Dispensing Naloxone to Prevent Overdose Deaths

Dear Arizona Pharmacist:

As you may know, opioid overdose is an epidemic ravaging Arizona families. There has been a 74% increase in opioid-related deaths in the state from 2012-2016, with 790 opioid overdose deaths in 2016 alone. Fortunately, death from overdose can be prevented with greater access to naloxone, with some communities seeing 37-90% reductions in overdose deaths1; and pharmacists can play a major role in its dissemination.

In 2016, HB 2355 was passed to allow prescribers to write prescriptions and to dispense naloxone to laypeople. It also allowed pharmacists to dispense the medication without a prescription, but this prevented many patients’ insurance from covering the medication. In 2017, HB 2493 was passed. This required pharmacists to utilize a standing order to dispense naloxone, rather than dispensing it without a prescription. In June 2017, in response to an Emergency Declaration from Governor Doug Ducey, Dr. Cara Christ from ADHS signed this standing order for utilization in all pharmacies across Arizona.

Board of Pharmacy protocols require pharmacists to undergo a 1-hour online training in order to begin dispensing naloxone through the standing order. The training may currently give directions for dispensing without a prescription, but please follow the updated law and utilize Dr. Cara Christ’s standing order to bill patients’ insurance to ensure that all Arizonans can have access to the life-saving medication. In accordance with the June 2017 Emergency Declaration, pharmacists must now also record all naloxone dispensed in the Controlled Substances Prescription Monitoring Program (CSPMP).

Attached to this letter is a copy of the statute changes and information on the emergency declaration, a matrix of different naloxone products, and an educational handout for naloxone recipients. Please consider stocking naloxone in your pharmacy to intervene in our epidemic of accidental overdose. You can truly make a difference in the lives of Arizonans.

The online pharmacist training can be found at
https://azpa.learningexpressce.com/index.cfm/fa=view&eventID=8362

More resources can be found here: http://prescribetoprevent.org/pharmacists/pharmacy-basics/

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Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 32-1968, Arizona Revised Statutes, is amended to read:

32-1968. Dispensing prescription-only drug; prescription orders; refills; labels; misbranding; dispensing soft contact lenses; opioid antagonists

A. A prescription-only drug shall be dispensed only under one of the following conditions:
   1. By a medical practitioner in conformance with section 32-1921.
   2. On a written prescription order bearing the prescribing medical practitioner's manual signature.
   3. On an electronically transmitted prescription order containing the prescribing medical practitioner's electronic or digital signature that is reduced promptly to writing and filed by the pharmacist.
   4. On a written prescription order generated from electronic media containing the prescribing medical practitioner's electronic or manual signature. A prescription order that contains only an electronic signature must be applied to paper that uses security features that will ensure the prescription order is not subject to any form of copying or alteration.
   5. On an oral prescription order that is reduced promptly to writing and filed by the pharmacist.
   6. By refilling any written, electronically transmitted or oral prescription order if a refill is authorized by the prescriber either in the original prescription order, by an electronically transmitted refill order that is documented promptly and filed by the pharmacist or by an oral refill order that is documented promptly and filed by the pharmacist.
   7. On a prescription order that the prescribing medical practitioner or the prescribing medical practitioner's agent transmits by fax or electronic mail E-MAIL.
   8. On a prescription order that the patient transmits by fax or by e-mail if the patient presents a written prescription order bearing the prescribing medical practitioner's manual signature when the prescription-only drug is picked up at the pharmacy.

B. A prescription order shall not be refilled if it is either:
   1. Ordered by the prescriber not to be refilled.
   2. More than one year since it was originally ordered.
   3. A prescription order shall contain the date it was issued, the name and address of the person for whom or owner of the animal for which the drug is ordered, refills authorized, if any, the legibly printed name, address and telephone number of the prescribing medical practitioner, the name, strength, dosage form and quantity of the drug ordered and directions for its use.

