Managing Pain Safely: Pharmacy Toolkit

Objective: *Increase knowledge of the MPS Program and share best practices regarding preventing opioid misuse and abuse with pharmacies throughout the 14 PHC counties.*

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Executive Summary

Our Ask

1.) *Avoid splitting prescriptions and allowing patients to pay cash, unless otherwise indicated- Split fills are discouraged with Schedule II prescriptions. Appropriate TAR submission for prescribed dosages and quantity limits exceeding PHC criteria is recommended.*
2.) *Stock Naloxone*
3.) *Routinely check and use CURES*
4.) *Look into becoming a certified safe disposal site*

Policy makers and public health experts are struggling to come up with strategies for countering the burgeoning problem of prescription opioid overuse, abuse, diversion and opioid-related mortality. In the midst of this, several non-for profit health plans have leveraged their control over paying for the medications and their strong relationships with the prescriber community to rapidly and substantially reduce opioid misuse. Partnership HealthPlan of California's approach is a helpful case study, and suggests that working with health plans is a key public health strategy to quickly turn the epidemic around.

Using the Model for Improvement methodology, PHC developed a framework to begin addressing the problems related to opioid use/misuse. In January 2014, internal workgroups of specific focus areas were convened (pharmacy, provider network, community initiatives, member services/care coordination/ utilization management, policy and communication, and data management) to begin planning and executing targeted initiatives.

About Partnership HealthPlan of California

Partnership HealthPlan of California (PHC) is a local governmental agency that was created in 1993 in Solano County, California. PHC, also called a County Organized Health System (COHS), is a non-profit community based health care organization that contracts with the State of California and local counties to ensure that children and adults with limited income and resources can receive medical services at little or no cost. With six offices in four locations in Eureka, Fairfield, Redding, and Santa Rosa, California, we provide quality health care to more than 557,000 Medi-Cal members throughout 14 Northern California counties – Del Norte, Humboldt, Lake, Lassen, Marin, Mendocino, Modoc, Napa, Shasta, Siskiyou, Solano, Sonoma, Trinity and Yolo.

Managing Pain Safely: An Overview

Using the Model for Improvement methodology, PHC developed a framework to begin addressing the problems related to opioid use/misuse. In January 2014, internal workgroups of specific focus areas were convened (pharmacy, provider network, community initiatives, member services/care

coordination/ utilization management, policy and communication, and data management) to begin planning and executing targeted initiatives. These workgroups produced the following outcomes:

- Opioid prescribing guidelines for primary care physicians, emergency departments, pharmacists, and dentists
- A formulary change for the sole purpose of addressing patient safety, including quantity limit restrictions, refill too soon policies, and status changes for multiple medications
- Community engagement strategies to assist in creating and supporting community initiatives
- PHC procedures and scripts for Member Services and Care Coordination to enhance patient interactions
- Educational opportunities for providers, including forums/webinars, website accessible tools/resources, Project ECHO (an educational pain management program through UC Davis)
- Implementation of key supporting policies, such as the requirement of a Treatment Authorization Request, to assist in reducing the number of members on high-dose opioids.[2]
- Key educational events and web-based learning sessions available for free to all providers within our network
- PHC Oversight Committee developed to assist providers create treatment plans for complicated cases of patients on high dose opioids
- Approval of alternative modality benefits for quality chronic pain patients- chiropractic, acupuncture, osteopathic manipulation therapy
- Managing Pain Safely Provider's Online Toolkit developed and distributed as a resource for providers

Managing Pain Safely Vision
- By December 31, 2016, we will improve the health of PHC members by ensuring that prescribed opioids are for appropriate indications, at safe doses, and in conjunction with other treatment modalities.

Outcome Measures

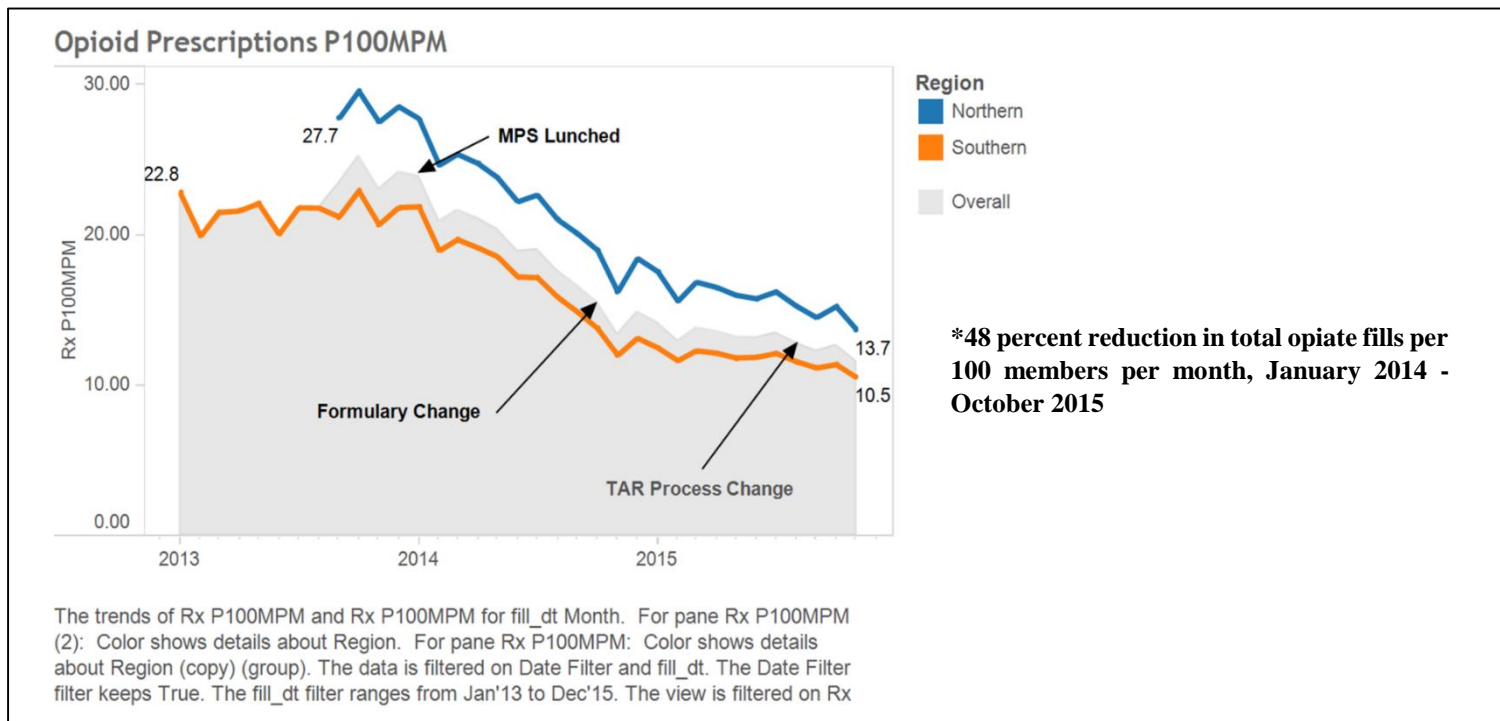The following are the defined outcome measures for this project.

1) Total opioid prescriptions (the rate of opioid prescriptions per member per month)
2) Initial opioid prescriptions (the rate of initial opioid prescriptions per member per month)
3) Opioid prescription escalations (the percentage of total opioid users with escalated dose in the measurement period)
4) Unsafe opioid dose (the percentage of total opioid users on a daily dose >120mg morphine equivalent)

Results
Data has been evaluated and analyzed for three of the four outcome measures. Results during the measurement period of January 2014 (project induction) to November 30, 2015:
- 52 percent reduction in total opiate fills per 100 members per month, plan-wide
- 40 percent reduction in percent of total opioid users on unsafe doses, plan-wide

- 39 percent* reduction in initial opiate fills per 100 members per month (*measurement period Feb 2014-June 2015 due to ACA expansion in Jan 2014), plan-wide

The trends of Rx P100MPM and Rx P100MPM for fill_dt Month. For pane Rx P100MPM (2): Color shows details about Region. For pane Rx P100MPM: Color shows details about Region (copy) (group). The data is filtered on Date Filter and fill_dt. The Date Filter filter keeps True. The fill_dt filter ranges from Jan'13 to Dec'15. The view is filtered on Rx

*48 percent reduction in total opiate fills per 100 members per month, January 2014 - October 2015

Looking Ahead in 2016
- Continued educational events
- Pain Specialist Tele-Consult Pilot
- Integrated Clinics Pilot
- Continued support of community initiatives
- Targeted initiatives for specific high-risk populations- specifically high utilizing prescribers and initial starts
- Increased focus on alternate specialty groups- EDS, orthopedics, hospitalists, etc.
- Continued sharing of county and provider level data
- Naloxone program
- Pharmacy toolkit and academic detailing

Community Pharmacies Guidelines: Recommendations

Recommendations

A. Every pharmacist working at a community pharmacy should have an account to be able to check CURES reports.

B. Each pharmacy should define the circumstances for checking the CURES report of a patient. Options include:

1. All patients with a prescription for a controlled drug

2. New prescriptions for a controlled drug

3. Patients with behavior suspicious for abuse or diversion. Examples include:

    a. Patient is paying cash for a medication when they have active insurance coverage.

    b. Patient has no active filling history at this pharmacy, but brings a prescription for a controlled medication.

    c. Patient brings in a prescription pad with multiple prescriptions, but only wants to pick up the narcotic.

    d. Patient has a prescription with an unusually high quantity of pain medications.

    e. Patient comes in with a prescription for narcotics on a weekend or at the end of the day when most doctors' offices are closed.

    f. Patient's doctor's office is not within reasonable distance of the pharmacy.

    g. Subject to professional judgment.

    h. Patient's home address is not within a reasonable distance from the pharmacy or the doctor's office.

    i. Patient looks nervous and tries to hurry the pharmacy staff.

    j. Patient is unable to provide a valid ID.

    k. Patient claims their prescription was stolen or lost.

    l. Patient presents a story that sounds too suspicious to be true.

    m. A significant number of customers appear with prescriptions from the same prescriber and for the same controlled medication.

    n. Patient shows "unusual knowledge of controlled substances."

C. Notify the patient's primary care clinician or primary prescriber when filling a controlled medication for a patient:

1. If the patient is picking up a prescription written by an Emergency Department clinician, a dental practice, or an out-of-area prescriber.

2. If the patient calls to request early refills.

3. If the medication prescribed is not indicated for the patient's diagnosis.

D. Pharmacists should counsel patients picking up opioid prescriptions of the risk of tolerance, addiction, opioid induced hyperalgesia, and overdose.

E.   Pharmacists should request photo ID for patients picking up controlled medications from the pharmacy.

Drug Disposal Information and Resources

Resources to become a disposal site

DISPOSAL REGULATIONS: REGISTRANT FACT SHEET

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"). The final rule is available for public view at http://www.federalregister.gov/public-inspection. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on http://www.regulations.gov, and our website, http://www.DEAdiversion.usdoj.gov. This Registrant Fact Sheet contains a general summary of some of the effects of the new rule on registrants. For detailed information, please visit our website or contact your local DEA office.

1. **What is the Disposal Act?**

   - The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

2. **What do the implementing regulations do?**

   - Effective October 9, 2014, the implementing regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

   - The new regulations reorganize and consolidate previously existing regulations on disposal, including the role of reverse distributors. Effective October 9, 2014, the existing regulation on disposal of controlled substances, 21 C.F.R. 1307.21, will be removed. New requirements on proper disposal procedure and security will be in a new part 1317.

   - As of October 9, 2014, all Memoranda of Agreement (MOA) and Memoranda of Understanding (MOU) issued pursuant to current 21 C.F.R. 1307.21 will be null and void. Registrants should consult 21 C.F.R. 1317.05(a) for information on new MOAs and MOUs for the disposal of controlled substances.

   - Effective October 9, 2014, the existing regulation on return and recall, 21 C.F.R. 1307.12, will be removed. New return and recall requirements for registrants and non-registrants are incorporated into new 21 C.F.R. 1317.10 and 1317.85.

   - Effective October 9, 2014, registrants must use DEA Form 41 to record the destruction of controlled substances. However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as "drug wastage" and "pharmaceutical wastage"). Such remaining substance must be properly recorded, stored, and

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destroyed in accordance with DEA regulations (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

3. **Who is an "ultimate user"?**

   - The CSA defines an "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

4. **What is "collection"?**

   - "Collection" means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term "collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

5. **How can a registrant become an "authorized collector"?**

   - Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at http://www.DEAdiversion.usdoj.gov. Once authorized, these entities are "authorized collectors."

   - Eligible registrants must have authority to handle schedule II controlled substances.

   - Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

6. **Who can operate a collection receptacle for the collection of pharmaceutical controlled substances?**

   - Authorized collectors may maintain collection receptacles inside their registered location; and Federal, State, tribal, or local law enforcement may continue to maintain collection receptacles inside their physical location.

   - Authorized hospitals/clinics with an on-site pharmacy, and retail pharmacies, may maintain collection receptacles at long-term care facilities.

7. **Who can operate a mail-back program for the collection of pharmaceutical controlled substances?**

   - Authorized collectors with an on-site method of destruction may operate a mail-back program.

8. **If I become an authorized collector and decide to stop, how do I do so?**

   - *Collection receptacle:* Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical controlled substances in their possession in accordance with the new rule, and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

- *Mail-back program:* Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

9. **What can I collect as an authorized collector?**

   - An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.

   - Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (*i.e.*, registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

10. **Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?**

    - No. Ultimate users may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

11. **I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?**

    - No. A collector shall not require any person to provide any personally identifying information.

12. **How does a registrant dispose of controlled substances when 21 C.F.R. 1307.21 is removed?**

    - The authorized methods and procedures regarding disposal are outlined, in 21 C.F.R. 1317.05, according to whether the substances being disposed of are practitioner inventory, non-practitioner inventory, or collected controlled substances.

13. **How can a registrant destroy controlled substances?**

    - The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceutical controlled substances must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.

    - "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

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Other safe disposal resources

FDA **Consumer Health Information**
www.fda.gov/consumer

How to Dispose of Unused Medicines

I s your medicine cabinet full of expired drugs or medications you no longer use? How should you dispose of them?

Many community-based drug "take-back" programs offer the best option. Otherwise, almost all medicines can be thrown in the household trash, but consumers should take the precautions described below.

A small number of medicines may be especially harmful if taken by someone other than the person for whom the medicine was prescribed. Many of these medicines have specific disposal instructions on their labeling or patient information leaflet to immediately flush them down the sink or toilet when they are no longer needed. For a list of medicines recommended for disposal by flushing, go to *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm*.

Drug Disposal Guidelines and Locations

The following guidelines were developed to encourage the proper disposal of medicines and help reduce harm from accidental exposure or intentional misuse after they are no longer needed:

- Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet unless this information specifically instructs you to do so.
- Take advantage of programs that allow the public to take unused drugs to a central location for proper disposal. Call your local law enforcement agencies to see if they sponsor medicine take-back programs in your community. Contact your city's or county government's household trash and recycling service to learn about

medication disposal options and guidelines for your area.
- Transfer unused medicines to collectors registered with the Drug Enforcement Administration (DEA). Authorized sites may be retail, hospital or clinic pharmacies, and law enforcement locations. Some offer mail-back programs or collection receptacles ("drop-boxes"). Visit the DEA's website (*www.deadiversion.usdoj.gov/drug_disposal/index.html*) or call 1-800-882-9539 for more information and to find an authorized collector in your community (*www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1*).

If no disposal instructions are given on the prescription drug labeling and no take-back program is available in your area, throw the drugs in the household trash following these steps:
1. Remove them from their original containers and mix them with an undesirable substance, such as used coffee grounds, dirt or kitty litter (this makes the drug less appealing to children and pets, and unrecognizable to people who may intentionally go through the trash seeking drugs).
2. Place the mixture in a sealable bag, empty can or other container to prevent the drug from leaking or breaking out of a garbage bag.

