

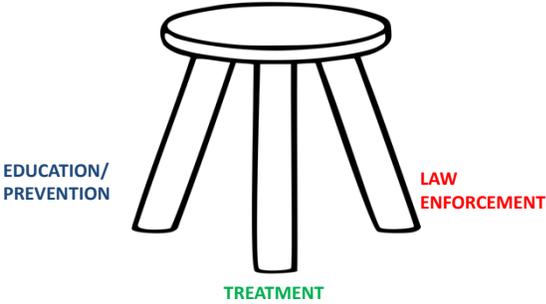
Ohio Attorney General's Office Perspective



Steve Schumaker
Mick Gyrko

MEXICO'S CARTELS
MORE DANGEROUS THAN ISIS?





EDUCATION/
PREVENTION

LAW
ENFORCEMENT

TREATMENT



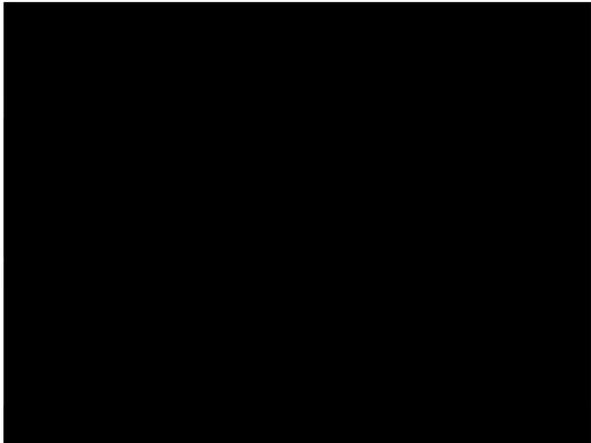


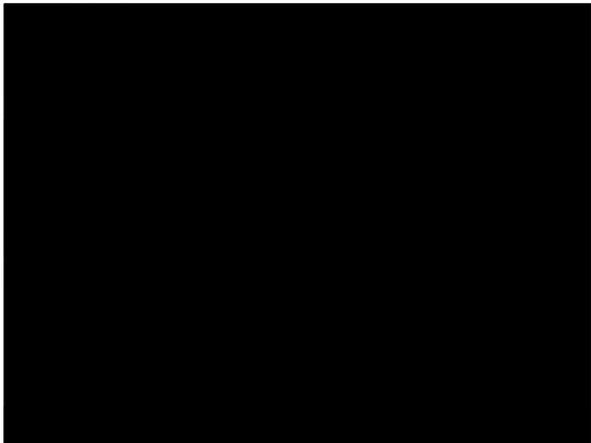
RESPECT

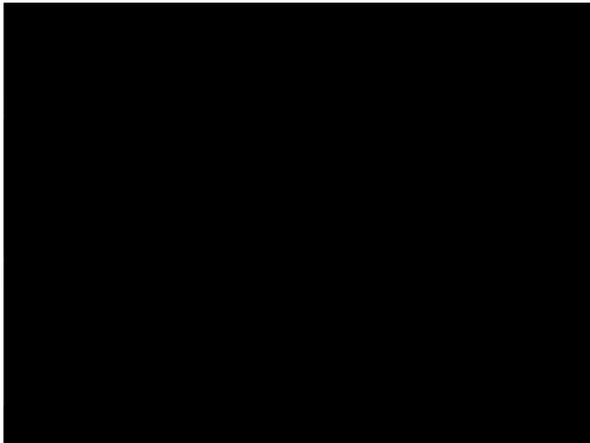


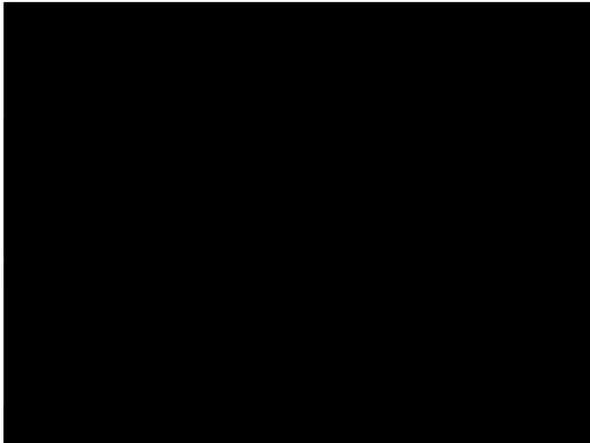
WHO IS THE ENEMY?













Heroin epidemic kills 52 people in Cuyahoga County in September, tying deadliest month on record
 The Plain Dealer, Thursday, October 6, 2016



MIKE DeWINE
 GOVERNOR OF OHIO

Twenty charged in multi-state drug ring that brought heroin, fentanyl, cocaine to Cleveland



Twenty people were charged in a multi-state drug ring. [@PlainDealer](#)
 by Eric Hsing | cleveland.com
 Follow on Twitter
 on October 12, 2016 at 12:31 PM, updated October 12, 2016 at 1:19 PM

Federal authorities say some of those charged have ties to the Sinaloa drug cartel.