D. Any drug dispensed in accordance with subsection A of this section is exempt from the requirements of section 32-1967, except SECTION 32-1967, subsection A, paragraphs 1, 10 and 11 and the packaging requirements of SECTION 32-1967, subsection A, paragraphs 7 and 8, if the drug container bears a label containing the name and address of the dispenser, THE serial number, THE date of dispensing, THE name of the prescriber, THE name of the patient, or, if an animal, the name of the owner of the animal and the species of the animal, directions for use and cautionary statements, if any, contained in the order. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or the internet or to a drug dispensed in violation of subsection A of this section.

E. The board by rule also may require additional information on the label of prescription medication that the board believes to be necessary for the best interest of the public's health and welfare.

F. A prescription-only drug or a controlled substance that requires a prescription order is deemed to be misbranded if, at any time before dispensing, its label fails to bear the statement "Rx only". A drug to which subsection A of this section does not apply is deemed to be misbranded if, at any time before dispensing, its label bears the caution statement quoted in this subsection.

G. A pharmacist may fill a prescription order for soft contact lenses only as provided in this chapter.

II. A PHARMACIST MAY DISPENSE NALOXONE HYDROCHLORIDE OR ANY OTHER OPIOID ANTAGONIST THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ON THE RECEIPT OF A STANDING ORDER AND ACCORDING TO PROTOCOLS ADOPTED BY THE BOARD PURSUANT TO SECTION 32-1979. FOR THE PURPOSES OF THIS SUBSECTION, "STANDING ORDER" MEANS A SIGNED PRESCRIPTION ORDER THAT AUTHORIZES THE PHARMACIST TO DISPENSE NALOXONE HYDROCHLORIDE OR ANY OTHER OPIOID ANTAGONIST FOR EMERGENCY PURPOSES AND THAT IS ISSUED BY A MEDICAL PRACTITIONER LICENSED IN THIS STATE OR A STATE OR COUNTY HEALTH OFFICER WHO IS A MEDICAL PRACTITIONER LICENSED IN THIS STATE.

Sec. 2. Section 32-1979, Arizona Revised Statutes, is amended to read:

32-1979. Pharmacists; dispensing opioid antagonists; board protocols; immunity

A. A pharmacist may dispense without a prescription, PURSUANT TO A STANDING ORDER ISSUED PURSUANT TO SECTION 36-2266 AND according to protocols adopted by the board, naloxone hydrochloride or any other opioid antagonist that is approved by the United States food and drug administration for use according to the protocols specified by board rule to a person who is at risk of experiencing an opioid-related overdose or to a family member or community member who is in a position to assist that person.
B. A pharmacist who dispenses naloxone hydrochloride or any other opioid antagonist pursuant to subsection A of this section shall:
   1. Document the dispensing consistent with board rules.
   2. Instruct the individual to whom the opioid antagonist is dispensed to summon emergency services as soon as practicable either before or after administering the opioid antagonist.
C. This section does not affect the authority of a pharmacist to fill or refill a prescription for naloxone hydrochloride or any other opioid antagonist that is approved by the United States food and drug administration.
D. A pharmacist who dispenses an opioid antagonist pursuant to this section is immune from professional liability and criminal prosecution for any decision made, act or omission or injury that results from that act if the pharmacist acts with reasonable care and in good faith, except in cases of wanton or wilful neglect.
Executive Order 2017-04
Enhanced Surveillance Advisory

WHEREAS, the deaths that are the direct result of opioid overdose are preventable; and

WHEREAS, the Arizona Department of Health Services requires more robust and more accurate data to successfully combat the opioid overdose epidemic; and

WHEREAS, on June 5, 2017, I declared that a State of Emergency exists in Arizona due to the opioid overdose epidemic; and

WHEREAS, consultation with the Director of the Arizona Department of Health Services in accordance with A.R.S. § 36-782, as well as the Director’s consultation with local health authorities in accordance with A.R.S. § 36-782(C), have informed me and provided the foundation for the following elements contained within this Enhanced Surveillance Advisory; and

WHEREAS, Article 5, Section 4 of the Arizona Constitution and Title 41, Chapter 1, Article 1 of the Arizona Revised Statutes vests the executive power of the State of Arizona in the Governor;

