



A Board of Pharmacy's Role: Restricting Access

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Restricting Access

1. Increasing PDMP utilization.
2. Prescribing limits.
3. Licensure.
4. Investigations.



Increasing PDMP Utilization



Increasing PDMP Use

Legislative and Regulatory Mandates:

For Prescribers:

- HB 341 (130th General Assembly) – Enacted April 2015.

For Pharmacists:

- Rule 4729-5-20 – Drug Utilization Review – Enacted February 2016.



Required Use Of OARRS

- House Bill 341 - Effective April 1, 2015
 - Required to review OARRS data when initially prescribing or personally furnishing an opioid or benzodiazepine to an Ohio patient.
 - Exceptions
 - Less than 7 day supply
 - Hospice, cancer, or end-of-life care
 - Immediately following surgery or other invasive procedure (**only applies to physicians**)
 - Registration required upon license renewal for practicing pharmacists and prescribers who prescribe opioids/benzos.



Required Use Of OARRS

- The prescriber must also make periodic requests for patient information from OARRS if the course of treatment continues for more than 90 days.
- The requests must be made at intervals not exceeding ninety days, determined according to the date the initial request was made.



OARRS Rules For Pharmacists

- Except for mandatory registration, HB 341 was silent on pharmacist requirements.
- Initial regulations promulgated in 2011 required use for signs of abuse.
- Board recognized role of pharmacist in addressing opioid abuse.



OARRS Rules For Pharmacists

OAC 4729-5-20 – Prospective Drug Utilization Review (DUR)

Corresponding responsibility :

“a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist is not required to dispense a prescription of doubtful, questionable, or suspicious origin.”



OARRS Rules Change - 2016

- OAC 4729-5-20, Prospective DUR (effective 2/1/16)
- Prior to dispensing an outpatient prescription for a reported drug, a RPh shall request & review an OARRS report, including a border state's PMP when the pharmacist is practicing pharmacy in a county bordering another state, for a one year period of time, if:



OARRS Rules Change - 2016

1. A patient adds a different or new reported drug to their therapy that was not previously included
2. OARRS report has not been run > 12 months as indicated on the patient profile
3. A **prescriber** is outside the pharmacy's usual geographic area



OARRS Rules Change - 2016

4. A **patient** is outside the pharmacy's usual geographic area
5. RPh suspects patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless prescriptions are from prescribers who practice at same physical location
6. Patient is exhibiting signs of potential abuse or diversion



Implementation

For Prescribers:

- Comprehensive prescriber FAQ document developed and disseminated through professional licensing Boards.
- Updates to OARRS website to include new educational resources including video tutorials. (www.ohiopmp.gov)
- Enhanced features (including online registration and password resets).
- Quick reference guide.



Implementation

For Pharmacists:

- Free online continuing education.
- Educational materials (quick reference guide).
- Its OK to Say No campaign.



Pharmacist and Prescriber Pocket Card

www.pharmacy.ohio.gov/OARRSRules

WHEN TO CHECK OARRS – PHARMACISTS

Effective February 1, 2016, prior to dispensing an outpatient prescription for a controlled substance, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

NOTE: An OARRS report must also include a border state's information when the pharmacist is practicing in a county bordering



Its OK to Say No...

www.pharmacy.ohio.gov/OKtoSayNo



STATE OF
OHIO
BOARD OF PHARMACY



SOMETIMES WE JUST HAVE TO **SAY NO.**

There are times when the laws and pharmacy board rules prohibit a pharmacist from dispensing a medication.

VALID PRESCRIPTION

To be valid, a prescription must be...

- **Issued for a legitimate medical purpose** by a prescriber acting in the usual course of his/her practice. The responsibility for the proper prescribing is upon the prescriber; however, a corresponding responsibility also rests with the

NOT VALID PRESCRIPTION

A prescription is not valid if...

- **The prescription is too old.** Prescriptions have time limits, even if there are still refills remaining. A pharmacist may not dispense a prescription that has expired. If refills were authorized, they are good for one year from the date the prescription was written on a non-controlled prescription, six months for a



OARRS Use Compliance

August 2016 – According to Data from OARRS:

- Top 25 Physicians* did not run an OARRS report on a total of 7,499 patients.
- Top 25 APRNs* did not run an OARRS report on a total of 2,678 patients.
- Top 25 Dentists did not run an OARRS report on a total of 144 patients.