FDA's Ilisa Bernstein, Pharm.D., J.D., offers a few more tips:
- Scratch out all identifying information on the prescription label to make it unreadable. This will help protect your identity and the privacy of your personal health information.
- Do not give your medicine to friends. Doctors prescribe medicines based on your specific symptoms and medical history. Something that works for you could be dangerous for someone else.

- When in doubt about proper disposal, ask your pharmacist.

Bernstein says the same disposal methods for prescription drugs could apply to over-the-counter drugs as well.

Why the Precautions?
Some prescription drugs such as powerful narcotic pain relievers and other controlled substances carry instructions for flushing to reduce the danger of unintentional use or overdose and illegal abuse.

For example, the fentanyl patch, an adhesive patch that delivers a potent pain medicine through the skin, comes with instructions to flush used or leftover patches. Too much fentanyl can cause severe breathing problems and lead to death in babies, children, pets and even adults, especially those who have not been prescribed the medicine.

"Even after a patch is used, a lot of the medicine remains in the patch," says Jim Hunter, R.Ph., M.P.H., an FDA pharmacist. "So you wouldn't want to throw something in the trash that contains a powerful and potentially dangerous narcotic that could harm others."

Environmental Concerns
Some people are questioning the practice of flushing certain medicines because of concerns about trace levels of drug residues found in surface water, such as rivers and lakes, and in some community drinking water supplies.

"The main way drug residues enter water systems is by people taking medicines and then naturally passing them through their bodies," says Raanan Bloom, Ph.D., an environmental assessment expert at FDA. "Many drugs are not completely absorbed or metabolized by the body and can enter the environment after passing through wastewater treatment plants."

"While FDA and the Environmental

Protection Agency take the concerns of flushing certain medicines in the environment seriously, there has been no indication of environmental effects due to flushing," Bloom says.

"Nonetheless, FDA does not want to add drug residues into water systems unnecessarily," adds Hunter.

FDA reviewed drug labels to identify products with disposal directions recommending flushing down the sink or toilet. This continuously updated listing can be found at FDA's Web page on Disposal of Unused Medicines (*www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm*).

Disposal of Inhaler Products
Another environmental concern involves inhalers used by people who have asthma or other breathing problems, such as chronic obstructive pulmonary disease. Traditionally, many inhalers have contained chlorofluorocarbons (CFCs), a propellant that damages the protective ozone layer. CFCs have been phased out of inhalers and are being replaced with more environmentally friendly inhaler propellants.

Read handling instructions on the labeling of inhalers and aerosol products, because they could be dangerous if punctured or thrown into a fire or incinerator. To ensure safe disposal that complies with local regulations and laws, contact your local trash and recycling facility. **FDA**

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*

Naloxone

Naloxone Guidelines for Pharmacists

Ordering

Intranasal- NDC#76329-3369-01

- 2mg/2mL naloxone is available from IMS/Amphastar (NDC 76329-3369-1). (This is the concentration that is to be used for IN administration)

- A complete naloxone kit should have a minimum of two doses of naloxone and two delivery devices

Billing

- Naloxone is covered by Medi-Cal (as a "carve-out" so submit directly to fee-for-service Medi Cal do not send a PA to the HMO plan)

- The atomizer will be provided by PHC

Counseling

- Instruct patients to administer if non-responsive from opioid use

- Explain how to assemble naloxone kit for administration

- Include family/ caregivers in patient counseling or instruct patients to train others

- Distribute Naloxone Fact Sheet (as provided by PHC) with medication and atomizer

Storage

- Naloxone should be stored are room temperature and protected from sunlight

- Extreme and repeated temperature fluctuations have been shown to degrade the medication over time- avoid temperature variations as much as possible

Side Effects

- Anxiety, sweating, nausea/vomiting or shaking. Talk to your doctor if these occur. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

**Information gathered from prescribetoprevent.org

Naloxone Fact Sheet

What is an opioid overdose?

Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone…

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit

www.prescribetoprevent.org

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
CALIFORNIA STATE BOARD OF PHARMACY

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

DEVELOPED BY
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

How to identify an opioid overdose:

Look for these common signs:
- The person won't wake up even if you shake them or say their name
- Breathing slows or even stops
- Lips and fingernails turn blue or gray
- Skin gets pale, clammy

In case of overdose:

1 Call 911 and give naloxone
If no reaction in 3 minutes, give second naloxone dose

2 Do rescue breathing or chest compressions
Follow 911 dispatcher instructions

3 After naloxone
Stay with person for at least 3 hours or until help arrives

How to give naloxone:

There are 3 ways to give naloxone. Follow the instructions for the type you have.

Nasal spray naloxone

1 Take off yellow caps.

2 Screw on white cone.

3 Take purple cap off capsule of naloxone.

4 Gently screw capsule of naloxone into barrel of syringe.

5 Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**

Push to spray.

6 If no reaction in 3 minutes, give second dose.

Injectable naloxone

1 Remove cap from naloxone vial and uncover the needle.

2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.

fill to 1 ml

3 Inject 1 ml of naloxone into an upper arm or thigh muscle.

4 If no reaction in 3 minutes, give second dose.

Auto-injector

The naloxone auto-injector is FDA approved for use by anyone in the community. It contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed.

Naloxone Counseling Tips

City and County of San Francisco

Edwin M Lee, Mayor

Department of Public Health

Community Behavioral Health Sciences
Community Oriented Primary Care
San Francisco General Hospital

**INTRANASAL NALOXONE
PATIENT COUNSELING**

COMMON BRAND NAMES: Narcan

USES: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

SIGNS OF AN OPIOID OVERDOSE: Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

HOW TO USE: If you suspect someone has overdosed on opioids:
1. Call 911
2. Give naloxone:
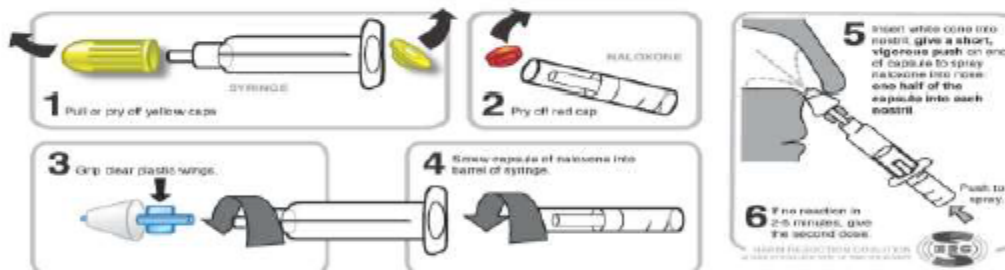
3. Give second dose of naloxone in 2-3 minutes if no response to first
4. Perform rescue breathing if comfortable doing so

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

SIDE EFFECTS: Anxiety, sweating, nausea/vomiting, shaking may occur. Talk to your doctor if these occur. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of serious allergic reaction, including: itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

Tips to Help Fight Against Opioid Misuse, Abuse, and Diversion

Warning Signs

- Patient will come in at the end of the business day/ after hours
- Patient is insistent on being seen immediately
- Patient does not live in town/ local- traveling long distances to come to your clinic
- Patient is adamant that only narcotics work to treat his/her pain
- Patient is seen by multiple doctors
- Patient refuses to give the name of his/her primary care physician
- Patient repeatedly states the prescription has been lost or stolen
- Patient frequently asks for refills more often than being prescribed
- Unpredictable and/or unusual behavior in the waiting room
- Patient frequently pays cash for medication or requests split fills- •
  - o Split fills are discouraged with Schedule II prescriptions. Appropriate TAR submission for prescribed dosages and quantity limits exceeding PHC criteria is recommended.

What to do when you suspect your patient may be abusing

- Check CURES to evaluate usage pattern
- Attempt to call patient's assigned primary care physician
- Confirm current address and insist on patient receiving treatment locally
- Consider the prescription of Naloxone for patient, refer to "Naloxone" section of this toolkit

Accuracy and Quality of Claims Submission Tips

- Reflect appropriate quantity and day supply when dispensing opioid prescription
- Timely submission of opioid to PDMP

Recognizing the need for TAR when quantity need exceed PHC Formulary Limits

CURES 2.0

- How to Sign Up - https://pmp.doj.ca.gov/pmpreg/Login.action

State *of* California Department *of* Justice

Kamala D. Harris

Office *of the* Attorney General

Attorney General

AG Home Page

Tools & Resources

Health Information Privacy
(HIPAA Guidelines)

PDMP Registration

CURES 2.0 is Live

The CURES 1.0 Registration Page is no longer active.

Existing CURES 1.0 users can sign onto CURES 2.0 at: https://cures.doj.ca.gov.

New Applicant Prescribers and Dispensers can register at:
https://cures.doj.ca.gov/registration/confirmEmailPnDRegistration.xhtml.

Please note that a contemporary browser (IE 11 or higher, Safari, FireFox or Chrome) is
required to perform the various interactive CURES registration steps.

If you have questions, please contact the CURES Help Desk at cures@doj.ca.gov or (916)
227-3843.

Cures 2.0 User Guide Highlights

CURES 2.0 Screens

First Time Login

Upon logging in for the first time to CURES 2.0, the user must update their user profile and agree to CURES 2.0 Terms and Conditions before proceeding to the Home Page (Dashboard).

To complete the first time login process:

1. Log in to CURES 2.0. The system automatically navigates to the User Profile page.

2. Review your user profile, complete additional required fields, and agree to the Terms and Conditions.

3. Click the "Update" button. The system automatically navigates to the Home Page.

Dashboard/Home Page

The Home Page is the landing page for all users upon login to CURES 2.0. It includes the following:

- Saved searches and searches initiated by delegates
- Advisories and bulletins from DOJ regarding the CURES Program or CURES 2.0 application
- A link to CURES 2.0 statistics and data trends
- For prescribers, user messages and patient alerts

User Profile – Prescriber and Dispenser Users

CURES 2.0 stores user profile information and provides the user with the ability to maintain personal information on the User Profile page. This page is pre-populated with information provided by the user during registration.

Instructions:

1. From the Global Navigation Menu, select "User Profile."

1. From the drop down list, select "Profile."

2. On the User Profile page, edit the user profile information by clicking the "Edit" Button:

   - Name and ID Section
   - Address Section

▾ Address

Note: The Primary Address is Required. All fields with (*) are required
Please enter physical addresses only. No post office boxes

Primary	Business Name	Address *	Address Line2	Zip Code *	State	City	County	
Y		1 Big Time Road		91127	CA	Hugeville	Alameda	✎
								✎
								✎

▾ Address

Note: The Primary Address is Required. All fields with (*) are required
Please enter physical addresses only. No post office boxes

Primary	Business Name	Address *	Address Line2	Zip Code *	State	City	County	
Y		1 Big Time Road		91127	CA	Hugeville	Alameda	✔ ✖
								✎
								✎

   - DEA Section (User may add up to 9 additional DEA numbers.)
   - Email Section
   - Delegations Section

Account Renewal

All CURES 2.0 users are required to renew their account on an annual basis. Users receive renewal notifications on the renewal date and thirty days after the user's one year renewal date.

Delegate Management – Adding a Delegate

Delegates are CURES 2.0 users who have the authority only to initiate PAR Requests for a "parent" prescriber or dispenser user. (No other functionality is accessible to the Delegate user.) The CURES 2.0 Delegate Registration Page allows users to create delegates within CURES 2.0. This process for delegates applies only to Prescriber and Dispenser Roles.

Delegate Registration is managed by a Prescriber or Dispenser or "Parent" CURES 2.0 users. From their own User Profile, Prescribers and Dispensers can view, add and remove Delegates.

The following rules apply to delegate registration and the delegate's access to CURES 2.0:

- A delegate can be associated with more than one prescriber or dispenser.
- A delegate must be associated with at least one prescriber or dispenser in order to initiate a PAR query.
- If a delegate is associated with more than one prescriber or dispenser, and one parent unlinks the delegate, the delegate will still have access to CURES 2.0 through the remaining associations.
- When a delegate account is created and associated with a new parent prescriber or dispenser, a notification will be sent to the parent user to indicate that the account has been created. A notification will also be sent to the delegate with login information.
- When an existing delegate account is associated with a new parent prescriber or dispenser, a notification will be sent to the parent user to indicate that the account has been created. A notification will also be sent to the delegate with login information.
- The system will allow up to 50 delegates per parent.
- The system will allow up to 50 parents per delegate.

Instructions:

1. Select 'User Profile' from Global Navigation

2. Select the "Delegations" section

3. Click on the "Manage Delegates" button.

4. User will be navigated to the "Manage Delegates" Screen

5. Enter the required fields:

- Delegate First Name*
- Delegate Last Name*
- Delegate Email Address*
- Confirm Delegate E mail Address*

6. Accept the terms and conditions*

7. Click on the "Add" button.

- Delegate will receive an email with access to CURES 2.0 and their associated parent name (that added delegate)

Patient Activity Report

The Patient Activity Search tab allows the user to search for patients on whom to view and export Patient Activity reports.

The following rules will be implemented on the Patient Activity Search tab:

- The system will allow partial search on First Name, Last Name, and Address fields.
- Prescribers and Dispensers will be required to enter Date of Birth as one of the search criteria.
- Unless the user selects a search mode of "Exact Match," the system will use Metaphone to return similar records based on first and last name.

The Patient Results Tab allows the user to view their search criteria and display desired Patient Details.

The Patient Activity Details tab allows the user to view patient activity for all patients selected on the Search tab. This tab also allows the user to download the patient activity records shown on the page to Excel (to save as .csv, .xls, or PDF) and generate a standard (formal) Patient Activity Report in PDF format.

Patient Load Saved Search

Once the user has saved a search, it can be run in the future by selecting the title of the saved search on the Patient Activity Search tab. Please note that saved searches that include a date range may become invalid if the start or end date falls outside of the allowed timeframe for searches.

To load a saved search:

1. On the Patient Activity Search tab, select a saved search from the Load Saved Search drop down list.
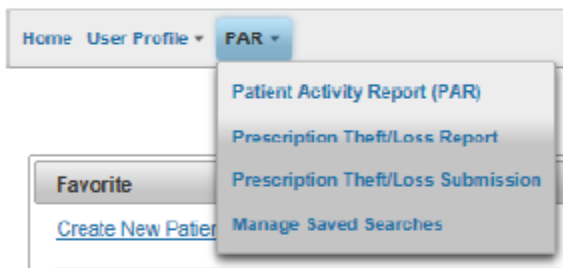

2. Search criteria will be populated with the selected saved search. Click the Search button to run the search.

Patient Search – Prescribers & Dispensers

For Prescriber, Dispenser, and Delegate users, CURES records can be searched up to 12 months using the date range option.

To search for patients:

1. From the Global Navigation Menu, select "PAR."

2. Select Patient Activity Report (PAR) from the drop down list.

3. Enter the following search criteria:

   o Last Name* (Last Name or First Name is required)
   o First Name* (Last Name or First Name is required)
   o DOB* (Date of Birth in the following format: mm/dd/yyyy)
   o Gender
   o Address
   o City
   o State

     o Zip Code

4. Search by period (drop down list defaults to 36 months) or by date range.

     o Start and End Date (must be in the following format: mm/dd/yyyy)

5. Set the search mode to either Partial or Exact Match.

6. Select the Search button to view the results.

Patient Activity

Search	Details

Search Criteria

Note: First Name and/or Last Name and DOB are required

Load Saved Search:			
Last Name:		First Name:	
Date of Birth:		Gender:	
Address:		City:	
State:	Select One	Zip Code:	
Search Mode:	Partial Match	My Compacts Only:	

Search By Time

Search By: ◉ Time Period (Months) ◯ Date Range 12 ▾

[Search] [Clear]

Patient Search – Save Search

CURES 2.0 provides the ability for the user to save search criteria for patient searches and access saved searches on the Manage Saved Searches page.