NOW, THEREFORE, I, Douglas A. Ducey, by virtue of the authority vested in me by the Constitution and laws of the State of Arizona do hereby issue an Enhanced Surveillance Advisory for the opioid overdose epidemic and direct the following actions in accordance with A.R.S. § 36-782(B):

1. Those persons and/or entities required to report data are as follows:
   • Healthcare providers licensed by Title 36;
   • Administrator of a health care institution or correctional facility;
   • EMS/Ambulance to include:
     • First response agencies
     • Ground and air ambulance services
   • Medical Examiners;
   • Pharmacists;
   • Arizona Criminal Justice Commission;
   • Arizona Department of Economic Security;
   • Arizona Health Care Cost Containment System;
   • Arizona Health and Medical Boards to include:
     • Arizona Medical Board
     • Arizona Board of Osteopathic Examiners
     • Arizona State Board of Nursing
     • Arizona Board of Dental Examiners
Executive Order 2017-04
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- Arizona Regulatory Board of Physicians Assistants
- Arizona State Board of Pharmacy
- Arizona Podiatry Board
- Arizona Naturopathic Board
- Arizona Optometry Board
- Arizona Veterinary Board
- Arizona Health Information Exchange (Health Current);
- Licensed Health Care Institutions, including behavioral health institutions;
- Local Law Enforcement Agencies to include:
  - County law enforcement agencies
  - County jails
  - County juvenile detention facilities
  - Police departments
  - County sheriff’s offices
- State Law Enforcement Agencies to include:
  - Arizona Department of Public Safety
  - Arizona Department of Corrections
  - Arizona Department of Juvenile Corrections

2. The specific health conditions to be reported are as follows:
- Suspected opioid overdoses;
- Suspected opioid deaths;
- Naloxone doses administered in response to either condition;
- Naloxone doses dispensed; and
- Neonatal abstinence syndrome.

3. Enhanced reporting requirements from the reporting persons and/or entities outlined in section 1, for the conditions noted in section 2, will begin forty-eight (48) hours from the issuance of this Enhanced Surveillance Advisory and will continue until this Enhanced Surveillance Advisory expires or is terminated.

4. Patient tracking will be implemented by the Arizona Department of Health Services, if necessary.

5. Information sharing will occur between the following partners:
- Law Enforcement to include:
  - Local Law Enforcement Agencies, to include, but not limited to: county jails, county juvenile detention facilities, county sheriff’s offices, police departments
  - State Law Enforcement Agencies, to include, but not limited to: Department of Public Safety, Department of Corrections, Department of Juvenile Corrections
- Pharmacy Board;
- Health and Medical Boards outlined in section 1;
- Arizona Department of Health Services;
- Arizona Health Care Cost Containment System;
- Licensed Health Care Institutions, including behavioral health institutions;
- Arizona Criminal Justice Commission;
- Arizona Department of Economic Services; and
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- Health Information Exchange.

If it is determined by the Director of the Arizona Department of Health Services that another entity or organization should be participating in this important information sharing effort, I am granting the Director of the Arizona Department of Health Services the delegated authority to expand upon this list, in accordance with A.R.S. § 36-782(G).

6. Specimen testing for all blood samples from suspected opioid overdose deaths is to be coordinated with and transferred to the Arizona State Public Health Laboratory for toxicological screening.

7. This Executive Order and Enhanced Surveillance Advisory will expire in sixty (60) days, in accordance with A.R.S. § 36-782(G), unless renewed by the Governor.

IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Arizona.

GOVERNOR

DONE at the Capitol in Phoenix on this 13th day of June in the Year Two Thousand Seventeen and of the Independence of the United States of America the Two Hundred and Forty-first.

ATTEST: Michele Reagan

Secretary of State
STANDING ORDERS FOR NALOXONE

This standing order is issued by Dr. Cara Christ, MD MS (NPI #1639369036), Director of Arizona Department of Health Services. The standing order authorizes any Arizona-licensed pharmacist to dispense naloxone to any individual in accordance with the conditions of this order.

