PCSS TRAINING
PROVIDERS' CLINICAL SUPPORT SYSTEM
For Opioid Therapies

College of Psychiatric & Neurologic Pharmacists
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Putting Naloxone Into Action!

College of Psychiatric and Neurologic Pharmacists (CPNP)
August 13, 2015 at 8:00 p.m. Eastern

Target Audience

- The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.
- Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.
- This activity is designed for pharmacists and other health care professionals interested in expanding Overdose Education and Naloxone Distribution (OEND) at their practice site.

Planning Committee, Disclosures

The planners, managers, and faculty have nothing to disclose related to the content of this CE activity.

Off-Label Use: This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA (see faculty information and disclosures). The opinions expressed in the educational activity do not necessarily represent the views of CPNP and any educational partners. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings. Presentations will include discussion of off-label, experimental, and /or investigational use of drugs or devices: naloxone IV used for intranasal administration (off-label).

Disclaimer: Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications on dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

Faculty, Disclosures

(see contact emails following Resources list)

	Chris Stock, PharmD, BCPP	Jef Bratberg, PharmD, BCPS	Theo Pikoulas, PharmD, BCPP	James Gasper, PharmD, BCPP	Shannon Saldaña, MS, PharmD, BCPP
Affiliation	George E Wahlen VA Medical Center and University of Utah Salt Lake City, UT	University of Rhode Island College of Pharmacy Kingston, RI	Behavioral Health Pharmacy Programs Community Care of North Carolina Raleigh, NC	California Department of Health Care Services Sacramento, CA	Intermountain Healthcare Salt Lake City, UT
No relevant financial relationships to disclose.	X	X	X	X	X
Will discuss off-label use of intranasal naloxone	X	X	X	X	X

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Educational Objectives

At the conclusion of this activity participants should be able to:

1. Identify a model for overdose education and naloxone distribution (OEND) that is most applicable to their practice setting.
2. Summarize patient overdose education (OE) elements that will fit best in their practice setting.
3. Describe strategies to bill an insurance carrier for OEND in their practice setting.
4. Describe strategies to overcome some of the barriers to developing OEND in their practice setting.

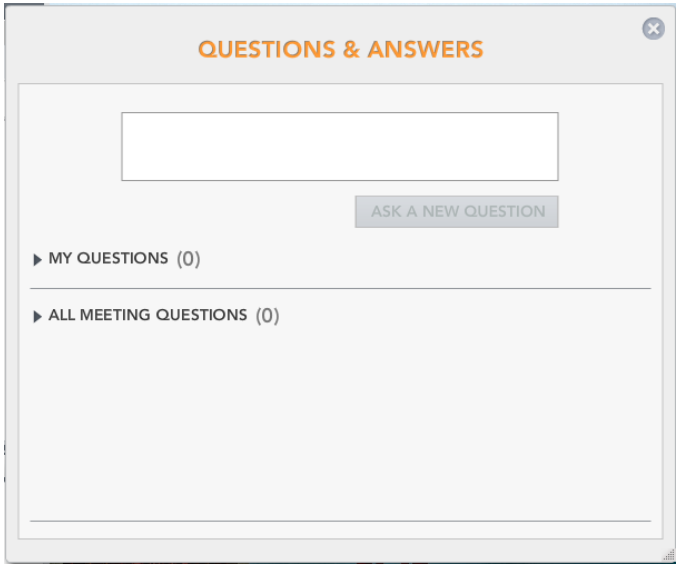
Participation Requirements

On or before August 20, participants in this course must complete an examination and achieve a score of 70% or greater at http://cpnp.org/ed/university/course/putting-naloxone-action. Successful completion of the course also requires the completion of a course evaluation. The ACPE universal program number assigned to the live course is 0284-0000-15-078-L04-P (1.0 contact hours).

Beginning August 21, the course will be available as home-study. Participants in the home-study course must complete an examination and achieve a score of 70% or greater and complete a course evaluation. The ACPE universal program number assigned to the home-study course is 0284-0000-15-078-H04-P (1.0 contact hours).

ACPE credit will be awarded through CPE Monitor.

Please ask questions!



During the live webinar, you can click the Q&A button (Q&A) at the top of the screen to send a question to the moderator at any time.

Case of CB

Age: 50

Past medical history:

- Alcohol use disorder (abstinent x 10 years)
- Panic disorder x 5 years
- HTN x 4 years

Past surgical history:

- L1-L4 Lumbar fusion 3 years ago
- Wisdom teeth extracted 30 years ago

Medications:

- Oxycodone ER 30 mg/325 mg APAP po twice daily for chronic back pain (90 morphine mg equivalent)
- Clonazepam 0.5 mg po three times daily PRN anxiety
- Lisinopril 5 mg po daily

Social history:

- Occasional marijuana use as teenager
- Both parents alive and well, F 81, M 83
- Married x 25 years
- Lives with son, 21, opioid use disorder x 6 years (Rx→ heroin); recently released from detoxification program, suspected relapse

Supporting Laws

- Medical and pharmacy practice laws and rules
  - Prescribing naloxone for legitimate patients is allowable in all states
  - Prescribing naloxone for non-patients or “third parties” likely requires special laws and rules including:
    - Third party prescribing
    - Liability protection
- Scope of practice
- Good Samaritan