To save a search:

1. On the Patient Activity Search tab, enter search criteria.

2. Click the Search button. Search criteria will display as read only.

3. Click the Save Search button.

4. A pop up will display with a text box field to title the saved search. Enter a title, then click the Save button.

Save Search   ✖

Title: [ ]

[Save] [Cancel]

APPENDIX

A. Full PHC Community Pharmacy Guidelines

B. CURES 2.0 Users Guide

C. PHC Formulary for Opioid Medication

D. Naloxone Access: A Practical Guideline for Pharmacists

E. Naloxone for Opioid Safety- A Provider's Guide to Prescribing Naloxone to Patients Who Use Opioids

F. PHC County Level Data
   Northeast Region
   Northwest Region
   Southeast Region
   Southwest Region

G. References

Community Pharmacy Guidelines

Introduction

Partnership HealthPlan is a County Organized Health System covering Medical and Mental Health Benefits for Medi-Cal beneficiaries in 14 counties in Northern California. Our mission is to help our members, and the communities we serve, be healthy. In this spirit, we have launched a community-wide initiative to promote safer use of opioid medications.

Why is this important? In the last decade, the death rate from opioid overdose has quadrupled, making opioid overdose as common a cause of death as motor vehicle accidents. For every overdose death, there are 130 people who have a long-term dependence on opioids and 825 non-medical users of opioids (see figure at end of this policy). These numbers originate in prescriptions for opioid pain medications written by health professionals, so health professionals must work together to reverse this trend.

Community pharmacies play a key role in helping prevent opioid overdoses, opioid-induced hyperalgesia, opioid diversion, and opioid addiction. They also have a recently-clarified legal responsibility to do so. PHC recommends that all community pharmacies develop policies and standards to fulfill this responsibility. Here are recommended components of this policy:

Recommendations

A. Every pharmacist working at a community pharmacy should have an account to be able to check CURES reports.

B. Each pharmacy should define the circumstances for checking the CURES report of a patient. Options include:
1. All patients with a prescription for a controlled drug
2. New prescriptions for a controlled drug
3. Patients with behavior suspicious for abuse or diversion. Examples include:
   a. Patient is paying cash for a medication when they have active insurance coverage.
   b. Patient has no active filling history at this pharmacy, but brings a prescription for a controlled medication.
   c. Patient brings in a prescription pad with multiple prescriptions, but only wants to pick up the narcotic.
   d. Patient has a prescription with an unusually high quantity of pain medications.
   e. Patient comes in with a prescription for narcotics on a weekend or at the end of the day when most doctors' offices are closed.
   f. Patient's doctor's office is not within reasonable distance of the pharmacy.
   g. Subject to professional judgment.
   h. Patient's home address is not within a reasonable distance from the pharmacy or the doctor's office.
   i. Patient looks nervous and tries to hurry the pharmacy staff.
   j. Patient is unable to provide a valid ID.
   k. Patient claims their prescription was stolen or lost.

        l.   Patient presents a story that sounds too suspicious to be true.

        m.   A significant number of customers appear with prescriptions from the same prescriber and for the same controlled medication.

        n.   Patient shows "unusual knowledge of controlled substances."

C.   Notify the patient's primary care clinician or primary prescriber when filling a controlled medication for a patient:

        1.   If the patient is picking up a prescription written by an Emergency Department clinician, a dental practice, or an out-of-area prescriber.

        2.   If the patient calls to request early refills.

        3.   If the medication prescribed is not indicated for the patient's diagnosis.

D.   Pharmacists should counsel patients picking up opioid prescriptions of the risk of tolerance, addiction, opioid induced hyperalgesia, and overdose.

E.   Pharmacists should request photo ID for patients picking up controlled medications from the pharmacy.

Other Guidelines for Safe Opioid Prescribing

Dental Guidelines

Emergency Room Guidelines

Primary Care & Specialist Prescribing Guidelines

Key Points from Other Guidelines

1.   Most experts world-wide advocate a maximum dose of 120 mg oral morphine equivalents daily (MED), to decrease the risk of overdose and opioid-induced hyperalgesia. This does not mean doses should be escalated to this point in all patients. Many are well-controlled at lower doses. PHC recommends this 120 mg MED limit be used as a community standard.

2.   Request a random toxicology screen performed at least once a year to detect prescribed and non-prescribed opioids and other controlled or illicit drugs.

3.   Require a signed medication use agreement with the prescriber or prescribing office, renewed yearly.

4.   Regularly check the CURES database in all patients being prescribed opioids, preferably each time a prescription is being authorized. At a minimum, the CURES database should be checked annually. If a finding on the CURES report is not consistent with the patient's history, PHC recommends contacting the relevant pharmacies to confirm the accuracy of the CURES report, as reporting errors do occur.

5.   Schedule at least three office visits yearly for chronic pain patients using opioids.

6.	Limit each opioid prescription to 28 days, writing this on the prescription (e.g. "must last 28 days"). The 28 day refill, scheduled for a Tuesday, Wednesday, or Thursday every 4 weeks, is a best practice, to avoid weekends, holidays, and Friday refills.

References

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Kahan M, Mailis-Gagnon A, Wilson L, and Srivastava A. Canadian Guideline for Safe and Effective Use of Opioids for Chronic Noncancer Pain: Clinical Summary for Family Physicians. The Official Journal of The College of Family Physicians of Canada. Vol 57, November 2011. Available at: http://www.cfp.ca/content/57/11/1257.full.pdf Accessibility Verified on November 05, 2013

Prescribe to Prevent: Prescribe Naloxone, Save a Life. Instructions for Healthcare Professionals: Prescribing Naloxone. Available at: http://www.prescribetoprevent.org/wp-content/uploads/2012/11/one-pager_12.pdf Accessibility Verified on November 05, 2013

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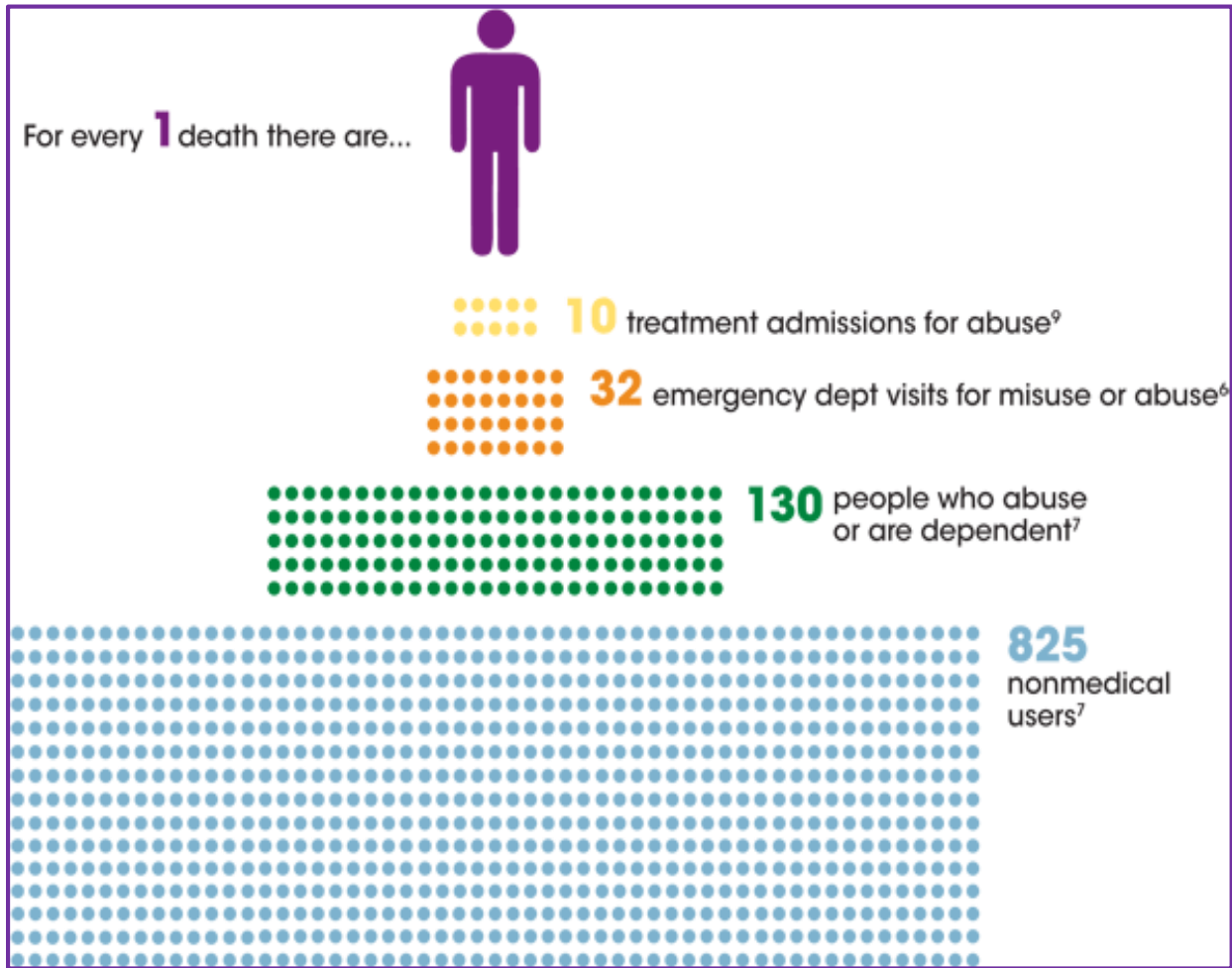http://www.painphysicianjournal.com/2009/may/2009;12;679-684.pdf

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http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf Accessibility Verified on November 05, 2013

Washington State Agency Medical Directors' Group (AMDG). Cautious Evidence-Based Opioid Prescribing. Available at: http://www.agencymeddirectors.wa.gov/Files/PrescGuide.pdf Accessibility Verified on November 05, 2013

For every **1** death there are...

10 treatment admissions for abuse[9]

32 emergency dept visits for misuse or abuse[6]

130 people who abuse or are dependent[7]

825 nonmedical users[7]

CDC statistics (2008)

Why we have shared responsibility to ensure safe opioid prescribing!

State of California
Department of Justice

Prescriber and Dispenser User Guide

CURES 2.0 Online Help

Table of Contents

Introduction

The Controlled Substance Utilization Review and Evaluation System (CURES) 2.0 is a database of Schedule II, III, and IV controlled substance prescriptions dispensed in California.

Access to CURES 2.0 is limited to licensed prescribers and pharmacists strictly for patients in their direct care; and regulatory board staff and law enforcement personnel for official oversight or investigatory purposes.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and confidentiality and disclosure provisions of California law cover the information contained in CURES 2.0.

CURES 2.0 is committed to the reduction of prescription drug abuse and diversion without affecting legitimate medical practice or patient care.

CURES 2.0 provides a vastly improved use interface, ease of use, robustness, and an analytics engine that provides prescribers and dispensers with critical information regarding at-risk prescription behavior.

System Navigation

The primary navigation in the CURES 2.0 system is a navigation bar across the top of each screen. In addition, the system makes use of drop down menus for the user to navigate between screens. This section also describes the standard web application fields and tools used in the design of the system.

Global Navigation

The primary method of navigation throughout CURES 2.0 is a global navigation bar that appears at the top of each page. The navigation bar is composed of drop down menus and links.

General Field and Tool Definitions

CURES 2.0 utilizes various types of data entry fields and formats. Fields default to blank unless otherwise specified in this User Interface Design document.

The following types of data entry fields are utilized within CURES 2.0. Each is applied in the design as appropriate to ensure accurate and simplified data entry.

Data Entry Fields

- Drop down fields – allow the user to select a single entry of a "drop down" list of values (LOV) by clicking on the entry they want to select. Drop down lists are alphabetically ordered and includes an "alpha jump" feature that allows the user to type a letter to jump to the first entry in the list of values that begins with that letter.

- Text fields – allow the user to enter data, which can be any character. Text fields that include formatting (such as the parentheses used around area codes for phone numbers) can be entered as numeric fields, and the system will automatically insert the additional formatting.

- Single check box fields – allow the user to select yes or no. Checking the box indicates a yes designation.

- Check box list fields – allow the user to select one or more than one item in a list (or leave it blank). Selection of more than one item in a check box list is determined to be an "and" selection.

- Radio buttons – allow the user to select one of two options.

General Formatting Rules

The following formatting rules are globally applied in the design of the CURES 2.0 page layouts:

- Field labels and content are left justified.

- Buttons that allow users to take action on one section of data on a page are left justified.

- Buttons that allow the user to take action on an entire page are center justified.

- Upon login, the user's name and role will display in the top right corner of each CURES 2.0 page in the format "First Name Last Name, Role."

- Dates can be typed into the date field or selected from a Date Picker calendar.

- Phone numbers will be displayed in the format (NNN) NNN-NNNN.

- Zip codes will be displayed in the format NNNNN.

Drop Down Menus

Drop down menus allow the user to navigate throughout the system. The menu options that appear in the navigation bar depend on the user's role. The navigation bar provides access to all screens accessible to the user grouped by the primary functions of the system. This approach allows the user to access any function on any CURES 2.0 page with minimal key strokes.

Tabs

Many functions within CURES 2.0 provide the ability to search for, view, add, and edit records. In these cases, the pages for these functions contain tabs to take any of these actions without leaving the page. This interface style is most common with web browsers, web applications, text editors and preference panes, allowing multiple panels to be contained in a single window.

Tables

On pages that provide the user with a view of multiple records, CURES 2.0 presents the records in tables. The tables display as many records as possible based on the available space on the page. If the number of records to be displayed exceeds the number of records that can be viewed at a time, scroll bars will be included to the right of the table to allow the user to view additional records. For tables that exceed the horizontal width of the screen, a horizontal scroll bar will be provided below the table to allow the user to view the additional fields.

Tables can be sorted by any column by clicking on a sort icon that appears in each column header. By clicking again, the user can modify the sort between ascending and descending order.

Users can view the details of a record by clicking on the table row. A single click displays the details on the same screen, when this option is available. A double click navigates the user to a detail screen, when this option is available.

Throughout CURES 2.0, when all fields related to a record can be displayed in a table format, the table itself will include action buttons to modify the record's editable fields within the table.

Editing Fields in CURES 2.0

Users can edit sections and fields within the screen, the following are editing functionalities. The 'Edit' functionality may come in the form of a button, an icon or a text box. Any of these may be displayed within CURES 2.0:

- Clicking the "Edit" Button. **Edit** Typically, when this button is selected, buttons change to the "Save" and "Cancel" buttons. **Save** **Cancel**

- Clicking on the pencil icon. ✏ This icon is displayed when the user can edit an individual field or a table row. When the pencil icon is selected, the field or row selected will become editable, with a checkmark to accept the edit or an 'x' to cancel the edit.

- Typing into a text box. [   ] The text box is presented whenever the user can enter text into a field.

Supporting Documents

Supporting documents are required for registration and other functions within CURES 2.0. The user can attach files where the "Choose" button is displayed:

+ Choose

Single File Upload – The user selects a file, which will immediately trigger the upload of the file to CURES 2.0. If the user uploads another file, the existing file is replaced with the latest upload. Files must be in PDF format and the file name must not exceed 50 characters. The

Multiple File Upload – The user may select up to ten files. The total size of all files must not exceed 10 MB. Files must be in PDF format and file names must not exceed 50 characters.

Supporting Document Description Field – This field allows the user to enter a text description for the uploaded file. The description must not exceed 250 characters.

To upload documents:

1. To attach a document, click Browse next to Supporting Documents section, or click Choose next to Attach File.

2. Browse for the file, select it, and click Open. There is a limit of 10 MB total for file uploads.

- If an unsupported file type is chosen, a message will display with the acceptable file type.

- To remove a selected file prior to uploading, click on the "X" button displayed next to the file name.

3. Once the selected files have been added, click the Upload button. (This button is displayed when multiple files are uploaded, not on single file upload.)