Dispense one of the three following naloxone products based on product availability and preference.

<table>
<thead>
<tr>
<th>For intranasal administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dispense:</strong> NARCAN™ 4mg/0.1mL nasal spray</td>
</tr>
<tr>
<td><strong>Sig:</strong> Administer a single spray of Narcan in one nostril. Repeat after 3 minutes if no or minimal response.</td>
</tr>
<tr>
<td><strong>Refills:</strong> PRN x 1 year</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td><strong>Dispense:</strong> 2mg/2mL single dose Luer-Jet prefilled syringe. Include 1 Luer-lock mucosal atomization device per dose dispensed.</td>
</tr>
<tr>
<td><strong>Sig:</strong> Spray 1 mL in each nostril. Repeat after 3 minutes if no or minimal response.</td>
</tr>
<tr>
<td><strong>Refills:</strong> PRN x 1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For intramuscular injection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disp:</strong> 0.4mg/mL ir 1mL single dose vials. Include one 3cc, 23g, 1” syringe per dose dispensed.</td>
</tr>
<tr>
<td><strong>Sig:</strong> Inject 1mL IM in shoulder or thigh. Repeat after 3 minutes if no or minimal response.</td>
</tr>
<tr>
<td><strong>Refills:</strong> PRN x 1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For intramuscular or subcutaneous injection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disp:</strong> EVZIO™ 2mg/0.4mL auto-injector, #1 Two-pack</td>
</tr>
<tr>
<td><strong>Sig:</strong> Follow audio instructions from device. Place on thigh and inject 0.4mL. Repeat after 3 minutes if no or minimal response.</td>
</tr>
<tr>
<td><strong>Refills:</strong> PRN x one year</td>
</tr>
</tbody>
</table>

Cara Christ, MD MS, Director of Arizona Department of Health Services

Effective date 6/9/17, Expiration date 6/9/19
<table>
<thead>
<tr>
<th>Brand name</th>
<th>Injectable (and intranasal- IN) generic¹</th>
<th>Intranasal branded²</th>
<th>Injectable generic³</th>
<th>Injectable generic</th>
<th>Auto-injector branded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcan Nasal Spray</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Evzio Auto-Injector</td>
</tr>
</tbody>
</table>

### Ordering information

<table>
<thead>
<tr>
<th>How supplied</th>
<th>IMS/Amphastar</th>
<th>Teleflex (IN adapter)</th>
<th>Adapt Pharma</th>
<th>Hospira</th>
<th>Mylan</th>
<th>kaléo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Box of 10 Luer-Jet™ prefilled glass syringes</td>
<td>Two-pack of single use intranasal devices</td>
<td>Box of 10 single-dose fliptop vials (1 ml) OR Case of 25 multi-dose fliptop vials (10 ml)</td>
<td>Box of 10 single-dose fliptop vials</td>
<td>Two pack of single use auto-injectors + 1 trainer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Web address</th>
<th>Customer service</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMS/Amphastar</td>
<td>Amphastar.com</td>
<td>800-423-4136</td>
<td>76329-3369-01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>866-246-6990</td>
<td>DME-no NDC</td>
</tr>
<tr>
<td></td>
<td>Teleflex.com</td>
<td>844-462-7226</td>
<td>69547-353-02</td>
</tr>
<tr>
<td></td>
<td>Narcannasalspray.com</td>
<td>877-946-7747</td>
<td>00409-1215-01 (1 ml)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>00409-1219-01 (10 ml)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>724-514-1800</td>
<td>67457-0292-02</td>
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<tr>
<td></td>
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<td>60842-030-01</td>
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</table>

¹ IMS/Amphastar has an additional naloxone product, which is *not recommended* for layperson and take-home naloxone use because it is too strong of a dose by injection only for laypersons. (Naloxone HCl Injection, USP, 2mg/2mL Min-I-Jet Prefilled syringe with 21 Gauge and 1 ½” fixed Needle NDC # 76329-1469-1 (10 pack) and 76329-1469-5 (25 pack)

² As of 1/12/16, Narcan Nasal Spray has been approved by the FDA, but is not yet publicly available.