*Patients may include exempted patients (i.e. hospice or cancer).

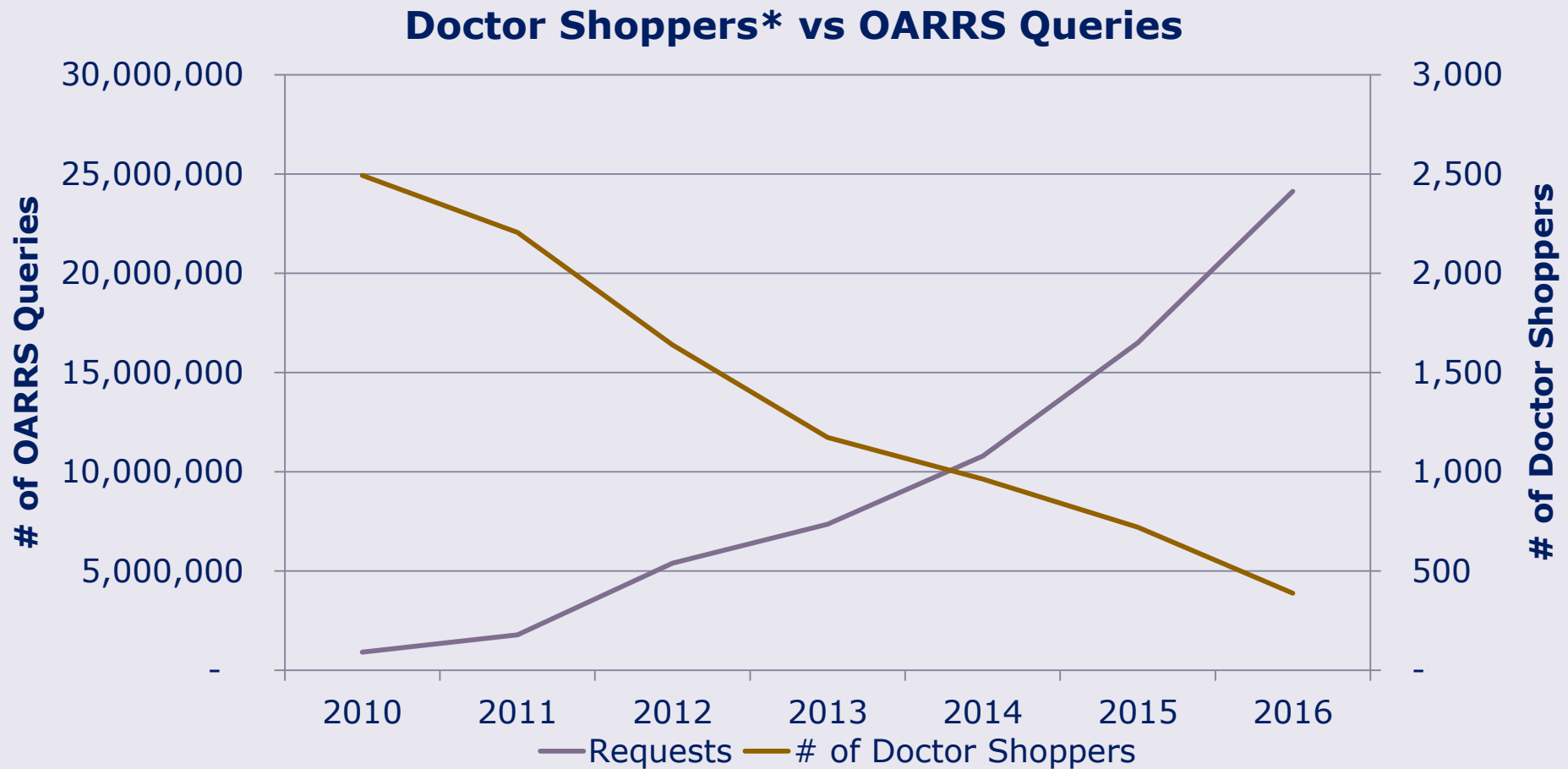


OARRS Use Compliance

- Letters sent from respective licensing Boards to most prescribers not in compliance (some prescribers were subject to investigation).
- OARRS queries increased from 83,544 to over 96,300 per weekday in the month following communication to prescribers.
- Compliance reports automatically generated on a monthly basis and sent to prescriber regulatory boards.
- Pharmacy Board working on similar compliance efforts for pharmacists.