To remove all updated files:

1. To remove all uploaded files, click on the Delete button.

2. File(s) are now attached/uploaded to Supporting Documents section.

*Note: When the user selects the Clear button, all screen content is cleared out, including uploaded files.

Error Messages and Confirmations

To support usability and user experience, CURES 2.0 includes on-screen error messages and confirmation messages. Error messages will display on-screen for failed field validations. These will be displayed directly below the page name at the top of the page, above any tabs. Failed field validations prevent the user from continuing with the attempted action (for example, saving a record or submitting a query). Confirmation messages (for example, leaving a page with unsaved changes) will appear as pop-up messages that require the user to take action using buttons in order to return to the page that generated the message.

CURES 2.0 Screens

First Time Login

Upon logging in for the first time to CURES 2.0, the user must update their user profile and agree to CURES 2.0 Terms and Conditions before proceeding to the Home Page (Dashboard).

To complete the first time login process:

1. Log in to CURES 2.0. The system automatically navigates to the User Profile page.

2. Review your user profile, complete additional required fields, and agree to the Terms and Conditions.

3. Click the "Update" button. The system automatically navigates to the Home Page.

Dashboard/Home Page

The Home Page is the landing page for all users upon login to CURES 2.0. It includes the following:

- Saved searches and searches initiated by delegates

- Advisories and bulletins from DOJ regarding the CURES Program or CURES 2.0 application

- A link to CURES 2.0 statistics and data trends

- For prescribers, user messages and patient alerts

User Profile – Prescriber and Dispenser Users

CURES 2.0 stores user profile information and provides the user with the ability to maintain personal information on the User Profile page. This page is pre-populated with information provided by the user during registration.

Instructions:

1. From the Global Navigation Menu, select "User Profile."

1. From the drop down list, select "Profile."

2. On the User Profile page, edit the user profile information by clicking the "Edit" Button:

   - Name and ID Section
   - Address Section

▼ Address								
Note: The Primary Address is Required. All fields with (*) are required **Please enter physical addresses only. No post office boxes**								
Primary	Business Name	Address *	Address Line2	Zip Code *	State	City	County	
Y		1 Big Time Road		91127	CA	Hugeville	Alameda	✎
								✎
								✎

▼ Address								
Note: The Primary Address is Required. All fields with (*) are required **Please enter physical addresses only. No post office boxes**								
Primary	Business Name	Address *	Address Line2	Zip Code *	State	City	County	
Y		1 Big Time Road		91127	CA	Hugeville	Alameda	✔ ✗
								✎
								✎

   - DEA Section (User may add up to 9 additional DEA numbers.)
   - Email Section
   - Delegations Section

Account Renewal

All CURES 2.0 users are required to renew their account on an annual basis. Users receive renewal notifications on the renewal date and thirty days after the user's one year renewal date.

Delegate Management – Adding a Delegate

Delegates are CURES 2.0 users who have the authority only to initiate PAR Requests for a "parent" prescriber or dispenser user. (No other functionality is accessible to the Delegate user.) The CURES 2.0 Delegate Registration Page allows users to create delegates within CURES 2.0. This process for delegates applies only to Prescriber and Dispenser Roles.

Delegate Registration is managed by a Prescriber or Dispenser or "Parent" CURES 2.0 users. From their own User Profile, Prescribers and Dispensers can view, add and remove Delegates.

The following rules apply to delegate registration and the delegate's access to CURES 2.0:

- A delegate can be associated with more than one prescriber or dispenser.

- A delegate must be associated with at least one prescriber or dispenser in order to initiate a PAR query.

- If a delegate is associated with more than one prescriber or dispenser, and one parent unlinks the delegate, the delegate will still have access to CURES 2.0 through the remaining associations.

- When a delegate account is created and associated with a new parent prescriber or dispenser, a notification will be sent to the parent user to indicate that the account has been created. A notification will also be sent to the delegate with login information.

- When an existing delegate account is associated with a new parent prescriber or dispenser, a notification will be sent to the parent user to indicate that the account has been created. A notification will also be sent to the delegate with login information.

- The system will allow up to 50 delegates per parent.

- The system will allow up to 50 parents per delegate.

Instructions:

1. Select 'User Profile' from Global Navigation

2. Select the "Delegations" section

3. Click on the "Manage Delegates" button.

4. User will be navigated to the "Manage Delegates" Screen

5. Enter the required fields:

- Delegate First Name*

- Delegate Last Name*

- Delegate Email Address*

- Confirm Delegate E mail Address*

6. Accept the terms and conditions*

7. Click on the "Add" button.

- Delegate will receive an email with access to CURES 2.0 and their associated parent name (that added delegate)

- Delegate will also receive via email a system generated Username and a separate email with a one-time temporary password

Delegate Management – Removing a Delegate

At any time a "parent" user may remove one of their delegates. By doing so, the delegate will no longer be able to generate a PAR search on behalf of the parent.

To remove a delegate:

1. From the Global Navigation Menu, select "User Profile."

2. Select "Manage Delegates."

3. On the Delegates tab, click on the Delete button in the row of the delegate you want to remove. A confirmation message will display in a pop-up window.

4. Click the OK button below the confirmation message to remove the delegate.

Note: Delegate user accounts are deleted from CURES 2.0 when:

- the delegate has no parent Prescriber or Dispenser Users for more than 30 days.
- the delegate has not logged into CURES 2.0 for 12 months.

Patient Activity Report

The Patient Activity Search tab allows the user to search for patients on whom to view and export Patient Activity reports.

The following rules will be implemented on the Patient Activity Search tab:

- The system will allow partial search on First Name, Last Name, and Address fields.
- Prescribers and Dispensers will be required to enter Date of Birth as one of the search criteria.
- Unless the user selects a search mode of "Exact Match," the system will use Metaphone to return similar records based on first and last name.

The Patient Results Tab allows the user to view their search criteria and display desired Patient Details.

The Patient Activity Details tab allows the user to view patient activity for all patients selected on the Search tab. This tab also allows the user to download the patient activity records shown on the page to Excel (to save as .csv, .xls, or PDF) and generate a standard (formal) Patient Activity Report in PDF format.

Patient Load Saved Search

Once the user has saved a search, it can be run in the future by selecting the title of the saved search on the Patient Activity Search tab. Please note that saved searches that include a date range may become invalid if the start or end date falls outside of the allowed timeframe for searches.

To load a saved search:

1. On the Patient Activity Search tab, select a saved search from the Load Saved Search drop down list.
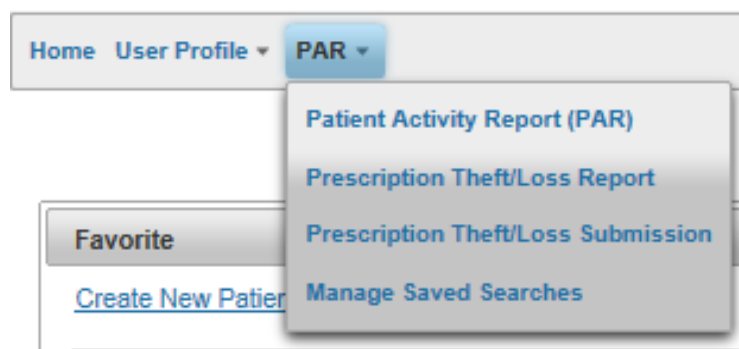

2. Search criteria will be populated with the selected saved search. Click the Search button to run the search.

Patient Search – Prescribers & Dispensers

For Prescriber, Dispenser, and Delegate users, CURES records can be searched up to 12 months using the date range option.

To search for patients:

1. From the Global Navigation Menu, select "PAR."

2. Select Patient Activity Report (PAR) from the drop down list.

3. Enter the following search criteria:

   o Last Name* (Last Name or First Name is required)

   o First Name* (Last Name or First Name is required)

   o DOB* (Date of Birth in the following format: mm/dd/yyyy)

   o Gender

   o Address

   o City

   o State

- o Zip Code

4. Search by period (drop down list defaults to 36 months) or by date range.

   - o Start and End Date (must be in the following format: mm/dd/yyyy)

5. Set the search mode to either Partial or Exact Match.

6. Select the Search button to view the results.

Patient Activity

Search	Details

Search Criteria

Note: First Name and/or Last Name and DOB are required

Load Saved Search: [▾]

Last Name:	[ ]	First Name:	[ ]
Date of Birth:	[ ] 🗓	Gender:	[▾]
Address:	[ ]	City:	[ ]
State:	[Select One ▾]	Zip Code:	[ ]
Search Mode:	[Partial Match ▾]	My Compacts Only:	[ ]

Search By Time

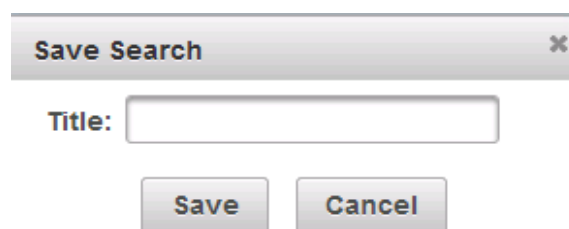Search By: ⦿ Time Period (Months) ◯ Date Range   [12 ▾]

[Search]   [Clear]

Patient Search – Save Search

CURES 2.0 provides the ability for the user to save search criteria for patient searches and access saved searches on the Manage Saved Searches page.

To save a search:

1. On the Patient Activity Search tab, enter search criteria.

2. Click the Search button. Search criteria will display as read only.

3. Click the Save Search button.

4. A pop up will display with a text box field to title the saved search. Enter a title, then click the Save button.

Patient Results

Once the user searches for patient records, the results are displayed in a table below the search criteria. A selection check-box displays on every row.

To view and select patient search results:

1. When search results are displayed, select the boxes to view details by clicking the "View Details" button.

2. Revise search criteria by clicking the Revise Search button or save search criteria by clicking the Save Search button. Revising the search will navigate you back to the search screen. (More information on saving searches is provided in the Manage Saved Searches section of this document.)

3. Select the View Details button to navigate to the Details tab.

Patient Details – Prescribers and Dispensers

The prescription activity history of each selected patient will display on the Details tab. From this page, the user can download the displayed patient activity records or generate Patient Activity reports with or without the DOJ certified cover letter.

To download patient details:

1. Click the Download PAR button to create an Excel spreadsheet of the displayed records. (The Excel spreadsheet can then be saved as .csv, .xls, or PDF.)
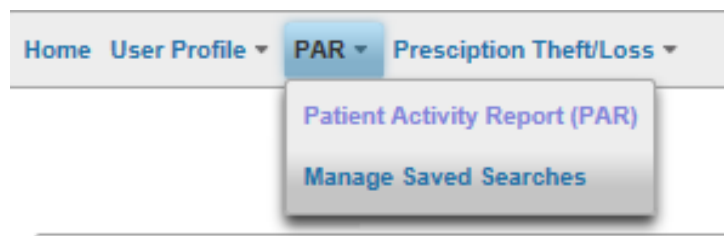
To generate a PAR:

1. Click the Print PAR button to create a PDF version of the PAR.

Manage Saved Searches

To view and manage saved searches:

1. From the Global Navigation Menu, select "PAR."

2. Select "Manage Saved Searches" from the drop down menu.

3. From the Manage Saved Searches page, select the saved search row to view details.

Compacts and Messaging – Prescriber and Dispenser

CURES 2.0 provides the ability for the prescriber user to set a compact with a patient through the Patient Activity Details tab. When a compact already exists, the user can view prescribers and compact information associated with a patient record. This page also provides prescriber and dispenser users with the ability to send a message to other CURES 2.0 users who have prescribed to the patient within the timeframe used for the patient activity search.

To set a compact:

1. From the Patient Activity Search tab, search for a patient, select the patient from the search results table, and click the View Details button.

2. Click the Compact & Messaging link for the patient in the carousel. The system navigates to the Compact and Messaging tab.

3. Click the Set Compact check-box (to select it). Your name, email address, and phone number will display in the Compact Details section of the page.

To remove a compact you have set:

1. From the Patient Activity Search tab, search for a patient, select the patient from the search results table, and click the View Details button.

2. Click the Compact & Messaging link for the patient in the carousel. The system navigates to the Compact and Messaging tab.

3. Click the Set Compact check-box (to de-select it). Your name, email address, and phone number will be removed from the Compact Details section of the page.

To send a message to prescribers for the selected patient:

1. From the Patient Activity Search tab, search for a patient, select the patient from the search results table, and click the View Details button.

2. Click the Compact & Messaging link for the patient in the carousel. The system navigates to the Compact and Messaging tab.

3. In the Messages section of the Compact and Messaging tab, enter a message to send to all prescribers listed in the Prescribers for Their Patient table.

4. Click the Send Message button to send the message to the prescribers.

The following rules apply for messages:

- All prescribers who are listed in the table will receive a Dashboard message if they have an active CURES 2.0 account.
- If the user who sends the message is not the prescriber who has a compact with the selected patient, the compact prescriber will also receive the Dashboard message.
- The message will contain the information displayed in the Messaging section, including the contact information for the user sending the message, the patient details, and the message text.

Report Prescription Theft/Loss

CURES 2.0 provides the ability for prescribers to directly report prescription pad theft or loss within the application.

To report a prescription pad theft/loss:

1. From the Global Navigation Menu, select "Prescription Theft/Loss."

2. Select "Report Prescription Theft/Loss" from the drop down menu.

CURES 2.0 Online Help
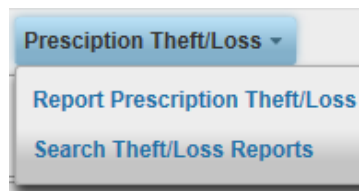
3. On the Prescription Theft/Loss Report Create tab, enter all required fields and any additional information needed to complete the report.
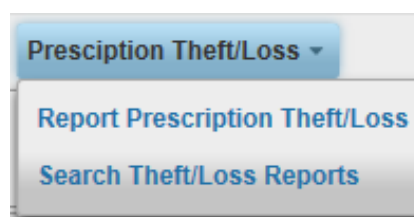

4. Click the Save button.

Search Prescription Theft/Loss Reports

CURES 2.0 provides the ability for prescribers to search for and view their prescription pad theft or loss reports.

To search for a prescription pad theft/loss report:

1. From the Global Navigation Menu, select "Prescription Theft/Loss."

2. Select "Search Theft/Loss Reports" from the drop down menu.

3. On the Prescription Theft/Loss Report Search tab, enter search criteria.

4. Click the Search button. The search criteria display as read-only, and the search results are displayed in a table below the search criteria.

5. Click on the row of the report you want to view. The Details tab will open and the report details will display.

Prescription Theft/Loss Report Details

Theft/loss reports are editable to the prescriber who submitted the report and to DOJ users. Other users who have the ability to view the report details will only see a read-only version of the page.