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Models

Naloxone Access Models

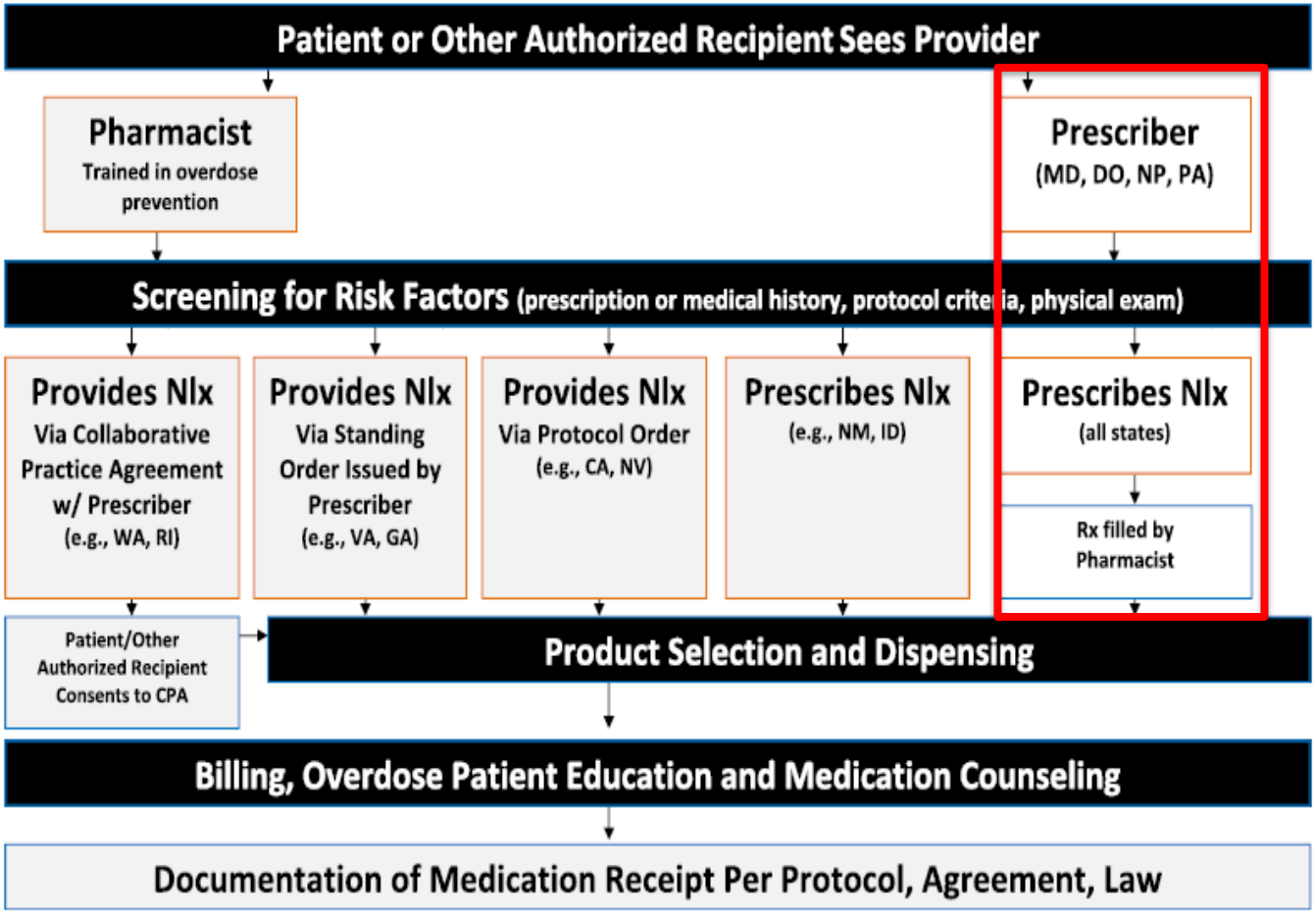

Figure 1 Pharmacy Naloxone Access Models. Process flow as experienced by patient and pharmacist. *Nlx* Naloxone, *Rx* prescription, *MD* medical doctor, *DO* doctor of osteopathic medicine, *NP* nurse practitioner, *PA* physician assistant, *CPA* collaborative practice agreement, State abbreviations: *WA* Washington, *RI* Rhode Island, *VA* Virginia, *GA* Georgia, *CA* California, *NV* Nevada, *NM* New Mexico, *ID* Idaho

Green, Traci C., et al. "Orienting patients to greater opioid safety: models of community pharmacy-based naloxone." *Harm Reduction Journal* 12.1 (2015): 25.

By order of prescription from CB's prescriber

How it works

Identify — Patients with overdose risks in your practice (CB is at risk)

Identify — Prescribers who treat those patients (CB's doctor)

Educate — All pharmacy patients so they will ask their prescriber to prescribe naloxone

Educate — Prescribers about overdose risks and support for co-prescribing

Supply — Supply prescriber with prescription forms and 'at risk' checklist

Call — Call prescriber to request naloxone prescription when you see at risk patients

Dispense

Bill — CB's private insurance is successfully billed for 2 prefilled naloxone syringes & she pays generic drug copay plus ~$10 for 2 atomizers

Educate — Pharmacist trains CB and her family in OD prevention, identification, response and naloxone kit administration & gives them written naloxone handout

Document — Pharmacist logs Rx date dispensed, manufacturer, and lot #

Coe,Walsh. Distribution of Naloxone for Overdose Prevention to Chronic Pain Patients." *Preventive Medicine* (2015).

Bailey, Wermeling. Naloxone for Opioid Overdose Prevention Pharmacists' Role in Community-Based Practice Settings *Annals of Pharmacotherapy* (2014)

Sample Patient Materials

(see Resource list)

Do you take strong pain medications?

For example:

Percocet, Vicodin, methadone, oxycodone, morphine, MSContin, Dilaudid, fentanyl, or any other "opiate" medication?

Ask your provider for naloxone!!

Naloxone is an antidote sprayed into the nose if you are too sleepy or can't be woken up due to these pain medications.

Talk to your provider for more information.

Naloxone is an antidote sprayed into the nose if you are too sleepy or can't be woken up due to these pain medications.

Naloxone could save my life...

Due to the current medication(s) I am taking, my pharmacist recommended that I talk to you about obtaining a prescription for Naloxone.

Attention Physician:

Please write prescription for Naloxone: 2x 2mg/2ml pre-filled Luer-Lock ready needleless syringes and direct your patient to have it filled at one of the participating pharmacies listed on the back of this card.

The atomization devices are included in a Project Lazarus Rescue Kit and will be given to your patient along with the Naloxone prefilled syringes and directions for use (See below). Naloxone is covered by Medicaid and some other insurers.

ENTS & FAMILY MEMBERS

prescription
ne, co-
ercodan®,
Norco®),
ne (Dilau-

brain, spinal cord and gastrointestinal tract. In doing so, they minimize the body's perception of pain. However, stimulating the opioid receptors or "reward centers" in the brain also can trigger other systems of the body, such as those responsible for regulating mood, breathing, and blood pressure.

A variety of effects can occur after a person takes opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis) to overdose, in which breathing and heartbeat slow or even stop.

Opioid overdose can occur when a patient misunderstands the directions for use, accidentally takes an extra dose, or deliberately misuses a prescription opioid or an illicit drug such as heroin.

Also at risk is the person who takes opioid medications prescribed for someone else, as is the individual who combines opioids — prescribed or illicit — with alcohol, certain other medications, and even some over-the-counter products that depress breathing, heart rate, and other functions of the central nervous system [4].

PREVENTING OVERDOSE

If you are concerned about your own use of opioids, don't wait! Talk with the health care professional/s who prescribed the medications for you. If you are concerned about a family member or friend, urge him or her to do so as well.