OARRS Usage vs Doctor Shopping



*Doctor shopper defined as an individual going to 5 prescribers and 5 pharmacies in 1 month



OARRS Integration

- 10/26/15, Governor announced a \$1.5 million/year initiative to integrate OARRS directly into electronic medical records and pharmacy dispensing systems across the state, allowing instant access for prescribers and pharmacists.
- For more information – www.pharmacy.ohio.gov/integration
- To sustain the integration effort, Medicaid worked with the Ohio Board of Pharmacy to secure HITECH funding from CMS.



OARRS Integration

- Process uses the patient's demographic information in the provider's system to make the request to OARRS and produces the report information within the provider's workflow.
- Removes manual data entry, logging into a separate system (i.e. requiring a provider to remember a second user name and password).
- End Result: the time to review OARRS data goes from three minutes to about **20 seconds**.

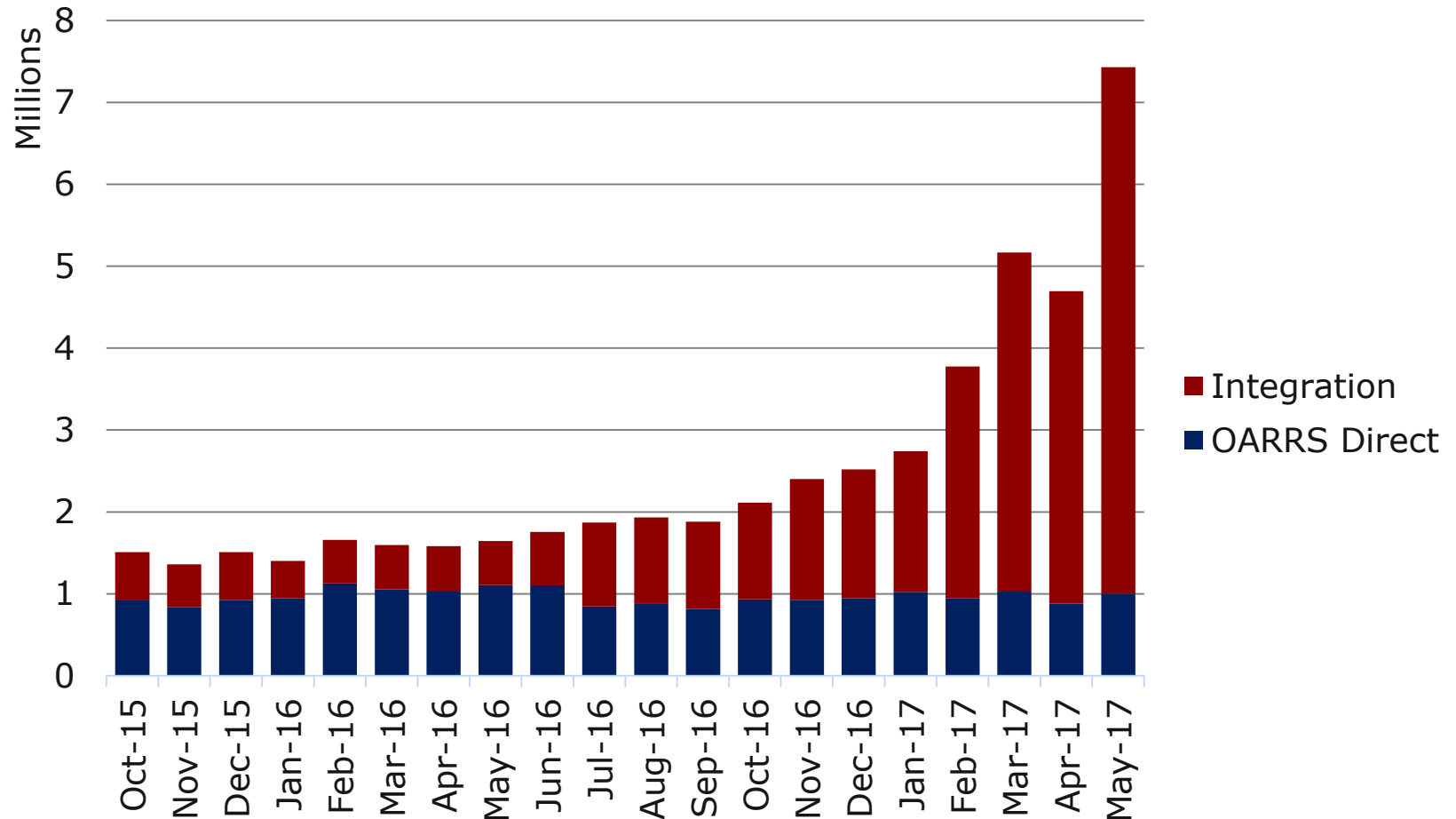


Kroger Case Study

- Kroger reports that pharmacist review of PDMP data has increased over 500 percent.
- The increase in PDMP review has been accompanied by a reduction in controlled substance dispensing.
- The proportion of all prescriptions dispensed that were for controlled substances was 1.2% less than for stores not using the integrated system (i.e. those outside of Ohio).
- As of August 2016, stores using the system showed collectively negative growth in controlled substance dispensing compared to 2015 (down 1.12%), compared to positive growth in stores not using it (up 1.25%).



Effect of Integration on Requests



OARRS Integration

- As a result of the integration initiative, nearly 17,700 prescribers and pharmacists have integrated access to OARRS to-date, including:
 - A number of major health systems and outpatient clinics, such as: Mount Carmel, Mercy Health, MetroHealth, The Ohio State University Wexner Medical Center, Cleveland Clinic, Avita Health, Southwest General, University Hospital (Cleveland), and Licking Memorial Health System.
 - 170 independent Ohio pharmacies.
 - Four chain pharmacies, Discount Drug Mart (73 Ohio stores), Kroger (226 Ohio stores), Giant Eagle (5 Ohio Stores), and Meijer (41 Ohio Stores).
- Integration efforts are ongoing to connect additional health systems and prescribers.



Prescribing Limits



Opioid Prescribing Limits for Acute Pain