To view details of a prescription pad theft/loss report:

1. From the Search Prescription Theft/Loss page, click on the row of the report you want to view.

2. The Prescription Theft/Loss Details tab will open and the report details will display.

To edit details of a prescription pad theft/loss report:

1. From the Search Prescription Theft/Loss page, click on the row of the report you want to view.

2. The Prescription Theft/Loss Details tab will open and the report details will display.

3. Edit the record as needed.

4. Click the Save button to save the updated record.

Opioid Quantity Limit/Restriction Table

GENERIC	STRENGTH	DOSAGE FORM	MAX QTY PER 1 DAY	MAX QTY PER 30 DAYS
MORPHINE SULFATE	100 MG	TABLET ER	NF	NF
MORPHINE SULFATE	200 MG	TABLET ER	NF	NF
METHADONE HCL	5 MG/5 ML	SOLUTION	NF	NF
METHADONE HCL	10 MG/5 ML	SOLUTION	NF	NF
METHADONE HCL	10 MG/ML	ORAL CONC	NF	NF
METHADONE HCL	40 MG	TABLET SOL	NF	NF
OXYCODONE HCL/ASPIRIN	4.8355-325	TABLET	NF	NF
HYDROMORPHONE HCL	2MG	TABLET	15	450
HYDROMORPHONE HCL	4 MG	TABLET	7	210
HYDROMORPHONE HCL	8 MG	TABLET	3	90
LEVORPHANOL TARTRATE	2 MG	TABLET	2	60
METHADONE HCL	10 MG	TABLET	NF	NF
METHADONE HCL	5 MG	TABLET	3	90
MORPHINE SULFATE	10 MG/5 ML	SOLUTION	60 ML	1800 ML
MORPHINE SULFATE	20 MG/5 ML	SOLUTION	30 ML	90 ML
MORPHINE SULFATE	100 MG/5 ML	SOLUTION	6 ML	180 ML
MORPHINE SULFATE	15 MG	TABLET	8	240
MORPHINE SULFATE	30 MG	TABLET	4	120
MORPHINE SULFATE	15 MG	TABLET ER	8	240
MORPHINE SULFATE	30 MG	TABLET ER	4	120
MORPHINE SULFATE	60 MG	TABLET ER	2	60
OXYCODONE HCL/ACETAMINOPHEN	5MG-325MG	TABLET	8	240
OXYCODONE-ACETAMINOPHEN	5 MG-500MG	TABLET	8	240
OXYCODONE HCL/ACETAMINOPHEN	5 MG-500MG	CAPSULE	8	240

Brand Name *Generic Name*	Therapeutic Class *Sub-class*	Dose/Strength	Status	Notes & Restrictions
Other Opioid Rx	**Analgesic Narcotic Agonists and Combinations** **Analgesic Narcotic Agonists**			

*Disclaimer: this table does not represent 100% of all prescription opioid medications. For a more complete list, please visit **http://www.partnershiphp.org/Providers/Pharmacy/Pages/Formularies.aspx**.

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NALOXONE ACCESS:
A Practical Guideline for Pharmacists
http://cpnp.org/guideline/naloxone

Background

Drug overdoses are occurring at an alarming rate in the United States. Most overdoses have been linked to opioid analgesics, which may have been obtained from community pharmacies. One potential solution is to offer take-home naloxone.

Patient Selection

Naloxone should be considered for all patients exposed to opioids regardless of the source. The risk of a potentially fatal opioid overdose is a hazard of the drug and the drug combinations that are used. This applies to those who take opioids for pain and to those who misuse them.

Additional overdose risk factors include the following:

- Concurrent use of benzodiazepines or alcohol[1,2]
- History of opioid addiction or other substance use disorder[3]
- Comorbid mental illness[3]
- Receiving prescriptions from multiple pharmacies and prescribers[4]
- Daily opioid doses exceeding 100 mg of morphine equivalents[3-6]
- Receiving a methadone prescription[7]
- Recent emergency medical care for opioid poisoning/intoxication/overdose[8]
- Recent release from incarceration/prison/jail[9]
- Recent discharge from opioid detox or abstinence-based program[10]
- Comorbid renal dysfunction, hepatic disease, or respiratory diagnoses (smoking/COPD/emphysema/asthma/sleep apnea/other)

Naloxone is a bystander-administered drug, and the request for naloxone may come from caregivers.

How It Is Supplied

Naloxone for take-home use can be supplied as an intramuscular (IM) injection or as an intranasal (IN) spray. Both formulations are effective. The nasal spray tends to be preferred by patients and caregivers, while the components of the IM kit are more readily available in pharmacies. There is also a recently available IM auto-injector, which is convenient to prescribe and dispense but costly.

Intranasal Spray

IN kits should contain: 2 naloxone 2 mg/2 ml prefilled syringes, 2 atomizers, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

Figure 1. Intranasal kit *Used with permission. San Francisco Department of Public Health. Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids. January 2015.*

Intramuscular Injection

IM kits should contain: 2 naloxone 0.4 mg/ml vials, 2 IM syringes, step-by-step instructions for responding to an opioid overdose, and directions for naloxone administration.

Figure 2. Intramuscular kit *Used with permission. San Francisco Department of Public Health. Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids. January 2015.*

IM auto-injector: commercially available as a twin pack with directions for administration included.

Prescribing and Dispensing

Intranasal

Naloxone 2 mg/2 ml prefilled syringe, 2 syringes

NDC No. 76329-3369-01

SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.

Atomizer No. 2

SIG: Use as directed for naloxone administration

Intramuscular

Naloxone 0.4 mg/ml single dose vial, 2 vials

NDC No. 00409-1215-01

SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.

Syringe 3 ml 25G ×1 inch No. 2

SIG: Use as directed for naloxone administration

Intramuscular Auto-injector

Naloxone 0.4 mg/0.4 ml

No. 1 twin pack

SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1.

Acquisition and Reimbursement

The single-dose vial, prefilled syringe, and IM syringes are available from pharmacy wholesale distributors. The atomizers for IN administration are available from medical supply vendors, and in some cases, can be purchased directly from the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

Table. Nasal Atomizer Vendor Contacts

Vendor	Item No.	Contact
Professional Hospital Supply	392322	707-429-2884
Cardinal	MAD 300	800-964-5227
Heathcare Logistics	17474	800-848-1633
Amazon	MAD 300	Amazon.com
American Medical	MAD 300	888-988-5350
Teleflex	MAD 300	919-544-8000

Medicaid, Medicare, and many private insurance companies will pay for naloxone. However, at present, health plans do not have a viable way to pay for the atomizer, which lacks any unique identifier, such as a NDC number.

To cover the cost of the atomizer, some pharmacies are charging patients directly. The cost is about $10 for 2. In other cases, the atomizers are included with the drug at no additional charge. New Mexico provides a reimbursement code for the entire kit, including the pharmacist's time.

Naloxone Storage Information

- Store naloxone in the original package at room temperature. Avoid light exposure.
- The shelf life of naloxone is generally 12 to 18 months. If stored properly, naloxone should be effective until at least the expiration date on the packaging.
- Do not insert naloxone into the prefilled syringe until ready to use. Once inserted it expires within 2 weeks.
- Monitor the expiration date on naloxone and replace before it expires. When there are no other alternatives, expired naloxone can be administered but may not be as effective.

Supporting Laws and Regulations

State laws to support naloxone access fall under three categories:

- Good Samaritan: Protects individuals who call for help at the scene of an overdose from being arrested for drug possession.
- Liability protection/third party administration: Protects both the prescriber and the bystander who may be administering the naloxone. It also allows bystanders to be prescribed naloxone for use on opioid overdose victims.
- Collaborative practice agreement: Allows pharmacists to prescribe naloxone to at-risk individuals. It may be done with individual physicians or on a statewide basis.

The Network for Public Health Law has an updated summary of state laws supporting access to naloxone.[11]

Examples of Successful State and Local Models

New Mexico: In 2001, New Mexico enacted legislation to protect third parties who administer naloxone to an overdose victim. This was followed by a Good Samaritan statute in 2007 and pharmacist prescribing in 2014. To obtain prescribing authority, pharmacists need to complete a 2-hour certification course every 2 years. The State Medicaid program pays for naloxone, the

atomizer, and the consultation time via a specific NDC number for the entire naloxone kit.

California: San Francisco's Department of Public Health expanded naloxone access by making the atomizer and education brochures available in primary care clinics. Naloxone was co-prescribed with opioid analgesics and picked up at community pharmacies. Patients were trained both at the primary care clinic and the community pharmacy. Pharmacist training and outreach was done by the Public Health Department. Pharmacists also make naloxone available to methadone and buprenorphine maintenance patients at a specialty mental health pharmacy run by the Department of Public Health under a collaborative practice agreement.

Rhode Island: All Walgreens and CVS Pharmacies in Rhode Island make IM and IN naloxone available without a prescription under a collaborative practice agreement. The pharmacy chains have secured atomizer access through their supply systems, and the collaborative drug therapy agreement is signed by one physician for the state. The University of Rhode Island offers continuing education training.[12]

Collaborative Practice Agreements
- New Mexico[13]
- Washington State[14]
- San Francisco Department of Public Health[15]
- Providers' Clinical Support System for Opioid Therapies (PCSS-O): Description of collaborative practice with focus on Rhode Island[16]

Frequently Asked Questions

What are signs of opioid overdose?
- Skin is pale and/or clammy to the touch.
- Body is limp.
- Fingernails or lips have a blue or purple cast.
- Patient is vomiting or making gurgling noises.
- Patient is unarousable.
- Breathing is very slow or stopped.

What is rescue breathing?
Rescue breathing involves essentially breathing for someone else. By providing rescue breathing during an opioid overdose, the rescuer can potentially prevent the patient from developing organ damage. See the patient information sheets for details on how to administer rescue breaths.

How quickly does naloxone work?
Naloxone works within 2 to 5 minutes, depending on how naloxone has been administered.

How long should a bystander remain with the overdose victim after naloxone has been administered?
Bystanders should remain with the overdose victim until help arrives. Naloxone only has a 30- to 90-minute duration of action. Patients who have overdosed on a long-acting opioid may initially respond and then succumb to overdose symptoms again. It is important to remain with the patient to continue to provide support and additional doses of naloxone (if required) until help arrives.

Is naloxone effective in treating other types of overdoses?
No, naloxone is only effective in reversing an opioid overdose. At times, it may be difficult to distinguish opioid overdose symptoms from other overdoses or illnesses. Therefore, it is important to immediately seek medical help.

What happens if you administer expired naloxone?
Naloxone's full efficacy cannot be guaranteed beyond the expiration date. However, in urgent situations without alternatives, it will not hurt the patient to administer expired naloxone and may provide some benefit.

Can the intranasal naloxone be assembled in advance?
The shelf life of the assembled prefilled syringe is only 2 weeks; therefore, it is recommended that the atomizer is attached to the syringe but the naloxone is not inserted until ready to administer.

Can naloxone be administered to pregnant women?
Yes, in an opioid overdose, naloxone can and should be administered to a pregnant woman. However, there is risk for opioid withdrawal.

For More Information
- www.prescribetoprevent.org
- Overdose rescue/naloxone long-format training. August 23, 2012[17]
- SAMHSA Opioid Overdose Prevention Toolkit[18]

Intranasal Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose
Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IN Naloxone
If you suspect someone is suffering from an opioid overdose:

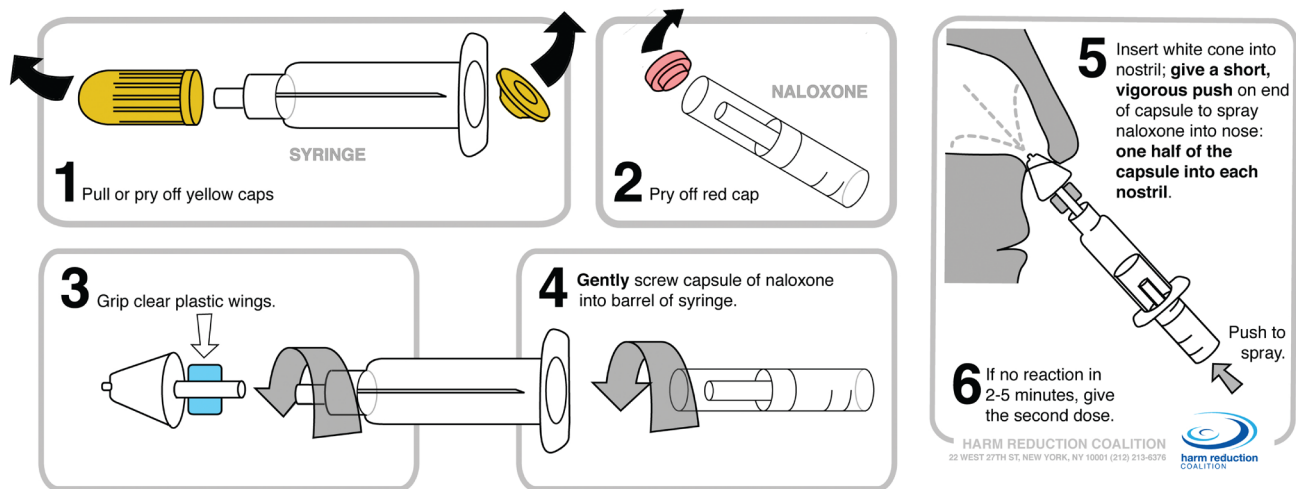**Step 1.** Call 911.

Step 2. Give naloxone.

1 Pull or pry off yellow caps

2 Pry off red cap

3 Grip clear plastic wings.

4 **Gently** screw capsule of naloxone into barrel of syringe.

5 Insert white cone into nostril; **give a short, vigorous push** on end of capsule to spray naloxone into nose: **one half of the capsule into each nostril**.

Push to spray.

6 If no reaction in 2-5 minutes, give the second dose.

HARM REDUCTION COALITION
22 WEST 27TH ST, NEW YORK, NY 10001 (212) 213-6376

harm reduction COALITION

Image by Harm Reduction Coalition. http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials/*. Updated October 2014.*

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow the 911 dispatcher's instructions or perform rescue breathing if comfortable doing so.

Rescue Breathing
The key components of rescue breathing include the following:

Step 1. Make sure nothing is in the individual's mouth.

Step 2. Tilt the head back, lift chin, and pinch nose shut.

Step 3. Give one slow breath every 5 seconds; chest should rise.

Side effects
Anxiety, sweating, nausea/vomiting, or shaking. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.

Intramuscular Naloxone Patient Information Sheet

Common brand names: Narcan

Uses: This medication is used to treat an opioid overdose. Naloxone works by reversing the effects of opioids.

Patients should be instructed to tell family/friends where naloxone is stored and how to administer it in case of an overdose.

Signs of an opioid overdose

Slow or shallow breathing, blue or gray lips and fingernails, pale and/or clammy skin, unable to wake up or respond.

How to Use IM Naloxone

If you suspect someone is suffering from an opioid overdose,

Step 1. Call 911.

Step 2. Give naloxone.

1 Remove cap from naloxone vial and uncover the needle	2 Insert needle through rubber plug with vial upside down	3 Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks)
	Pull back on plunger and take up 1 mL	

Images in Public Domain. San Francisco Department of Public Health. Naloxone for opioid safety: a provider's guide to prescribing naloxone to patients who use opioids. January 2015.

Step 3. Give a second dose of naloxone in 2 to 3 minutes if there is no response to the first dose.

Step 4. Follow 911 dispatcher's instructions or perform rescue breathing if comfortable doing so.

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Naloxone
for opioid safety

A provider's guide to prescribing
naloxone to patients who use opioids

Overdose is the leading cause of injury-related death in the U.S.