Effective treatment of opioid use disorders can reduce the risk of overdose and help a person who is misusing or addicted to opioid medications attain a healthier life. An evidence-based practice for treating opioid addiction is the use of FDA-approved medications, along with counseling and other supportive services. These services are available at SAMHSA-certified and DEA-registered opioid treatment programs (OTPs) [19-20]. In addition, physicians who are trained to provide treatment for opioid addiction in office-based and other settings with medications such as buprenor-phine/naloxone and naltrexone may be available in your community [21].

IF YOU SUSPECT AN OVERDOSE

An opioid overdose requires immediate medical attention. An essential first step is to get help from someone with medical expertise as soon as possible.

Call 911 immediately if you or someone you know exhibits any of the symptoms listed below. All you have to say: "Someone is unresponsive and not breathing." Give a clear address and/or description of your location.

Signs of **OVERDOSE**, which is a life- threatening emergency, include:

- Face is extremely pale and/or clammy to the touch
- Body is limp
- Fingernails or lips have a blue or purple cast
- The patient is vomiting or making gurgling noises
- He or she cannot be awakened from sleep or is unable to speak
- Breathing is very slow or stopped
- Heartbeat is very slow or stopped.

Signs of **OVERMEDICATION**, which may progress to overdose, include:

- Unusual sleepiness or drowsiness
- Mental confusion, slurred speech, intoxicated behavior
- Slow or shallow breathing
- Pinpoint pupils
- Slow heartbeat, low blood pressure
- Difficulty waking the person from sleep.

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

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

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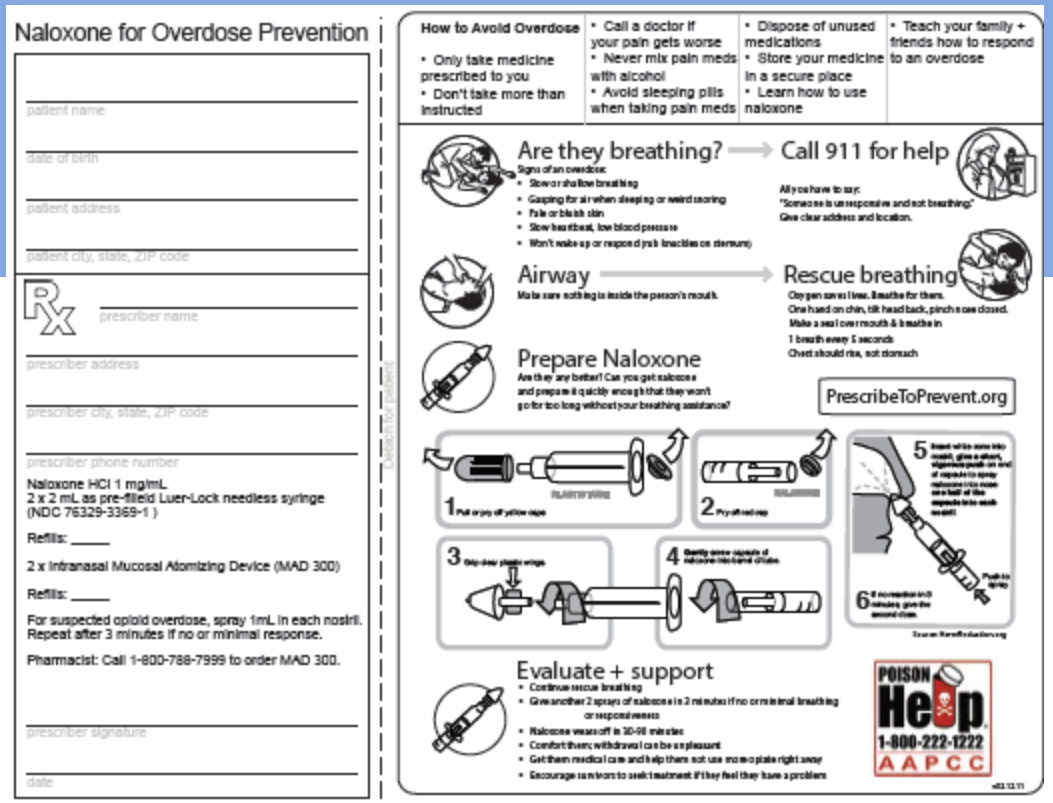
Sample Prescriber Materials

(see Resource list)



Naloxone for Overdose Prevention

patient name

date of birth

patient address

patient city, state, ZIP code

Rx

prescriber name

prescriber address

prescriber city, state, ZIP code

prescriber phone number

Naloxone HCl 1 mg/mL
2 x 2 mL as pre-filled Luer-Lock needless syringe
(NDC 76329-3369-1)

Refills: ____

2 x Intranasal Mucosal Atomizing Device (MAD 300)

Refills: ____

For suspected opioid overdose, spray 1mL in each nostril. Repeat after 3 minutes if no or minimal response.

Pharmacist: Call 1-800-788-7999 to order MAD 300.

prescriber signature

date

How to Avoid Overdose

- Only take medicine prescribed to you
- Don't take more than instructed
- Call a doctor if your pain gets worse
- Never mix pain meds with alcohol
- Avoid sleeping pills when taking pain meds
- Dispose of unused medications
- Store your medicine in a secure place
- Learn how to use naloxone
- Teach your family + friends how to respond to an overdose

Are they breathing? → Call 911 for help

Signs of an overdose:
- Slow or shallow breathing
- Gasping for air when sleeping or weird snoring
- Pale or bluish skin
- Slow heartbeat, low blood pressure
- Won't wake up or respond (rub knuckles on sternum)

All you have to say:
"Someone is unresponsive and not breathing."
Give clear address and location.

Airway → Rescue breathing

Make sure nothing is inside the person's mouth.

Oxygen saves lives. Breathe for them.
One hand on chin, tilt head back, pinch nose closed.
Make a seal over mouth & breathe in
1 breath every 5 seconds
Chest should rise, not stomach

Prepare Naloxone

Are they any better? Can you get naloxone and prepare it quickly enough that they won't go for too long without your breathing assistance?

PrescribeToPrevent.org

1 2 3 4 5 6

Evaluate + support

- Continue rescue breathing
- Give another 2 sprays of naloxone in 2 minutes if no or minimal breathing or respond weeks
- Naloxone wears off in 30-90 minutes
- Comfort them; withdrawal can be unpleasant
- Get them medical care and help them not use more opiate right away
- Encourage survivors to seek treatment if they feel they have a problem

POISON Help 1-800-222-1222 AAPCC

You Can Prevent Opioid Overdose Deaths

Is Your Patient At Risk?