³ Hospira has an additional naloxone product, which is *not recommended* for layperson and take-home naloxone use because it is complicated to assemble. (Naloxone Hydrochloride Injection, USP, 0.4 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle) NDC# 0409-1782-69)

Image development supported by 1R01DA038082-01 Friedmann/Richardson.
Arizona has seen a sharp rise in opioid use and accidental overdose death.

It is important to understand what causes an overdose in the first place, and how to respond with naloxone to ensure survival if an overdose does occur.

**WHAT IS AN OPIOID?**

Opioids are a class of drugs that slow down the central nervous system. They include prescription painkillers like Vicodin, Percocet, Oxycodone, Dilaudid, Morphine, Methadone and Fentanyl. Heroin is also an opioid and has the same effect on the body.

**WHAT IS AN OPIOID OVERDOSE?**

When a person overdoses on opioids, their brain stops telling their lungs to breathe. This can happen immediately after using, or can take up to three hours. Once a person stops breathing, they can die within four minutes.

An overdose usually occurs for a few main reasons:

- Taking more opioids than the body can handle. Most frequently this happens after a person exits drug treatment, jail, or a setting where they had been abstinent from opioids.
- Mixing opioids with other depressants such as benzodiazepines (Valium, Xanax, etc.) and/or alcohol
- The opioids are stronger than a person thinks they will be, either because they are more pure, or mixed with potent opioids like fentanyl.

**Steps to revive an overdose victim**

1. Rub your knuckles hard on their sternum to wake them up. If they wake up, keep an eye on them and consider seeking medical attention. They may slip into an overdose if left alone. If they do not wake up, proceed to step 2.

2. Call 911. Let them know a person is not breathing and needs immediate medical attention.

3. Administer naloxone. Give the person one dose of naloxone. If they do not respond after two minutes, give them a second dose. Continue administering doses two minutes apart until the person responds.

4. While you are waiting for the naloxone to kick in, or if you do not have naloxone, breathe into the person's mouth. Tilt their head back, plug their nose, and give one deep breath every five seconds.

**Signs of an overdose include**

- The person is unconscious and not responding to a sternum rub or other physical stimuli
- Breathing is slow, shallow, or has stopped
- Snoring or gurgling may occur
- Lips, nails, or skin turn blue or gray

**What is naloxone?**

Naloxone, also known as Narcan, is an emergency response medication that is used to reverse an opioid overdose. It is a non-addictive prescription medication that has no side effects besides causing opioid withdrawal. Naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent. Although historically administered by emergency response personnel, naloxone can now be administered by minimally trained laypeople. There are four different naloxone devices and it can be given as an intramuscular injection or as a nasal spray.

**Who should have naloxone?**

Everybody! If you are at risk of an overdose because you use prescription opioids or heroin, you and the people you spend time with should have a naloxone kit just in case. Even if you take your pills as prescribed, somebody else in the household may ingest them and accidentally overdose. If you live with, work with, or spend time with people who are at risk for overdose, you should obtain naloxone.

**Legal protections**

HB 2355 (passed in 2016) allows a doctor to prescribe naloxone to a person at risk of an overdose or to a person who may be able to revive an overdose victim. If you carry or administer naloxone, you are legally protected and cannot be sued. The law also allows pharmacists to sell naloxone without a prescription.
How to get naloxone

**DOCTOR**
Ask your doctor for a prescription – most insurance will pay for it (including AHCCCS) with a prescription.

**PHARMACY**
You can also buy it directly from the pharmacy without a prescription but your insurance may not pay for it.

**COMMUNITY**
There are community organizations that give out free naloxone to people who have significant barriers to obtaining it.

If you or someone you know is at risk of overdose:

Please ask your doctor for a prescription for naloxone, talk to your pharmacist, or contact Sonoran Prevention Works for alternative ways to obtain naloxone.

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