100 PEOPLE DIE FROM DRUG OVERDOSE EVERYDAY IN THE UNITED STATES.

FIGURE 1. DEATH BY LEADING CAUSE OF INJURY (PER 100,000)[1]

■ = Motor vehicle
■ = Drug poisoning

	1980	1995	2012
Motor vehicle	51,930	42,331	36,415
Drug poisoning	6,094	12,779	41,502
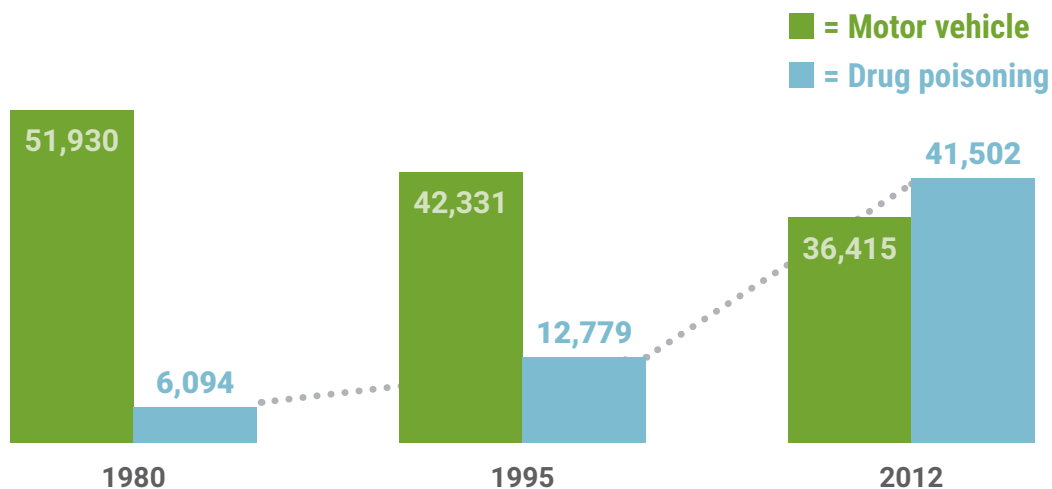
FIGURE 2. OVERDOSE DEATH BY DRUG TYPE[2]

Opioid analgesic
Cocaine
Heroin

Number of deaths

'99 '00 '01 '02 '03 '04 '05 '06 '07 '08 '09*
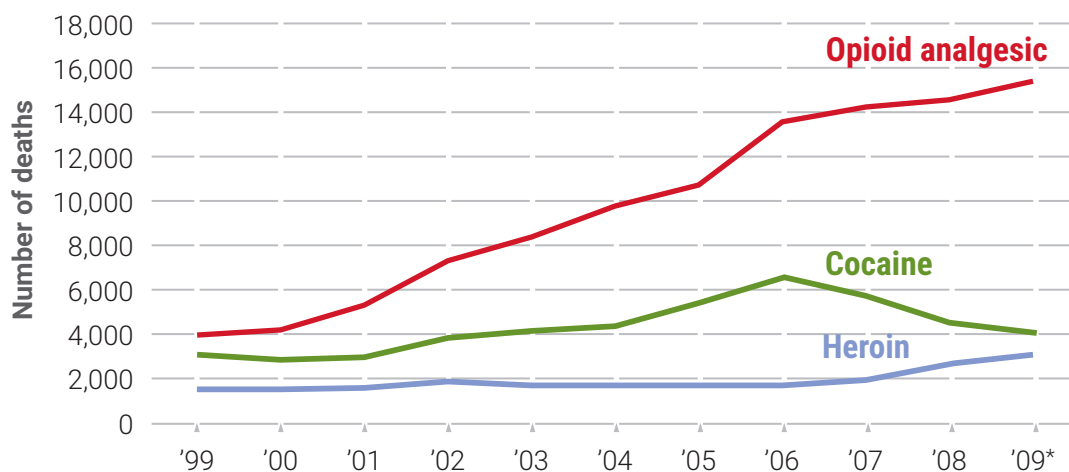
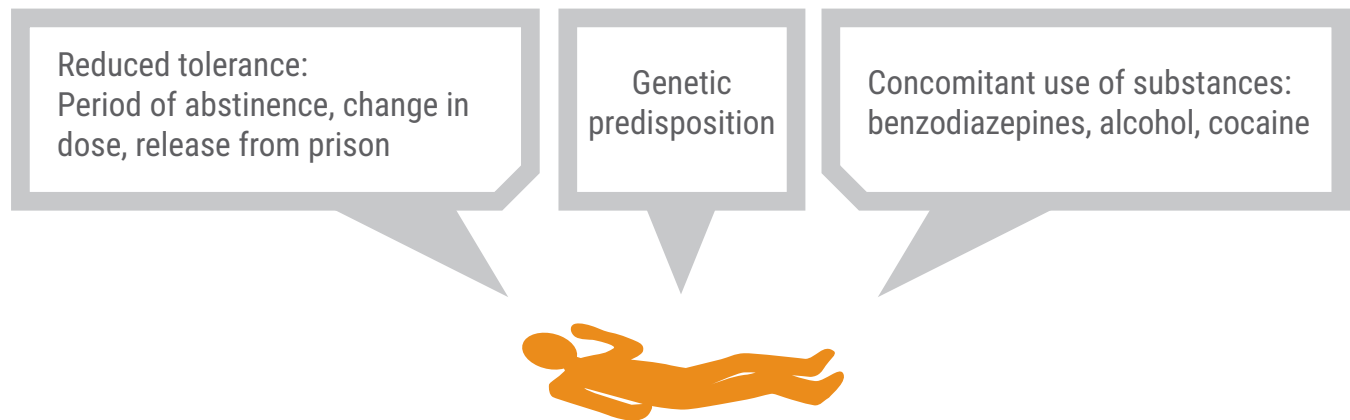**Opioid analgesics accounted for over 16,000 deaths in 2010.**

* The reported 2009 numbers are underestimates. Some overdose deaths were not included in the total for 2009 because of delayed reporting of the final cause of death.

Accidental opioid overdose is preventable

The main risk of death from an opioid overdose is prior overdose. A patient who has previously overdosed is 6 times more likely to overdose in the subsequent year.[3]

OTHER FACTORS THAT INCREASE RISK OF OVERDOSE:

> Reduced tolerance:
> Period of abstinence, change in dose, release from prison

> Genetic predisposition

> Concomitant use of substances: benzodiazepines, alcohol, cocaine

»» The majority of opioid overdose deaths involve at least one other drug, including benzodiazepines, cocaine or alcohol.[4]

FIGURE 3. OVERDOSE MORTALITY RATE BY WEEK SINCE PRISON RELEASE:
An example of overdose risk if opioids are discontinued and restarted [5]

Number of deaths per 100,000 person years vs. Weeks since release from prison
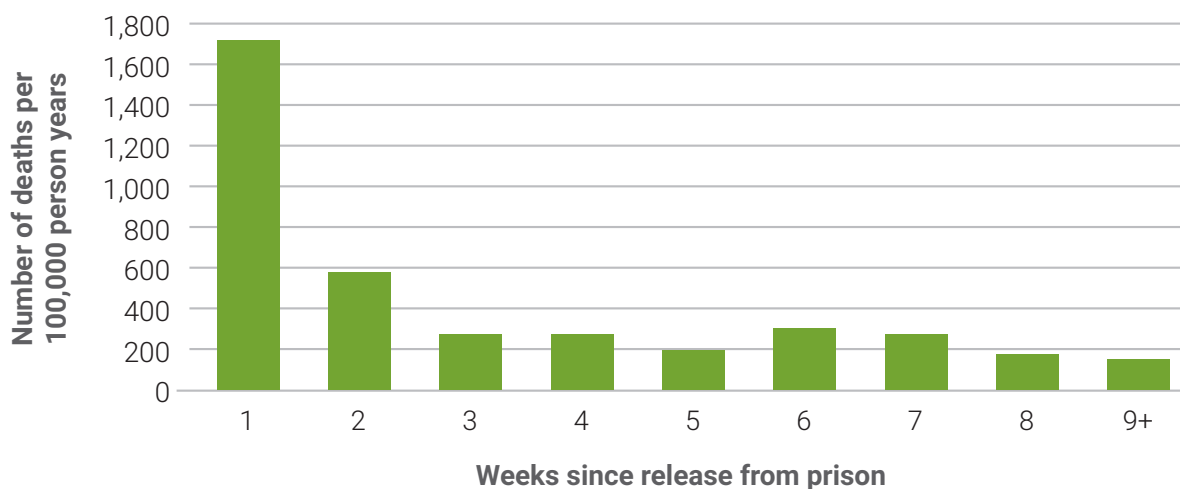
When a patient reduces or stops opioid use, there is an increased risk of overdose death if opioid use increases again.

Naloxone

- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids.

- Can be safely administered by laypersons via intramuscular or intranasal* routes, with virtually no side effects and no effect in the absence of opioids.

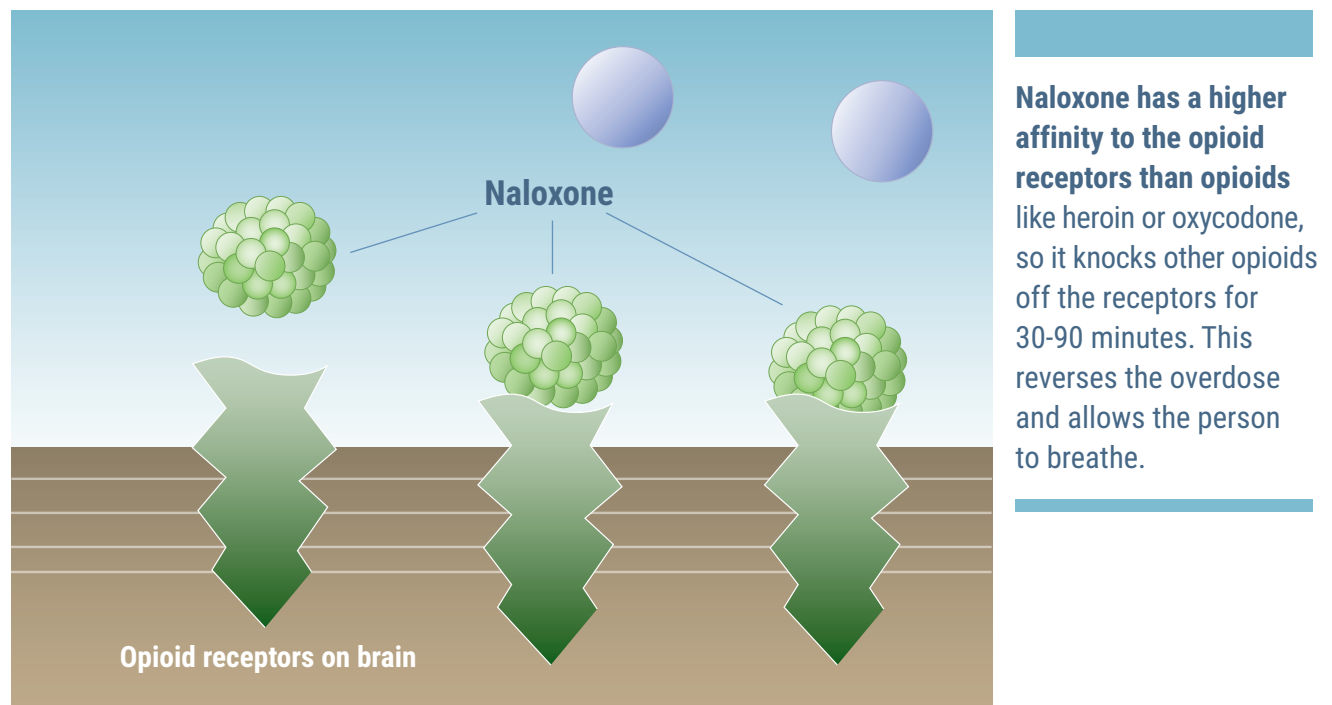- Effects last 30-90 minutes; usually sufficient for short-acting opioids but help should always be sought.

- While high doses of intravenous naloxone by paramedics have been associated with withdrawal symptoms, lower lay-administered doses produce much more mild symptomatology.[6]

FIGURE 4. NALOXONE MECHANISM OF ACTION[7]

Naloxone

Opioid receptors on brain

Naloxone has a higher affinity to the opioid receptors than opioids like heroin or oxycodone, so it knocks other opioids off the receptors for 30-90 minutes. This reverses the overdose and allows the person to breathe.

The American Medical Association has endorsed the distribution of naloxone to anyone at risk for having or witnessing an opioid overdose.[8]

There are 240 sites across 18 states that prescribe or distribute naloxone. Since 1996, naloxone has been distributed to over 53,000 people and more than 10,000 overdose reversals have been reported.[9]

* Intranasal is off-label but is supported by the American Medical Association and has become the preferred route for many emergency responders.[10, 11, 12]

Naloxone is effective

FIGURE 5. FATAL OPIOID OVERDOSE RATES BY NALOXONE IMPLEMENTATION IN MASSACHUSETTS[10]

In California, counties with naloxone programs had an overall slower rate in the growth in opioid overdose death compared to counties without naloxone programs.[13]
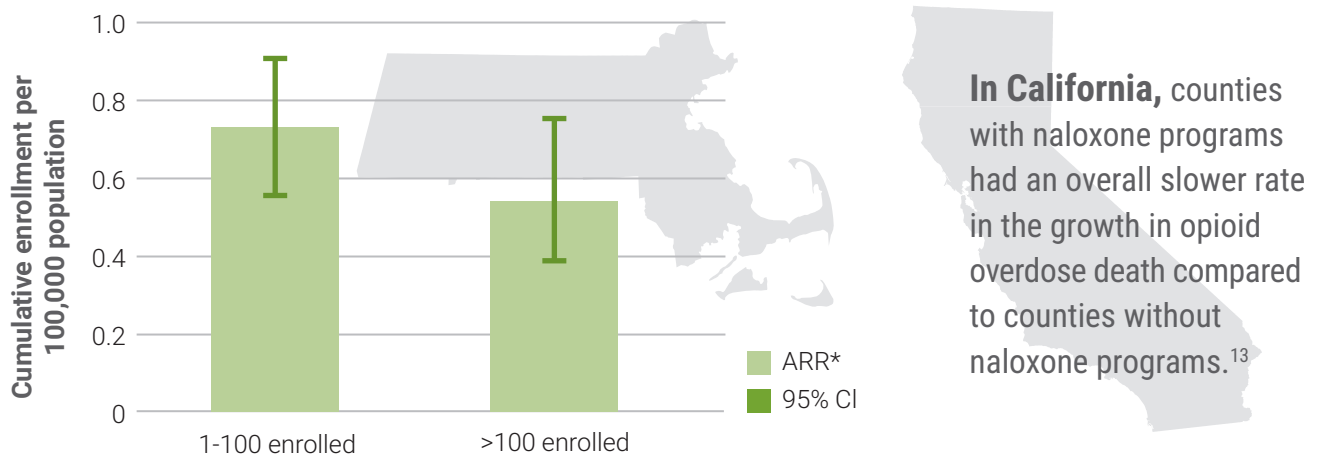
* Adjusted Rate Ratios (ARR) adjusted for population age <18, male; race/ethnicity; below poverty level; medically supervised inpatient withdrawal, methadone and buprenorphine treatment; prescriptions to doctor shoppers, year

...and cost-effective[14]

A manuscript in the *Annals of Internal Medicine* indicated that providing naloxone to heroin users is robustly cost–effective and possibly cost-saving. Investigators believe similar results apply to other opioid users.

Cost:

$421 per quality-adjusted life-year gained

Benefit:

164 naloxone scripts = 1 prevented death
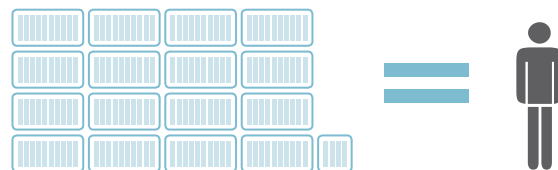
Emerging data suggests that providing naloxone may encourage patients to be safer with their opioid use. If this is the case, the intervention would be cost-saving and **36 prescriptions** would prevent one death.

Indications for naloxone prescription

CONSIDER OFFERING A NALOXONE PRESCRIPTION TO:

- All patients prescribed long-term opioids
- Anyone otherwise at risk of experiencing or witnessing an opioid overdose

WHY PRESCRIBE TO ALL PATIENTS ON LONG-TERM OPIOIDS?

It is difficult to predict which patients who take prescription opioids are at risk for overdose.

Many patients do not feel they are at risk for overdose. Prescribing to all patients on opioids will help patients understand naloxone is being prescribed for risky drugs, not risky patients.

About 40% of overdose deaths result from diverted medications.[15] Whether intentional or unintentional, diverted opioids are a serious risk. Co-prescribing naloxone increases the chance that the antidote will remain with the medication.

Potential behavioral impact

Being offered a naloxone prescription may lead to safer opioid use.

U.S. army base Fort Bragg in North Carolina averaged 8 overdoses per month. After initiating naloxone distribution, the overdose rate dropped to zero—with no reported naloxone use.[16]

> *"[W]hen I prescribe naloxone...there's that realization of how important this is and how serious this is in their eyes."* —US army Fort Bragg primary care provider

Selected San Francisco Health Network clinics began co-prescribing naloxone to patients on opioids in 2013.