Changes in tolerance after a period of abstinence

Taking other substances such as alcohol, benzodiazepines, anti-depressants and illicit drugs with an opioid

Co-morbid conditions such as emphysema, asthma, sleep apnea, COPD, heavy smoking, renal issues and hepatic dysfunction.

The Project Lazarus Rescue Kit

Rescue kits are available at participating pharmacies *(see back)* and can help simplify bystander naloxone use. The kit provides everything necessary for a nasal rescue except

Rx Three Steps to Prescribing

1. Educate patients on how to recognize an overdose, how to respond with naloxone, and how changes in tolerance can increase the risk of opioid overdose *(See back)*. Overdose prevention education could be a part of a Screening, Brief Intervention and Referral to Treatment (SBIRT), which can be billed as CPT 99408, G0396, or H0050.
2. Write a prescription for Naloxone: 2x 2mg/2ml pre-filled Luer-Lock ready needleless syringes and direct your patient to have it filled at one of the participating pharmacies *(see participating pharmacies on back)*. The atomization devices are included in a Project Lazarus Rescue Kit *(See left)*.
3. Gauge patient's interest in behavioral change. As appropriate, present support services and treatment options.

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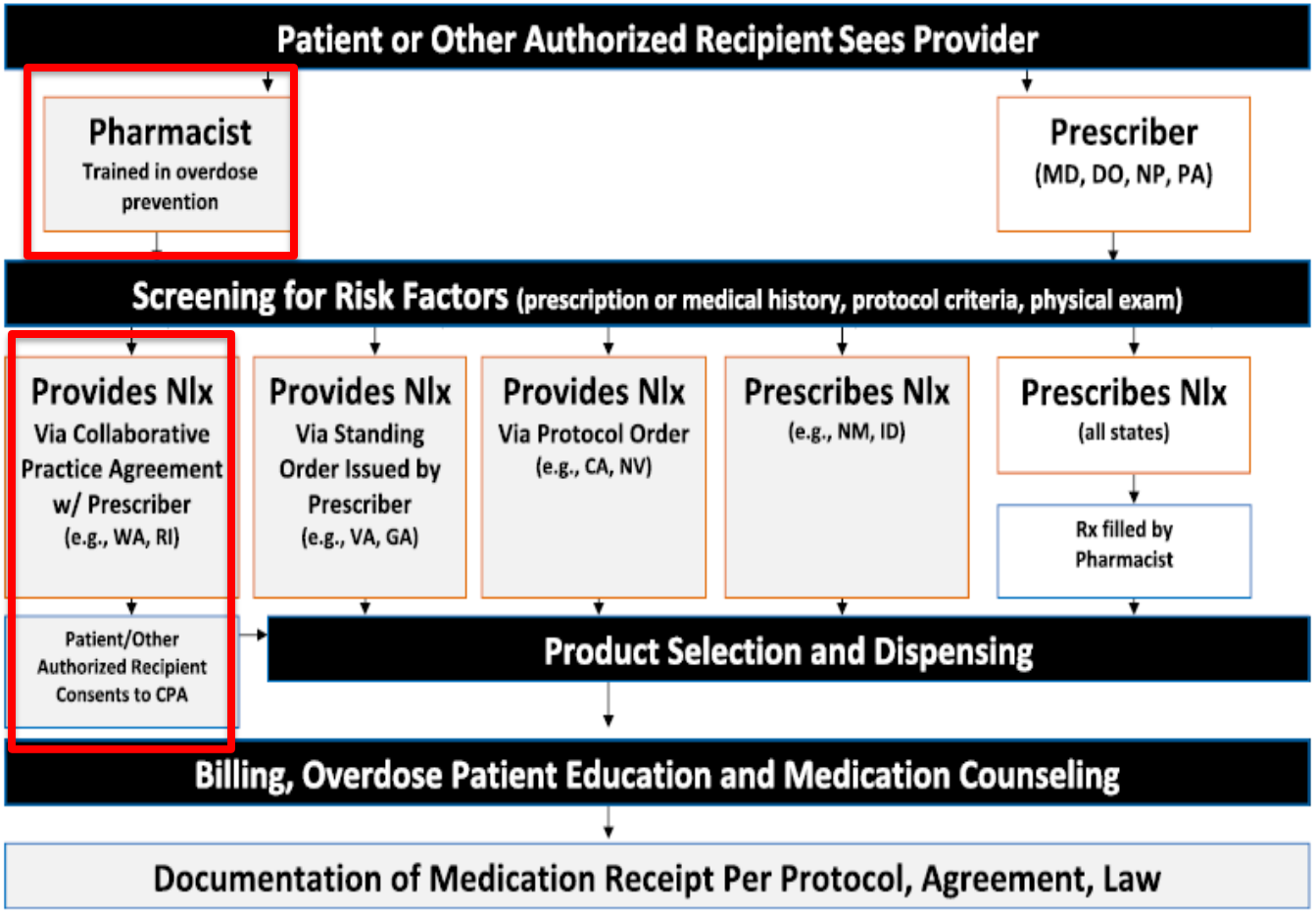
Naloxone Access Models



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Collaborative Practice Agreement

- The Collaborative Practice Agreement allows pharmacists to initiate naloxone therapy under a regulatory waiver from the RI Board of Pharmacy
- Pharmacist qualifications:
  - Possess an active Rhode Island Pharmacist license in good standing
  - CPR certified
  - Complete a appropriate training program containing:
    - Identifying those who are at risk for opioid overdose
    - Identifying the signs and symptoms of opioid overdose
    - Use of naloxone in overdose situations
    - Dispensing of naloxone pursuant to this protocol
    - Naloxone administration techniques
    - Patient and caregiver counseling regarding the use of naloxone and overdose response steps

CPA Continuing Professional Education Requirements

- Pharmacist shall complete **1 hour** of ACPE-accredited continuing professional education **annually** in the area of practice covered by the agreement
- Continuing Education ***may*** include any of the following areas related to the safe prescribing of opioids:

  - Opioid overdose prevention
  - Reducing the risk of prescription opioid abuse
  - The safe use of opioids for the management of chronic pain
  - The use of screening tools to detect opioid abuse or dependency, specialist referrals and management of difficult patients
  - Preventing diversion of prescribed opioid medications
  - Treating patients with pain and addiction
  - Naloxone administration technique
  - Review of collaborative practice agreement

Eligible patients to participate

- Voluntarily requesting
  - Does not have to be someone at risk of overdose- can be a friend, family member, etc.
- Recipient of emergency medical care for acute opioid poisoning
- Suspected illicit or nonmedical opioid user
- High dose opioid prescription (>100 morphine mg equivalent daily)
- Prescription for a long acting/extended release opioid
- Methadone prescription to opioid naïve patient

Kinner SA, Milloy M-J, Wood E, Qi J, Zhang R, Kerr T. Incidence and risk factors for non-fatal overdose among a cohort of recently incarcerated illicit drug users. *Addictive Behaviors*. 2012;37(6):691-696.
Dunn KM, Saunders KW, Rutter CM, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med*. 2010;152(2):85-92.
Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No (SMA) 14-4742.
Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.
Wolff K. Characterization of methadone overdose: clinical considerations and the scientific evidence. *The Drug Monit.* 2002;24(4):457-470.