- Effective August 31, 2017, Ohio healthcare regulatory boards enacted new rules for prescribing opioid analgesics for the treatment of acute pain.
- In general, the rules limit the prescribing of opioid analgesics for acute pain, as follows:
 1. No more than seven days of opioids can be prescribed for adults.
 2. No more than five days of opioids can be prescribed for minors.
 3. Except as provided for in limited circumstances, the total morphine equivalent dose (MED) of a prescription for acute pain cannot exceed an average of 30 MED per day.
 4. The new limits do not apply to opioids prescribed for cancer, palliative care, end-of-life/hospice care or medication-assisted treatment for addiction.



Opioid Prescribing Limits for Acute Pain

- Starting December 29, 2017, prescribers will be required to include the first four characters of the diagnosis code (ICD-10) or the full procedure code (Current Dental Terminology - CDT) on opioid prescriptions, which will be entered into Ohio's prescription monitoring program, OARRS.
- This requirement will take effect for all other controlled substance prescriptions on June 1, 2018.



Opioid Prescribing Limits for Acute Pain

- Inclusion of the diagnosis or procedure codes will ensure that opioid prescriptions for acute pain that exceed the limits are done so in accordance with the rules.
- The codes will also provide prescriber regulatory boards additional insight regarding the circumstances of why patients are prescribed opioids.
- The Board of Pharmacy will provide regular reports from OARRS to the Medical, Dental, and Nursing boards of licensees who may be in violation of the rules. This will help to facilitate a robust enforcement effort and achieve our shared goal of reducing the overprescribing of opiates for the treatment of acute pain.



Opioid Prescribing Limits for Acute Pain

- The rules have the potential to reduce the number of opioids prescribed for acute pain by an additional 109 million doses.
 - Calculated using impact of rules on 2016 prescribing data.



Licensure



Licensure of all Facilities Storing Controlled Substances

- Exempted locations were ordering more than 3 million doses of opioids annually.
- Board expanded authority to license all facilities that possess controlled substances (including all physician offices).
- The Board of Pharmacy may conduct unannounced inspections of sites where drugs, including controlled substances, are stored and dispensed to safeguard against tampering or diversion.