> *"I had never really thought about [overdose] before…it was more so an eye opener for me to just look at my medications and actually start reading [about] the side effects, you know, and how long should I take them…I looked at different options, especially at my age."*
> —San Francisco patient[17]

Offering a naloxone prescription can increase communication, trust and openness between patients and providers.

> *"By being able to offer something concrete to protect patients from the danger of overdose, I am given an opening to discuss the potential harms of opioids in a non-judgmental way."*
> —San Francisco primary care provider[18]

How to educate patients on naloxone

Clinic staff can educate patients about naloxone. Education generally includes:

- When to administer naloxone

- How to administer naloxone (including demonstration)

- Informing patients to alert others about the medication, how to use it and where it's kept, as it is generally not self-administered

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Brochures remind patients and caregivers how to manage an overdose. Example brochures can be found at **www.prescribetoprevent.org**.
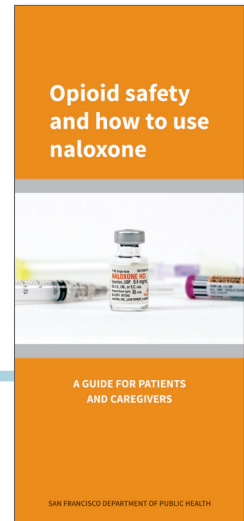
OPIOID SAFETY LANGUAGE

The word "overdose" has negative connotations and prescription opioid users may not relate to it.

Patients prescribed opioids (including high-risk persons with a history of overdose) reported their risk of "overdose" was 2 out of 10.[19]

1 **2** 3 4 5 6 7 8 9 10

Instead of using the word "overdose," consider using language like "accidental overdose," "bad reaction" or "opioid safety." You may also consider saying:

"Opioids can sometimes slow or even stop your breathing."

"Naloxone is the antidote to opioids—to be [sprayed in the nose/injected] if there is a bad reaction where you can't be woken up."

"Naloxone is for opioid medications like an epinephrine pen is for someone with an allergy."

State law encourages naloxone prescribing

Naloxone is NOT a controlled substance. **Any licensed healthcare provider can prescribe naloxone.** California State law provides additional protections to encourage naloxone prescribing and distribution:

PROVIDER AND PATIENT PROTECTIONS (CA AB635 effective 1/1/14)

- **Providers are encouraged to prescribe naloxone** to patients receiving a chronic opioid prescription.

- **Naloxone prescriptions also can be written directly to third party individuals** (caregivers, family members, friends, etc.) who are in a position to witness and assist a person at risk of an opioid overdose.

- **A licensed healthcare prescriber can issue a standing order** for the dispensing of naloxone by healthcare or community workers to individuals at risk of experiencing or witnessing an overdose.

- **Lay persons can possess and administer naloxone** to others during an overdose situation.

GOOD SAMARITAN PROTECTION (CA AB472 effective 9/17/12)

- **Witnesses of an overdose who seek medical help are provided legal protection** from arrest and prosecution for minor drug and alcohol violations.

PHARMACIST PROVISION OF NALOXONE (CA AB1535 effective 1/1/15*)

- **Pharmacists are allowed to directly prescribe and dispense naloxone** to patients at risk of experiencing or witnessing an opioid overdose.

* Pending pharmacy and medical board agreement on regulations.

Examples of how to prescribe naloxone

INJECTABLE

- Naloxone 0.4mg/1ml IM if overdose. Call 911. Repeat if necessary. #2
- IM syringes (3ml 25g 1" syringes are recommended) #2

INTRANASAL (OFF-LABEL)

- Naloxone 2mg/2ml prefilled syringe, spray ½ into each nostril if overdose. Call 911. Repeat if necessary. #2
- MAD (Mucosal Atomization Device) nasal adapter

Atomizer access is complicated. Select pharmacies now carry the atomizer, but most still have trouble accessing it. Insurers may require a TAR for reimbursement.

AUTO-INJECTOR

- Naloxone auto-injector 0.4mg #1 two pack, use PRN for suspected opioid overdose

SBIRT CODES COVER TRAINING (per 15 min intervals)

MediCare: G0396	
MediCal: H0050	
Commercial: CPT99408	

Please copy or scan and send to your local pharmacist.

Pharmacy access

All pharmacies can fill naloxone prescriptions, but naloxone is new for many pharmacists so some may not know how. If a pharmacist is unsure how to fill a naloxone prescription, the information outlined on this page may be helpful.

ORDERING:

- Injectable: **Hospira** NDC#00409-1215-01; **Mylan** NDC#67457-292-00
- Intranasal: NDC#76329-3369-01
- MAD (atomizer) nasal devices produced by Teleflex*
- Auto-injector: NDC#60842-030-01

BILLING:

- Naloxone is covered by MediCal (as a "carve-out" **so submit directly to FFS MediCal**— do NOT send a PA to the HMO plan), and many other plans
- The MAD does not have an NDC, therefore cannot be billed through usual pharmacy billing routes. Pharmacies may be willing to cover the cost of the MAD or patients may be requested to pay for the cost of the MAD, which is around $5 per atomizer.

COUNSELING:

- Instruct patients to administer if non-responsive from opioid use and how to assemble for administration.
- Include family/caregivers in patient counseling or instruct patients to train others.

> **SIDE EFFECTS:** Anxiety, sweating, nausea/vomiting or shaking. Talk to your doctor if these occur. This is not a complete list of possible side effects. If you notice other effects not listed, contact your doctor or pharmacist.
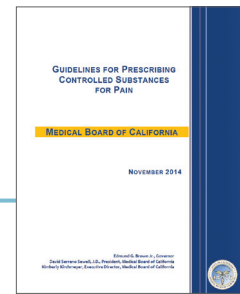
* Contact Michelle Geier, PharmD, with questions or concerns related to pharmacies, at (415) 503-4755 or michelle.geier@sfdph.org

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Resources

Medical Board of California: Guidelines for Prescribing Controlled Substances for Pain: **www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf**

California Society of Addiction Medicine: Naloxone resources for providers, naloxone legal status, webinars and trainings: **www.csam-asam.org/naloxone-resources**

Prescribe to Prevent: Clinic-based prescribing information and guidelines: **www.prescribetoprevent.org**
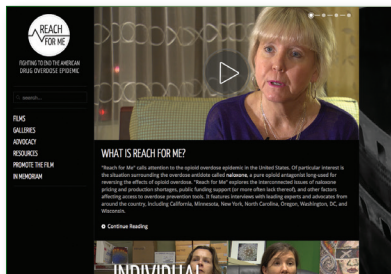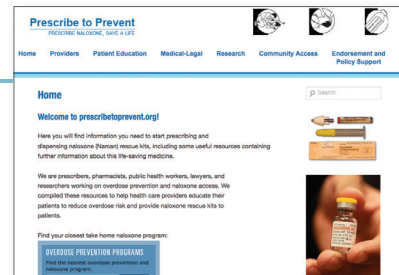
Reach for Me: Film and resource materials for advocates, families and providers: **www.reach4me.org**

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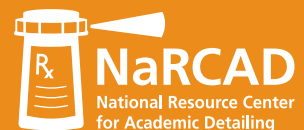
About this publication

This publication was produced by the San Francisco Department of Public Health. Support was provided by the National Resource Center for Academic Detailing (NaRCAD). No pharmaceutical company resources were used in the development of these materials and authors (Phillip Coffin MD, Assistant Clinical Professor of HIV/AIDS at University of California San Francisco, and Emily Behar MS) deny any financial conflicts of interest.

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

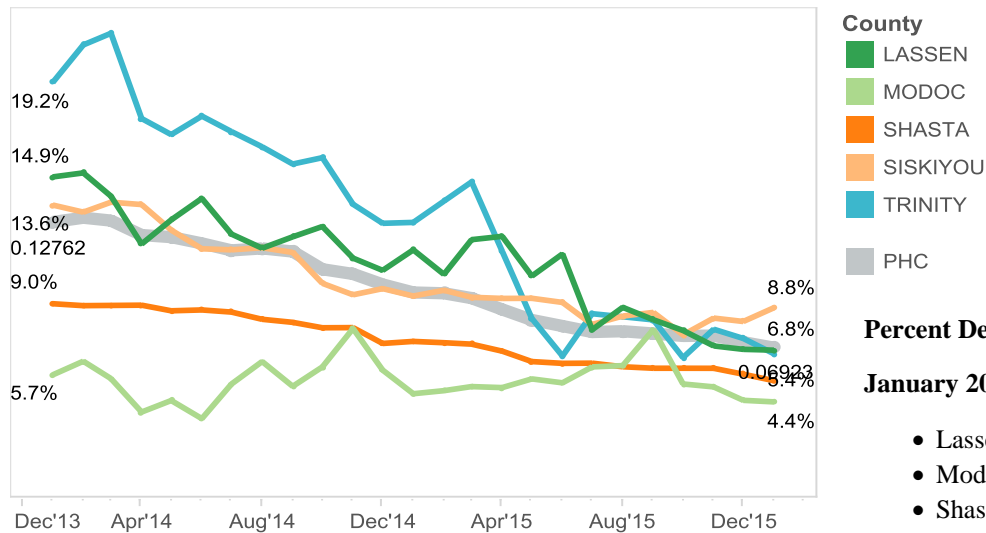**SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH**

NaRCAD
National Resource Center
for Academic Detailing

PHC COUNTY LEVEL DATA

Northeast Region

% Users on Unsafe Dose (>120 MED), Region: Northeast

County
- LASSEN
- MODOC
- SHASTA
- SISKIYOU
- TRINITY
- PHC

Chart y-axis values: 19.2%, 14.9%, 13.6%, 0.12762, 9.0%, 5.7%; right-side values: 8.8%, 6.8%, 0.06923, 5.4%, 4.4%

Chart x-axis: Dec'13, Apr'14, Aug'14, Dec'14, Apr'15, Aug'15, Dec'15
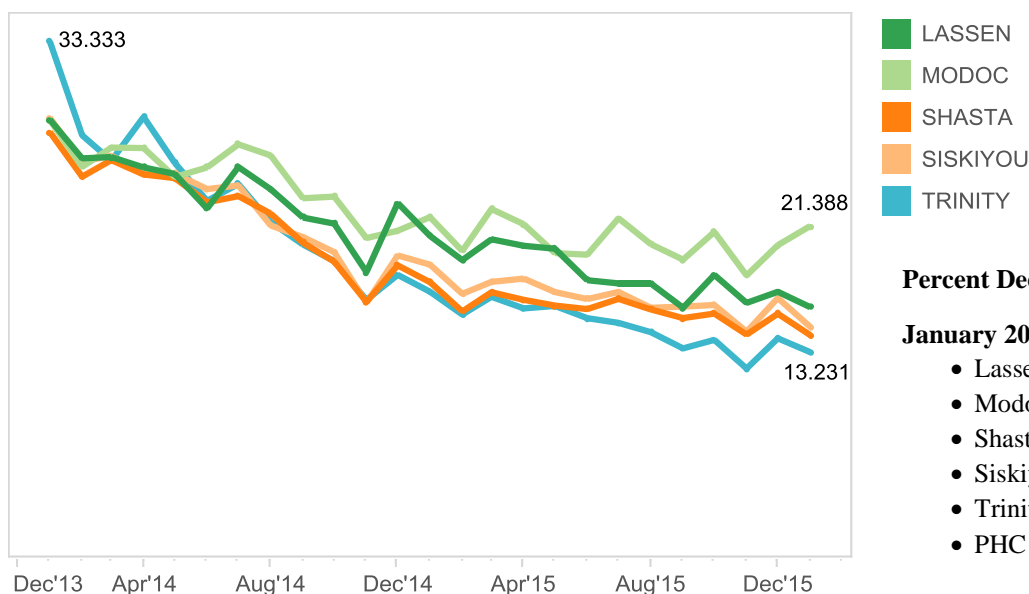
Percent Decrease % Unsafe Dose

January 2014 - January 2016

- Lassen - 54%
- Modoc - 23%
- Shasta - 40%
- Siskiyou - 35%
- Trinity - 66%
- PHC - 46%

The trends of sum of % High dose PHC and % High Dose for Latest Fill Month. For pane % High Dose : Color shows details about County. For pane Sum of % High dose PHC: Color shows details about Location. The data is filtered on Subregion Filter, Latest Fill and Date Filter. The Subregion Filter filter keeps True. The Latest Fill filter ranges from 1/1/2013 to 1/31/2016. The Date Filter filter keeps True.

Opiate Fills P100MPM, Region:Northeast

- LASSEN
- MODOC
- SHASTA
- SISKIYOU
- TRINITY

Chart values: 33.333, 21.388, 13.231

Chart x-axis: Dec'13, Apr'14, Aug'14, Dec'14, Apr'15, Aug'15, Dec'15

Percent Decrease Total Rx P100MPM
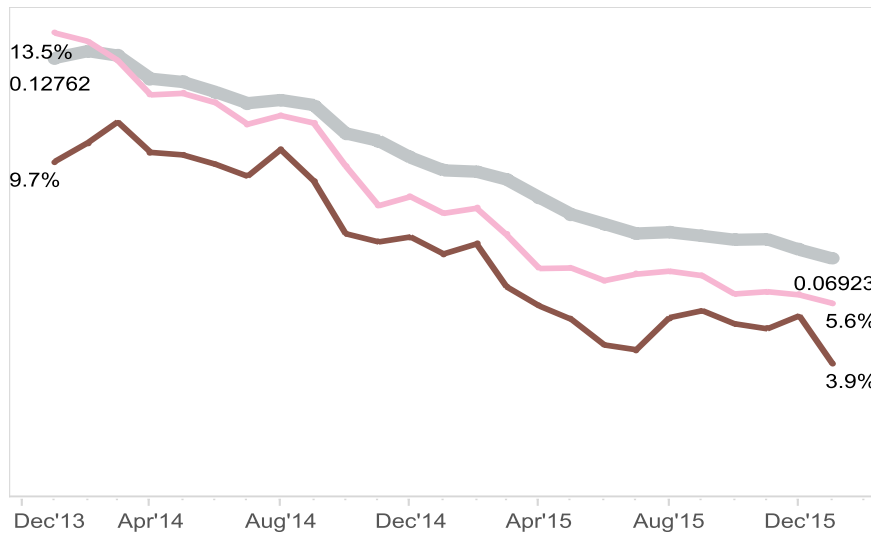
January 2014 - January 2016
- Lassen - 43%
- Modoc - 24%
- Shasta - 48%
- Siskiyou - 48%
- Trinity - 60%
- PHC - 51%

The trend of Rx P100MPM for fill_dt Month. Color shows details about County. The data is filtered on Sub-Region Filter and Date Filter. The Sub-Region Filter filter keeps True. The Date Filter filter keeps True.

Northwest Region

% Users on Unsafe Dose (>120 MED), Region: Northwest

13.5%
0.12762

9.7%

0.06923

5.6%

3.9%

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15

County
- DEL NORTE
- HUMBOLDT
- PHC

Percent Decrease % Unsafe Dose

January 2014 - January 2016
- Del Norte - 60%
- Humboldt - 59%
- PHC - 46%

The trends of sum of % High dose PHC and % High Dose for Latest Fill Month. For pane % High Dose : Color shows details about County. For pane Sum of % High dose PHC: Color shows details about Location. The data is filtered on Subregion Filter, Latest Fill and Date Filter. The Subregion Filter filter keeps True. The Latest Fill filter ranges from 1/1/2013 to 1/31/2016. The Date Filter filter keeps True.