Eligible patients to participate **(Highest Risk)**

- ***Opioid prescription*** and:
  - History of smoking
  - COPD
  - Respiratory illness or obstruction
  - Renal dysfunction or hepatic disease
  - Known or suspected concurrent alcohol abuse
  - **Concurrent benzodiazepine prescription**
  - Concurrent SSRI or TCA anti-depressant prescription

Jann, M., Kennedy, W.K., Lopez, G., 2014. Benzodiazepines: a major component in unintentional prescription drug overdoses with opioid analgesics. *J. Pharm. Pract.* 27 (1), 5–16.

Mack KA, Zhang K, Paulozzi L, Jones C. Prescription Practices involving Opioid Analgesics among Americans with Medicaid, 2010. *J Health Care Poor Underserv*ed 2015;26(1):182-98.

Zedler B, Xie L, Wang L, et al. Risk factors for serious prescription opioid-related toxicity or overdose among Veterans Health Administration patients. *Pain Med.* 2014;15(11):1911-29. doi: 10.1111/pme.12480.

Eligible patients to participate **(Highest Risk)**

- Recently released prisoners from a correctional facility
- **Released from opioid detoxification or mandatory abstinence program**
- Patients newly entering a methadone maintenance treatment program
- Patients that may have difficulty accessing emergency medical services

Moller LF, Matic S, van den Bergh BJ, Moloney K, Hayton P, Gatherer A. Acute drug-related mortality of people recently released from prisons. *Public Health*. 2010;124(11):637-639. doi: 10.1016/j.puhe.2010.08.012.
Strang J, McCambridge J, Best D, et al. Loss of tolerance and overdose mortality after inpatient opiate detoxification: follow up study. *BMJ*. 2003;326(7396):959-960.

Contraindications

- ~~A history of a~~ known hypersensitivity to naloxone or any of its components

Protocol: Informed Consent

Prior to providing services to patients pursuant to this CPA, the *pharmacy* will obtain informed consent from each patient, which shall include:

- A signed authorization for the release of protected health information by and between the pharmacy and the Collaborating Physician
- A provision allowing the patient to withdraw at any time from the collaborative practice described in this CPA
- An acknowledgment that patient has been offered the education and training described in Section 6 of the CPA
- Pharmacy will **retain a copy** of the informed consent

Protocol: Procedure

- The pharmacist shall initiate a naloxone prescription pursuant to the protocol described, and issue that prescription in the name of the collaborating medical provider participating in this CPA

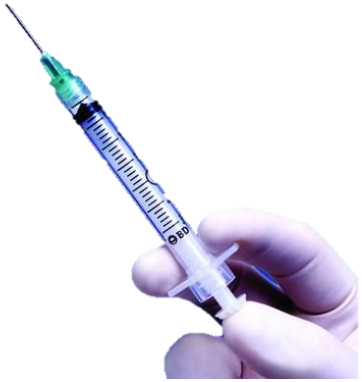
- The pharmacist shall contact the physician entered in the CPA in the event that medical consultation is required for a particular patient

Protocol: Dispensing

- **Intramuscular injection into deltoid muscle**
  - Naloxone HCl solution 0.4mg/ml 1 ml single use vial
    - Dispense 2 (two) vials
    - 2 (two) syringes **- OR -**
  - Naloxone HCl solution 0.4mg/ml 10 ml multi-dose vial
    - 1 (one) vial
    - 9 (nine) syringes
- **Intranasal**
  - Naloxone HCl solution 1mg/1ml prefilled 2 ml Luer-Jet syringes
    - 2 (two) pre-filled syringes
    - At least 1 (one) nasal drug delivery device
- **No refills** - Total amount dispensed not to exceed 10 mL

Protocol: Dispensing

- IM syringes
  - 1-1.5”, 21-23 gauge needle, with a syringe capacity of 1-3mL
- A nasal mucosal atomization device or devices must be dispensed with the Luer-Jet syringes **without** needles for intranasal use



Protocol: Education

- Before receiving naloxone patients must have overdose prevention, identification, and response training
  - Purpose for naloxone
  - Correct naloxone administration
  - Precautions regarding interacting medications
  - Identifying and avoiding high risk situations for overdose
  - Risk reduction strategies
- Opioid Overdose Response
  - How to identify an overdose
  - Rescue breathing
  - Calling 9-1-1
  - How to administer naloxone (either IM or IN)
  - What to do and expect after naloxone administration (withdrawal, rescue position)

Green T**, Bratberg J**, Dauria E, Rich J. Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need to Go. *R I Med J (2013).* 2014;97:29-33.

Protocol: Documentation

- Record the date the prescription was dispensed, the manufacturer and lot number, and the name and title of the person providing medication and education
- Alert the physician entered into the collaborative practice agreement via fax when naloxone is dispensed within 7 days
- Maintain records for minimum of 5 years
  - Informed consent
  - Re-fill form
  - Log of monthly activity
  - Staff / CPA prescriber will review monthly
- Licensing and liability insurance information of participating pharmacist(s) and prescriber (s) will be maintained
- Protocol shall remain in effect until rescinded or for 2 years after the effective date

How it works

Request: CB requests naloxone for her son from Overdose Trained Pharmacist

Screen: CB is identified as being in contact with someone at risk and/or at risk herself for opioid overdose

Consent: CB completes and signs an informed consent authorizing release of her PHI to Collaborating Prescriber

Prescribe: Pharmacist Initiates naloxone prescription with collaborating prescriber as prescriber and CB as patient

Select: Naloxone formulations discussed with CB and she chooses intranasal

Dispense:

Bill: CB's private insurance is successfully billed for 2 prefilled naloxone syringes & she pays generic drug copay plus ~$10 for 2 atomizers