Licensure of all Facilities Storing Controlled Substances

- Licensure process gathers important information that enables the Board of Pharmacy to conduct background investigations.
- Without such safeguards, individuals with drug convictions, those currently under investigation by the board or those who have been sanctioned by their licensing boards could have unfettered access to controlled substances.
- Licensure by the Board of Pharmacy also serves as an opportunity to educate prescribers on how to safely store and dispose of dangerous drugs.
- Pharmacy Board staff have years of experience investigating possible cases of misuse and diversion by office staff. Inspections provide an additional opportunity to reduce any potential liability.



Investigations



Overdose Death Investigations

- Linking data from OARRS to overdose death data provided by the Ohio Department of Health to identify prescribers linked to drug overdose decedents.
- The Board works closely with prescriber regulatory boards to conduct joint investigations of prescribers for violations of criminal and administrative law.



Prescriber Investigations

- Received \$400,000, two-year federal grant from the U.S. Department of Justice in 2016 to hire two additional agents to review data in OARRS and initiate criminal and/or administrative investigations against prescribers.
- Requested and received support from the Ohio National Guard for a criminal intelligence analyst to support the Board's mission to investigate violations of Ohio's drug laws.



Pre-Criminal Intervention Program

- Received grant from the U.S. Department of Justice to fund a two-year pre-criminal intervention pilot program (PCIP).
- The program will utilize data from OARRS to identify those who are exhibiting possible signs of prescription drug abuse, including those who are see multiple prescribers to illegally obtain controlled substances – a practice commonly referred to as “doctor shopping”.
- Once identified, specially trained Board staff, with the help of local law enforcement and county treatment agencies, will engage those individuals to limit their overutilization of the healthcare system and connect them with appropriate drug treatment or other support services.



Expanding Access to Naloxone



Naloxone – HB 4

Board helped to develop and supported passage of HB 4 signed into law on July 16, 2015.

- Authorizes a pharmacist or pharmacy intern under the direct supervision of a pharmacist to dispense naloxone without a prescription in accordance with a physician-approved protocol.



Pharmacy Dispensing

- Any formulation of naloxone that is approved in the protocol can be dispensed (intramuscular, auto injector or intranasal).
- Any pharmacy dispensing pursuant to a protocol must notify the Board of Pharmacy within 30 days.
 - Process automated and completely paperless.



Naloxone at Pharmacies

www.pharmacy.ohio.gov/stopoverdose



**STATE OF OHIO
BOARD OF PHARMACY**

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Columbus, OH 43215

ABOUT

OARRS

PUBLICATIONS

LICENSING / CE

LAWS & RULES

LAW ENFORCEMENT

FAQ

OHIO PHARMACIES DISPENSING NALOXONE WITHOUT A PRESCRIPTION

*The list below is of Ohio licensed pharmacies which dispense naloxone pursuant to OAC 4729-5-39.
For more information on naloxone, visit our [naloxone resources page](#).*

Filter by county:

License Number	Business Name	Phone	Address	County
020961050	CVS/PHARMACY #4445	4199910010	2620 W. BREESE RD. LIMA, OH 45806	Allen
020882750	CVS/PHARMACY #4447	4192277970	900 BELLEFONTAINE ROAD LIMA, OH 45804	Allen
021374200	WALGREENS #07441	(419) 222-9462	701 N. CABLE RD LIMA, OH 45805	Allen
021435000	WALGREENS #07684	4192221600	2366 HARDING HWY LIMA, OH 45804	Allen
			730 W MARKET STREET	

OARRS



Naloxone in the Pharmacy

- The Board of Pharmacy led an aggressive campaign to encourage pharmacies to dispense naloxone without a prescription, including developing resources such as a sample protocol, patient education brochures, and guidance documents.
- Developed dedicated resources for pharmacies
 - www.pharmacy.ohio.gov/naloxone
- Printed brochures offered to pharmacies at no-cost



Naloxone in the Pharmacy

Overdose Risk Factors & Prevention

Opioids include both heroin as well as prescription medications used to treat pain such as morphine, codeine, methadone, oxycodone (Oxycontin, Percodan, Percocet), hydrocodone (Vicodin, Lortab, Norco), fentanyl (Duragesic, Fentora), hydromorphone (Dilaudid, Exalgo), and buprenorphine (Subutex, Suboxone). The following are some common risk factors for opioid overdose as well as some prevention strategies:

Mixing Drugs

Many overdoses occur when people mix heroin or prescription opioids with alcohol and/or benzodiazepines. Alcohol and benzodiazepines (Xanax, Klonopin, Ativan and Valium) are particularly dangerous because, like opioids, these substances impact an individual's ability to breathe. ***Avoid mixing opioids with other drugs or alcohol. If prescribed an opioid and a benzodiazepine by a prescriber, take only as directed.***

Tolerance

Tolerance is your body's ability to process a drug. Tolerance changes over time so that you may need more of a drug to feel its effects. Tolerance can decrease rapidly when someone has taken a break from using an opioid. When someone loses tolerance and then takes an opioid again, they are at-risk for an overdose, even if they take an amount that caused them no problem in the past. ***If you are using opioids after a period of abstinence, start at a lower dose.***

Physical Health

Your physical health impacts your body's ability to manage opioids. Since opioids can impair your ability to breathe, if you have asthma or other breathing problems you are at higher risk for an overdose. Individuals with liver (hepatitis), kidney problems and those who are HIV-positive are also at an increased risk of an overdose.

Previous Overdose

A person who has experienced a nonfatal overdose in the past has an increased risk of a fatal overdose in the future. ***To prevent a fatal overdose, teach your family and friends how to recognize and respond to an overdose. If you or someone you know needs help, please call 1 (877) 275.6364 to find an addiction services provider near you.***

How do I know if someone is overdosing?

If someone takes more opioids than their body can handle, they can pass out, stop breathing and die. An opioid overdose can take minutes or even hours to occur.

A person who is experiencing an overdose may have the following symptoms:

- Slow breathing (less than 1 breath every 5 seconds) or no breathing.
- Vomiting.
- Face is pale and clammy.
- Blue lips, fingernails or toenails.
- Slow, erratic, or no pulse.
- Snoring or gurgling noises while asleep or nodding out.
- No response when you yell the person's name or rub the middle of their chest with your knuckles.

**An overdose is a MEDICAL EMERGENCY!
Call 9-1-1 immediately**

For patient education, videos and additional materials, please visit
www.prescribeto prevent.org



**STATE OF
OHIO**
BOARD OF PHARMACY

www.pharmacy.ohio.gov

Overdose Recognition and Response Guide



**A GUIDE FOR PATIENTS
AND CAREGIVERS**

State of Ohio Board of Pharmacy

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Naloxone in the Pharmacy

- 1,635 Ohio retail pharmacies (77%) offer naloxone without an Rx.
- 87 out of 88 counties offer naloxone without a prescription.



Unlimited Sharing of Naloxone Between Jurisdictions

- Ohio Senate Bill 319 (the Opiate Mid-Biennium Review) included a provision to authorize EMS agencies and other licensed locations (such as health departments) to transfer or share naloxone.
- This allows EMS, health departments and other licensed locations to reallocate the naloxone to avoid expiration.
- The law and the accompanying rules do not place any limitations on the amount that may be shared or transferred.
- The Board developed a guidance document, which was disseminated to all licensees, to facilitate sharing between jurisdictions. It can be accessed by visiting: www.pharmacy.ohio.gov/transferEMS



Mailing of Naloxone from Local Health Departments

- Authorized a new policy that permits Project DAWN sites to deliver naloxone via delivery agent or by mail (USPS, FEDEX, UPS).
- This was at the request of a local health department seeking to expand access throughout the county, particularly for those with limited transportation options. A guidance document can be accessed here:
www.pharmacy.ohio.gov/NaloxoneDeliver



Naloxone Availability for Entities Serving High-Risk Individuals

- Through SB 319, authorized access to non-patient specific doses of naloxone for entities that serve individuals who may be at risk of experiencing an opioid-related overdose (known as service entities).
- More information can be found here:
www.pharmacy.ohio.gov/service.



Additional Efforts

- Developed guidance materials to promote the distribution of naloxone to at-risk individuals who are being discharged from a local hospital (www.pharmacy.ohio.gov/hospitalnaloxone) and those who are treated and released by local EMS (www.pharmacy.ohio.gov/EMSnaloxone).
- Provided an additional \$20,000 to existing state funding to support the purchase of naloxone by Project DAWN sites.