Opiate Fills P100MPM, Region:Northwest

31.199

25.294

17.906

11.597

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15
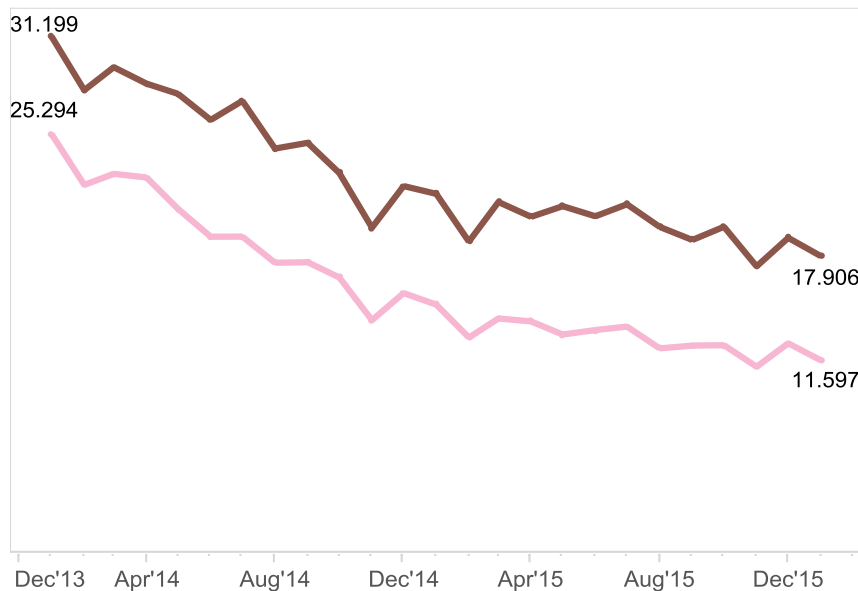
- DEL NORTE
- HUMBOLDT

Percent Decrease Total Rx P100MPM
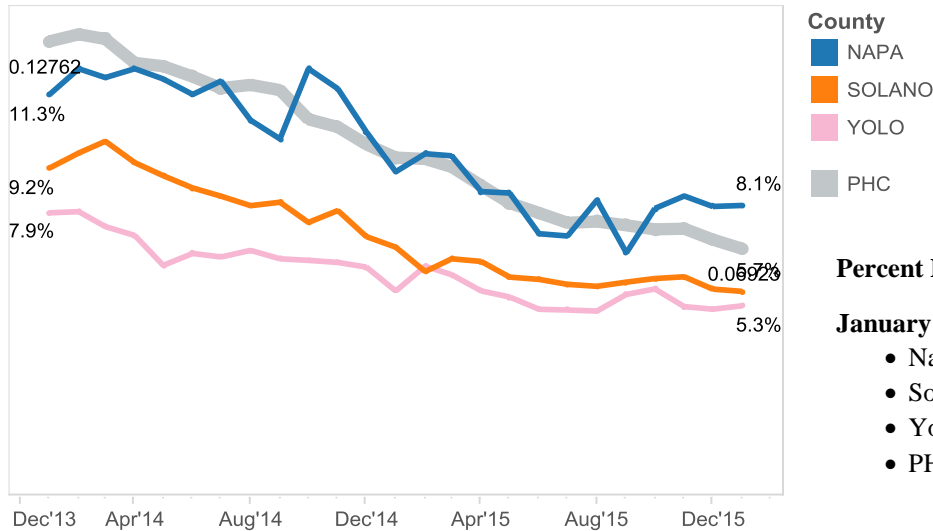
January 2014 - January 2016
- Del Norte - 43%
- Humboldt - 54%
- PHC - 51%

The trend of Rx P100MPM for fill_dt Month. Color shows details about County. The data is filtered on Sub-Region Filter and Date Filter. The Sub-Region Filter filter keeps True. The Date Filter filter keeps True.

Southeast Region

% Users on Unsafe Dose (>120 MED), Region: Southeast

County
- NAPA
- SOLANO
- YOLO
- PHC

0.12762
11.3%
9.2%
7.9%

8.1%
0.05720
5.3%

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15

The trends of sum of % High dose PHC and % High Dose for Latest Fill Month. For pane % High Dose : Color shows details about County. For pane Sum of % High dose PHC: Color shows details about Location. The data is filtered on Subregion Filter, Latest Fill and Date Filter. The Subregion Filter filter keeps True. The Latest Fill filter ranges from 1/1/2013 to 1/31/2016. The Date Filter filter keeps True.

Percent Decrease % Unsafe Dose

January 2014 - January 2016
- Napa - 28%
- Solano - 38%
- Yolo - 33%
- PHC - 46%

Opiate Fills P100MPM, Region:Southeast

- NAPA
- SOLANO
- YOLO

19.368
15.516

9.990
8.339
7.855

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15

The trend of Rx P100MPM for fill_dt Month. Color shows details about County. The data is filtered on Sub-Region Filter and Date Filter. The Sub-Region Filter filter keeps True. The Date Filter filter keeps True.
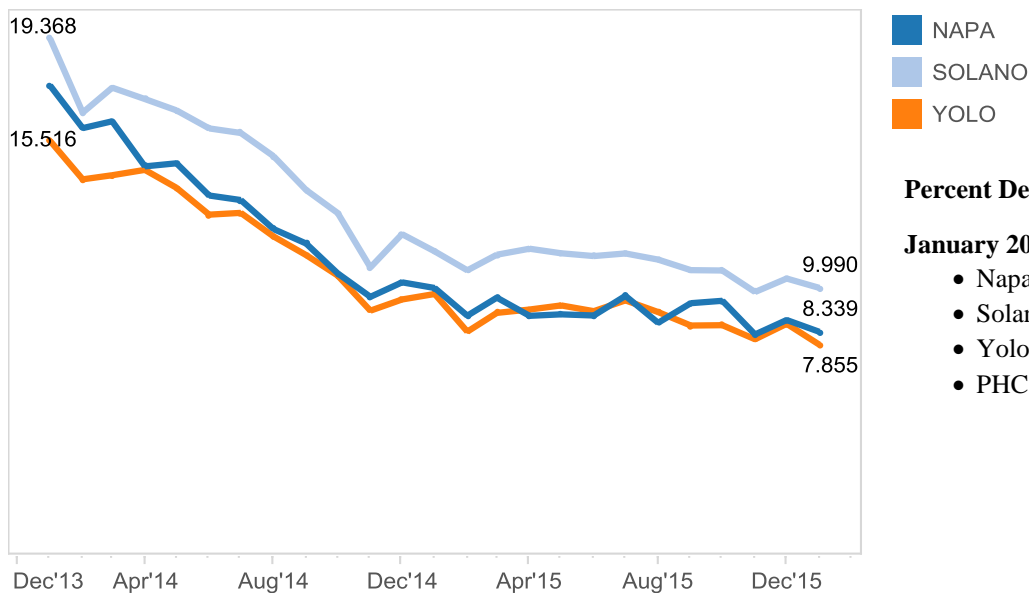
Percent Decrease Total Rx P100MPM

January 2014 - January 2016
- Napa - 53%
- Solano - 48 %
- Yolo - 49%
- PHC - 51%

Southwest Region

% Users on Unsafe Dose (>120 MED), Region: Southwest

23.7%
17.6%
17.3%
17.7%
0.12762

11.0%
10.5%
7.2%
6.9%
0.06923

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15

County
- LAKE
- MARIN
- MENDOCINO
- SONOMA
- PHC

Percent Decrease % Unsafe Dose

January 2014 - January 2016
- Lake - 59%
- Marin - 53%
- Mendocino -46%
- Sonoma - 39%
- PHC - 46%

The trends of sum of % High dose PHC and % High Dose for Latest Fill Month. For pane % High Dose : Color shows details about County. For pane Sum of % High dose PHC: Color shows details about Location. The data is filtered on Subregion Filter, Latest Fill and Date Filter. The Subregion Filter filter keeps True. The Latest Fill filter ranges from 1/1/2013 to 1/31/2016. The Date Filter filter keeps True.
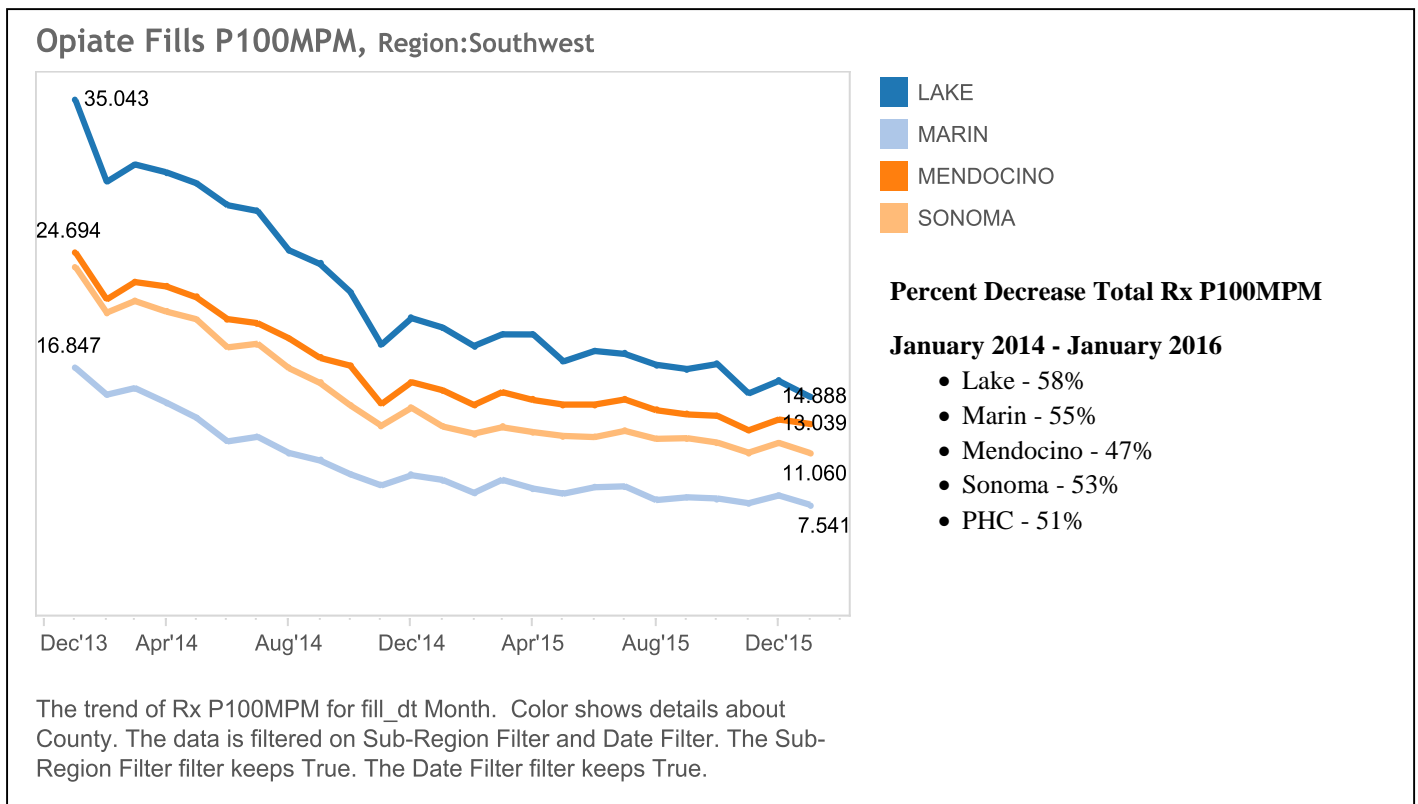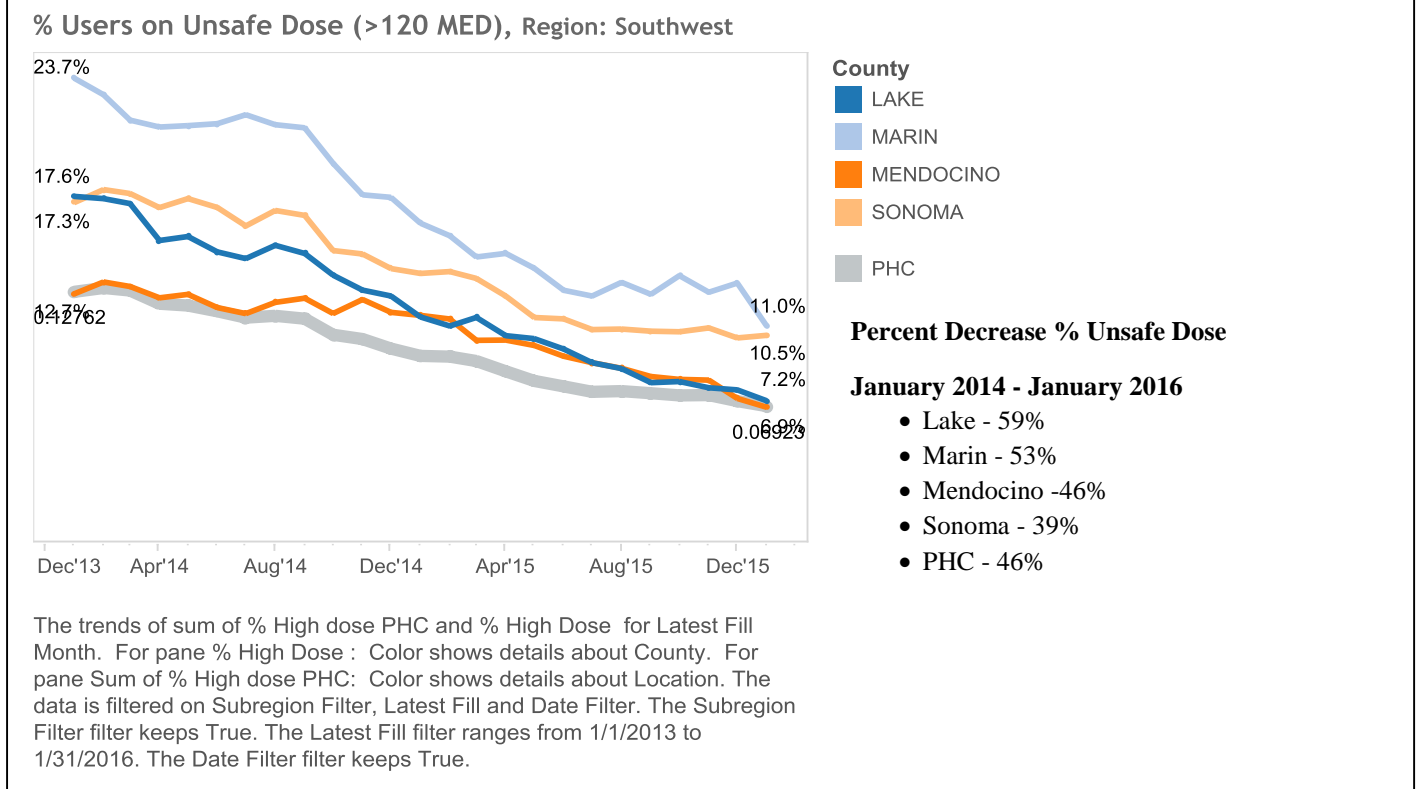
Opiate Fills P100MPM, Region:Southwest

35.043
24.694
16.847

14.888
13.039
11.060
7.541

Dec'13   Apr'14   Aug'14   Dec'14   Apr'15   Aug'15   Dec'15

- LAKE
- MARIN
- MENDOCINO
- SONOMA

Percent Decrease Total Rx P100MPM

January 2014 - January 2016
- Lake - 58%
- Marin - 55%
- Mendocino - 47%
- Sonoma - 53%
- PHC - 51%

The trend of Rx P100MPM for fill_dt Month. Color shows details about County. The data is filtered on Sub-Region Filter and Date Filter. The Sub-Region Filter filter keeps True. The Date Filter filter keeps True.

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Tips to help fight against opioid misuse, abuse, and diversion

U.S. Department of Justice, Drug Enforcement Administration. Don't Be Scammed By a Drug Abuser. Vol. 1, Issue 1. December 1999. http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm

CURES 2.0

State of California Department of Justice. CURES 2.0 Prescriber and Dispenser User Guide. https://oag.ca.gov/sites/all/files/agweb/pdfs/pdmp/cures-2.0-user-guide.pdf