Educate: Pharmacist trains CB in OD prevention, identification, response and naloxone kit administration & gives her written naloxone handout

Document: Pharmacist logs Rx date dispensed, manufacturer, and lot #

Rx & consent faxed to Collaborating Prescriber within 7 days

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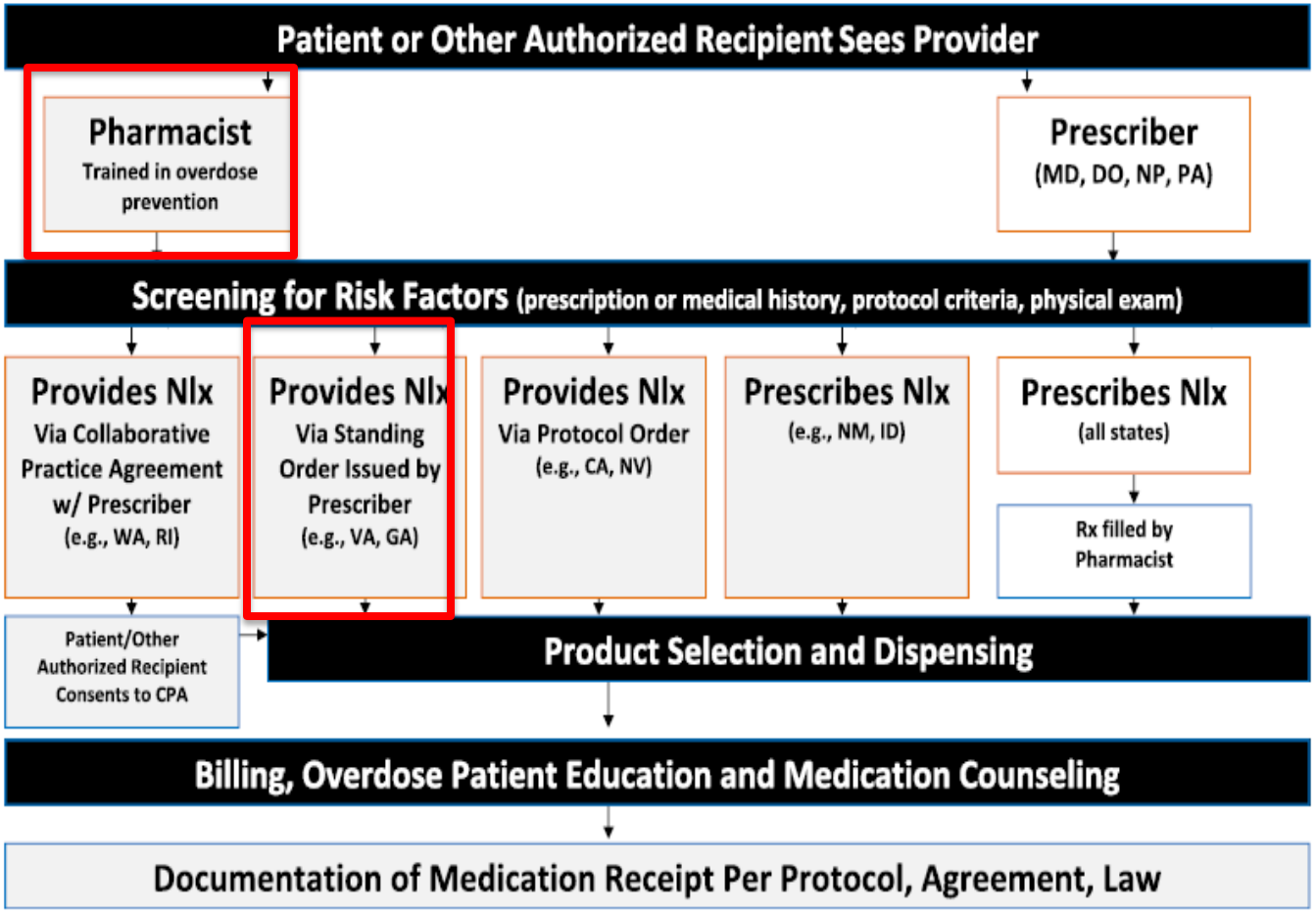
Naloxone Access Models



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Standing Order Model

- A standing order is a written instruction issued by a medical practitioner that authorizes a specified person or class of people, who do not have prescribing rights, to administer and/or dispense naloxone to a patient who may be unknown to the prescriber at the time of the order
  - Used to improve a patient's timely access to medicines
  - Eliminates the need for hand-written, faxed, or phoned prescription
  - Collaborative model

States With Standing Order Legislation

As of June 2015, 27 states have legislative language that allows for standing orders

- AL
- CA
- CO
- DE
- IL
- IN
- KY
- LA
- ME
- MN
- MS
- NC
- ND
- NH
- NJ
- NV
- NY
- PA
- RI
- SC
- TN
- TX
- VT
- VA
- WA
- WI
- WV

Davis, C. Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws. Last updated June, 2015.

NC Standing Order Legislation

- Third party prescribing
- “Immune from any civil or criminal liability”
  - Practitioner who prescribes naloxone
  - Any person who administers naloxone
- Effective August 1, 2015
  - Specifies that NC pharmacists can dispense under standing order
  - Specifies that NC pharmacists are immune from any civil or criminal liability
- Encourages bystanders to contact emergency responders without fear of arrest

Senate Bill 154. General Assembly of NC, Session 2015.

NC Specifics

- Pharmacist Qualifications:
  - Possess active NC pharmacist license

- No mandated pharmacist training
- No specific criteria required for receiving naloxone
- Pharmacist can dispense intranasal, IM, or auto-injector as specified by the standing order

How it works

Pharmacy X sets up a standing order with Physician Y or Health Department Z

↓

CB requests naloxone for her son at Pharmacy X

↓

CB is identified as being in contact with someone at risk and/or at risk herself for opioid overdose

↓

Pharmacist initiates naloxone RX with standing order physician as prescriber and CB as patient

↓

Since intranasal naloxone is specified on standing order, this formulation is discussed with CB

Pharmacist processes/dispenses RX

↓

CB's private insurance is successfully billed for 2 prefilled naloxone syringes & she pays generic drug copay plus ~$10 for 2 atomizers

↓

Pharmacist trains CB in OD prevention, identification, response and naloxone kit administration & gives her written naloxone handout

