air while sleeping; pale, clammy, or bluish skin or fingernails; slowed heartbeat; low blood pressure; won’t wake up or respond (rub knuckles on sternum)

2 Call 911 and give naloxone
   - Administer dose per instructions in patient education guides provided with naloxone products, or view educational videos online: prescribetoprevent.org/patient-education/videos.
   - Assess response; give repeat dose if no or minimal response in 2-3 minutes.
   - Lay the person on his or her side to prevent choking.
   - Quick response improves survival.
   - Say “Someone is unresponsive and not breathing.” Give clear address and location.

3 Follow 911 dispatcher instructions
   - Clear airway, give rescue breaths if not breathing and/or chest compressions.
   - With victim laying flat on back, put one hand on chin, tilt head back, pinch nose closed, make seal over mouth, and breathe 1 breath every 5 seconds. Chest should rise, not stomach.

4 Stay until help arrives—naloxone effects last 30-90 minutes
   - Patient can go back into overdose if long-acting opioids were taken (e.g., fentanyl patch, methadone, extended release formulations of morphine or oxycodone).
   - Following up naloxone administration with medical care is important.
Naloxone formulations

These devices are designed for lay use. Manufacturers provide written patient education.

**INTRANASAL (NARCAN)**

- Naloxone 4mg (two pack, NDC: 69547-353-02)
- Dispense #1
- SIG: Use as needed for suspected opioid overdose. Spray into one nostril upon signs of opioid overdose. Repeat into other nostril after 2-3 minutes if no or minimal response. Call 911.

**AUTO-INJECTOR (EVZIO)**

- Naloxone auto-injector 2mg (two pack, NDC: 60842-051-01)
- Dispense #1
- SIG: Use as needed for suspected opioid overdose. Inject IM into outer thigh, depress and hold for 5 seconds, as directed by voice prompt system upon signs of opioid overdose. Repeat with second device in 2-3 minutes if no or minimal response. Call 911.

*Note: Evzio 0.4 mg auto-injector no longer manufactured.*

- Inform patients to alert others about naloxone, how to use it and where it’s kept, as it is generally not self-administered.
- Shelf life is 12-24 months; store at room temperature.
- Side effects include risk for withdrawal, anxiety, sweating, nausea/vomiting, or shaking.
Naloxone formulations (continued)

If the devices on the previous page are not available, dispense the following formulations and provide thorough education on assembly and use.

**INTRANASAL—ASSEMBLY REQUIRED**

- Naloxone 2mg/2ml prefilled needleless syringe (NDC: 76329-3369-01)
  - Dispense #2
  - SIG: Use as needed for suspected opioid overdose. Spray ½ of syringe into each nostril upon signs of opioid overdose. Repeat after 2-3 minutes if no or minimal response. Call 911.
- Mucosal atomizer device (MAD-300) nasal adapter produced by Teleflex
  - Dispense #2
  - Use as directed for naloxone administration.

*Note: Atomizer considered durable medical equipment.*

**INJECTABLE**

- Naloxone 0.4mg/ml 1ml single dose vial (NDC: Hospira 00409-1215-01; Mylan 67457-292-00)
  - Dispense #2
  - SIG: Use as needed for suspected opioid overdose. Inject 1 ml IM in shoulder or thigh upon signs of opioid overdose. Repeat after 2-3 minutes if no or minimal response. Call 911.
- 3ml syringe with 25g 1” needle
  - Dispense #2
  - Use as directed for naloxone administration.

**Clinical pearls**

- Can use 3ml syringe with 23-35 gauge 1-1.5 inch needles
- All components available at community pharmacies
- Third party reimbursement possible
- Some patients may not be comfortable with needles
Frequently asked questions

Who is the prescriber on record when naloxone is furnished by pharmacists?
The pharmacist who furnished the naloxone should be identified as the prescriber on record in the pharmacy prescription database using his or her individual National Provider Identifier.

What laws in California address health care providers prescribing or furnishing naloxone?

CALIFORNIA CIVIL CODE §1714.22
• Allows for licensed health care providers to prescribe naloxone to both persons at risk of an opioid overdose and their friends and family members (also known as third party prescribing).
• Provides protection to licensed health care providers acting with reasonable care from civil and criminal liability when they prescribe, dispense, or oversee naloxone distribution and for the lay persons who may administer naloxone to someone suspected of an opioid overdose.

What laws in California address lay persons possessing and administering naloxone?

CALIFORNIA CIVIL CODE §1714.22
• Provides protection for anyone who has received a prescription for naloxone from a prescriber, pharmacy, or overdose prevention program who possesses and administers naloxone during a suspected overdose.

CALIFORNIA HEALTH AND SAFETY CODE §11376.5
• Protects lay persons from arrest for use or possession of small amounts of drugs when seeking medical assistance for a suspected drug overdose.

Can a patient’s insurance be billed for naloxone?
Yes, naloxone furnished under the statewide protocol can be billed to insurance companies. Although third party prescribing is permitted for naloxone, it must be billed under and dispensed to the person requesting it at the pharmacy.
Additional resources

Centers for Disease Control and Prevention (CDC) Clinical Tools: tinyurl.com/ltduw3v
- Guideline for Prescribing Opioids for Chronic Pain
- Pharmacists: On the Front Lines
- Tapering Opioids for Chronic Pain
- Nonopioid Treatments for Chronic Pain
- Assessing Benefits and Harms of Opioid Therapy
- Calculating Total Daily Dose of Opioids for Safer Dosage
- Prescription Drug Monitoring Programs
- Free Opioid Guide App (calculate total daily opioid dose, clinical guidance, motivational interviewing communication skills): tinyurl.com/kw4jbav
- Prescription Opioids: What You Need to Know: One-page patient education fact sheet for patients taking prescription opioids: tinyurl.com/n3ylg6p

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov/medication-assisted-treatment
- Regulations, training resources, and treatment guidelines for medication-assisted treatment (MAT) of opioid use disorder with buprenorphine, methadone, and naltrexone
- Opioid treatment program directory (services locator)

College of Psychiatric and Neurologic Pharmacists (CPNP)
- Opioid Use Disorders: Interventions for Community Pharmacists: Guideline to educate community pharmacists on interventions to provide safe access to opioids while protecting communities from consequences of misuse: cpnp.org/guideline/opioid
- Naloxone Access: A Practical Guide for Pharmacists: Guideline to educate community pharmacists on increasing access to naloxone: cpnp.org/guideline/naloxone
Additional resources (continued)

Prescribe to Prevent: prescribetoprevent.org
- Information on prescribing and dispensing naloxone
- Resources targeted to prescribers and pharmacists
- Excellent resources for patient education including posters and videos
- Resources related to legal and advocacy issues

California State Board of Pharmacy Naloxone Information: tinyurl.com/l45d5c3
- Naloxone protocol
- Sample naloxone Rx labels
- Naloxone fact sheets for patients in several languages
- Naloxone screening questions in several languages
References


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The recommendations contained in this brochure are general and informational only; specific clinical decisions should be made by providers on an individual case basis.