↓

Pharmacist notifies standing order physician as a courtesy when complete

Naloxone Access Models

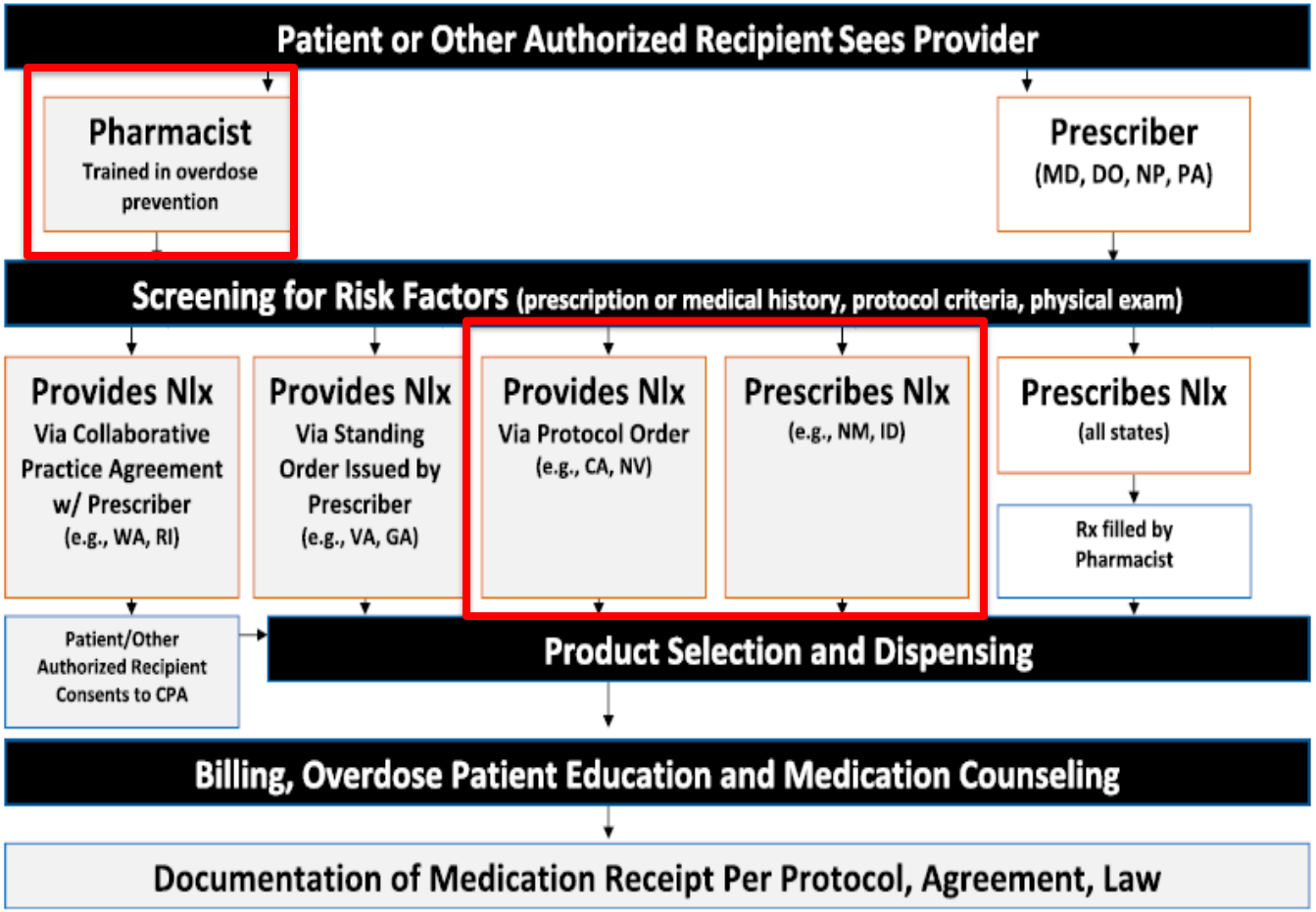

Figure 1 Pharmacy Naloxone Access Models. Process flow as experienced by patient and pharmacist. *Nlx* Naloxone, *Rx* prescription, *MD* medical doctor, *DO* doctor of osteopathic medicine, *NP* nurse practitioner, *PA* physician assistant, *CPA* collaborative practice agreement, State abbreviations: *WA* Washington, *RI* Rhode Island, *VA* Virginia, *GA* Georgia, *CA* California, *NV* Nevada, *NM* New Mexico, *ID* Idaho

Green, Traci C., et al. "Orienting patients to greater opioid safety: models of community pharmacy-based naloxone." *Harm Reduction Journal* 12.1 (2015): 25.

Pharmacist-as-Prescriber

Requirements and common themes

- Pharmacist independently makes the decision about the appropriateness of naloxone
- Adopted by statewide protocol approved by the Board of Pharmacy, Medical Board, and other invested parties
- Example States: NM, CA, ID, VT, NV

Pharmacists-as-Prescriber

New Mexico

- 2 hour Board Approved CE
- Screening of patient
- Patient consent
- Patient education
- Primary care notification
- Prescription record
- Documentation of why naloxone was used

California

- 1 hour CE or eq from School of Pharmacy
- Allows “furnishing” without a prescription
- Screening of recipient/bystander
- Patient education
- Primary care notification
- Record of dispensing

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How it works

CB requests naloxone for her son from Pharmacist

↓

CB is identified as being in contact with someone at risk

↓

Naloxone formulations discussed with CB and she chooses intranasal

→

- CB is trained
- Prescription for CB recorded in pharmacy software
- She pays cash for 2 atomizers, 2 prefilled syringes, and professional fee

In a Health System

- Not-for-profit health system includes
  - 22 hospitals
  - >185 clinics
  - 25 Community Pharmacies
  - Health insurance plan
- UT Naloxone access, Good Samaritan legislation in 2014
- Leadership decision to make naloxone rescue kits available in all 25 Community Pharmacies in Feb 2015
- Community Pharmacists trained in 30-minute interactive presentation prior to kit availability to the public

In a Health System

- Rescue kits assembled in central supply chain center and distributed to Community Pharmacies
  - IM and IN: 2 naloxone doses, 2 syringes or atomizers
  - Instructions from prescribetoprevent.org
  - Utah Department of Health Prescription Drug Overdose Pocket Card*
- Dispensing for outpatient use must take place in Community Pharmacy, pursuant to a prescription

* Pocket Card available at
http://www.health.utah.gov/vipp/pdf/RxDrugs/rxdrug-overdose-pocketcard.pdf

YOU ARE AT HIGH RISK FOR AN OVERDOSE IF YOU:

- Are taking high doses of opioids for long-term management of chronic pain.
- Have a history of substance abuse or a previous non-fatal overdose.
- Have lowered opioid tolerance as a result of completing a detoxification program or recently being released from incarceration.
- Are using a combination of opioids and other drugs such as alcohol and benzodiazepines (Klonopin, Valium, Xanax).
- Are unfamiliar with the strength and dosage of prescription opioids and the purity of street drugs like heroin.
- Are alone when using drugs.
- Smoke cigarettes or have a respiratory illness, kidney or liver disease, cardiac illness, or HIV/AIDS.

The Utah State Legislature passed two laws in 2014 to help reduce drug overdose deaths.

Good Samaritan Law (House Bill 11)

Enables bystanders to report an overdose without fear of criminal prosecution for illegal possession of a controlled substance or illicit drug.

Naloxone Law (House Bill 119)

Permits physicians to prescribe naloxone to third parties (someone who is usually a caregiver or a potential bystander to a person at risk for an overdose). Permits individuals to administer naloxone without legal liability.

Resources

Use Only As Directed
useonlyasdirected.org

USE ONLY AS DIRECTED

Call 2-1-1 for local services and treatment centers or visit
findtreatment.samhsa.gov

YOU CAN PREVENT DEATH FROM AN OVERDOSE

Recognize Overdose Warning Signs:

- Very limp body and very pale face
- Blue lips or blue fingertips
- No response when you yell his/her name or rub hard in the middle of the chest (sternal rub)
- Slowed breathing (less than 1 breath every 5 seconds) or no breathing
- Making choking sounds or a gurgling, snoring noise

If you see or hear any one of these behaviors, call 9-1-1 or get medical help immediately!

WHAT TO DO AFTER CALLING 9-1-1

1. **Try to wake the person.**
   Yell his/her name and rub hard in the middle of the chest (sternal rub).
2. **Try rescue breathing.**
   - Make sure nothing is in his/her mouth.
   - Tilt his/her head back, lift chin, and pinch nose shut.
   - Give 1 slow breath every 5 seconds until he/she starts breathing.

3. **Administer naloxone,** if available.
4. **Prevent choking.** Put the person on his/her side.
5. **Don't leave.** Stay until an ambulance arrives.

Call 9-1-1, get medical help, or call the Utah Poison Control Center.

POISON Help 1-800-222-1222

WHAT IS NALOXONE?

Naloxone (Narcan) is a drug that can reverse overdoses from heroin or prescription opioids such as oxycodone, hydrocodone, methadone, morphine, and fentanyl.

There is no potential for abuse and side effects are rare; however, a person may experience abrupt withdrawal symptoms.

How long does it take to work?

Naloxone may work immediately or may take up to five minutes. The effects of naloxone can last 30-90 minutes, so more than one dose may be needed.

REMEMBER, NALOXONE WORKS FOR OPIOIDS ONLY!

If you are at risk for an opioid overdose or care for someone who is at risk, talk to your doctor or pharmacist about getting a prescription for naloxone.

HOW IS NALOXONE ADMINISTERED?

Naloxone may be injected into the muscle or sprayed into the nose.

Intramuscular administration:

Inject 1cc/mL in large muscle.

Intranasal administration:

Screw parts together. Use one full vial. Spray half in each nostril.

(Image courtesy of Prescribe to Prevent)

In a Health System

- CPA between licensed prescriber(s) and pharmacist(s)
  - Permitted by Utah Pharmacy Practice Act
  - No state-mandated restrictions
  - “Required” education and training are established by the parties engaging in the collaboration
  - As in other states, pharmacists may initiate naloxone overdose kit distribution and educate patients according to an approved protocol

In a Health System

- Health insurance plan
  - Auto-injector covered: tier 3, non-preferred, prior authorization required
  - Kits were not recognized; NDC for naloxone corresponded to medical benefit
  - Petitioned health insurance plan to add naloxone rescue kits to prescription drug formulary
  - P&T approved kit coverage to begin July 2015
- Health care system is not-for-profit

Strategies to Overcome Barriers

- Billing and reimbursement
  - Cash
  - Medicaid
  - Third-party – insurance
    - For enrolled patient
    - For non-enrolled
- Atomizers
  - Ordering
  - Billing
  - Compounding
- Stigma
  - Most naloxone reversals involve heroin use.
  - Rx opioid overdoses account for twice those from heroin.

Patient Education

- How do you reach people who may witness prescription opioid analgesic overdoses?
- Avoid stigma: “Overdose” may turn off or scare them
  - Stigma and association with drug abuse or ‘addicts’
- Non-judgmental, less scary, use their language
  - “Has your spouse ever mentioned you snoring or being hard to awaken?”
  - “I want to improve the safety of your pain medications”
  - “In case you have an unexpected reaction”
  - “Just in case” – like having a fire extinguisher in your home

Resources

1) Your own state's board of pharmacy – CPA's, Standing Orders, Protocols
2) Videos, ordering information, prescription forms, etc:
   - http://cpnp.org/guideline/naloxone
   - www.prescribetoprevent.org
   - www.stopoverdose.org
   - *www.**getnaloxonenow**.org*
   - Example of overdose pocket card available at
   - http://www.health.utah.gov/vipp/pdf/RxDrugs/rxdrug-overdose-pocketcard.pdf

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PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in **addiction medicine/psychiatry and pain management.**
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit:

www.pcss-o.org/colleague-support

- **Listserv:** A resource that provides an "Expert of the Month" who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.

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PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
For questions email: pcss-o@aaap.org

Twitter: @PCSSProjects

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The College of Psychiatric and Neurologic Pharmacists (CPNP) is an association of specialty pharmacists who work to improve the minds and lives of those affected by psychiatric and neurologic disorders. These professionals apply their clinical knowledge in a variety of healthcare settings and positions ranging from education to research with the goal to apply evidence-based, cost efficient best practices in achieving patient recovery and improving quality of life.

Psychiatric pharmacists are uniquely qualified to work with opioid use disorder patients and are experts in medication use and abuse/diversion. Psychiatric pharmacists receive graduate professional pharmacy degrees and many hold doctorates. They also receive post-graduate residency training in psychiatry and substance abuse or have equivalent work experience. Psychiatric pharmacists are eligible to become board certified psychiatric pharmacists (BCPP) by completing required prerequisites and a rigorous national exam.

For more information visit cpnp.org
Contact us at info@cpnp.org
View the CPNP Naloxone Access Guideline Document at http://cpnp.org/guideline/naloxone

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