MIKE DeWINE
 GOVERNOR OF OHIO

Mexico's 2016 fight with crime:
Seizures of drugs, guns and vehicles down

Comparing figures from January through July of 2015 and 2016

| CATEGORY | 2015 | 2016 | DECREASE (%) |
|---|--------|--------|--------------|
| Marijuana crops eradicated (hectares) | 2,532 | 2,459 | -3% |
| Opium poppy crops eradicated (hectares) | 17,178 | 15,967 | -7.1% |
| Marijuana seized (tons) | 558 | 414 | -25.6% |
| Cocaine seized (tons) | 4.9 | 4.2 | -14.2% |
| Opium seized (tons) | 510 | 86 | -83% |
| Heroin seized (kilos) | 232 | 194.9 | 16.2% |

MIKE DeWINE
 GOVERNOR OF OHIO

Mexican Drug Cartel Violence Spreading To Rural U.S. As Police Crack Down In Big Cities

By Andrew O'Reilly / Published August 12, 2014 / Fox News Latino



MIKE DEWINE
GOVERNOR OF OHIO

(U) United States: Areas of Influence of Major Mexican Transnational Criminal Organizations

DEA
INTELLIGENCE
REPORT

DEA-DCT-ENR-063-13
01/07/2013

13 This product was prepared by the DEA Strategic Intelligence Section. Comments and questions may be addressed to the Chief Analyst and Production Section at 063.13@dea.gov.

UNCLASSIFIED

MIKE DEWINE
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(U) Figure 2: United States: Areas of Influence of Major Mexican Transnational Criminal Organizations



MIKE DEWINE
GOVERNOR OF OHIO



PHOTO ILLUSTRATION BY THE DAILY BEAST

SHOWDOWN

Mexico's Cartels Are Much More Dangerous To Americans Than ISIS

Both are brutal and bloodthirsty—but the cartels are a greater, more immediate security risk, and they're already deeply embedded inside the United States.

MIKE DeWINE
GOVERNOR OF OHIO

OOCIC BULK CURRENCY TASK FORCE

| | Central Ohio BC | Miami Valley BC | Toledo BC |
|------------------------------|------------------|-----------------|------------------|
| Heroin (\$100/gram) | 96.1 lbs. | 99.75 lbs. | 9.51 lbs. |
| Fentanyl (\$200/gram) | 15.6 lbs. | 2.4 lbs | 0 |
| Cocaine (\$100/gram) | 377.9 lbs. | 81 lbs. | 25 lbs. |
| Marijuana (\$1,500/lb.) | 5,585 lbs. | 2,490 lbs. | 240 lbs. |
| Methamphetamine (\$100/gram) | 38.1 lbs. | 47.87 lbs. | 2.2 lbs. |
| Crack (\$100/gram) | 74 grams | 105 grams | 139.1 grams |
| Pills (\$5/pill) | 1,424 ud | 6,509 ud | 3,635 ud |
| Other: | Khat - 17 pounds | | Ecstasy - 319 ud |
| Total Street Value | \$33,058,690 | \$16,563,300 | \$2,424,855 |
| US Currency | \$11,834,321 | \$4,349,682 | \$527,786 |
| Firearms | 169 | 45 | 7 |
| Arrests (#of persons) | 626 | 274 | 112 |

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GOVERNOR OF OHIO

El Chapo's son among group kidnapped from Mexico restaurant, authorities say
Rival criminal group blamed for abduction of Jesús Alfredo Guzmán Salazar, son of imprisoned drug lord, in Puerto Vallarta



MIKE DeWINE
GOVERNOR OF OHIO

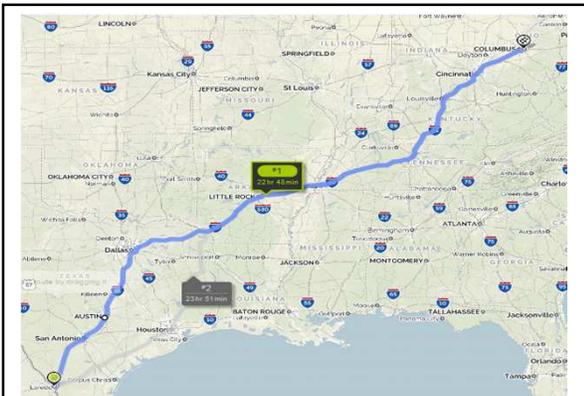
Chapo's sons said behind attack on Mexican army convoy

Published October 01, 2016 [EFE](#)



A soldier stands guard on a pick-up truck where a military convoy was ambushed using grenades and high-powered guns, killing five soldiers in the city of Culiacan, Mexico, early Friday, Sept. 30, 2016. Local military commander Gen. Alfonso Duarte said it is very probable that the attack was carried out by the sons of imprisoned drug lord Joaquin El Chapo Guzman. (AP Photo/Rashide Frias) (PARRA ZURITA)

MIKE DeWINE
GOVERNOR OF OHIO



MIKE DeWINE
GOVERNOR OF OHIO









The state of Ohio has **955** law enforcement agencies (not including federal agencies) employing **33,896** sworn police officers.





WHAT ARE WE DOING?



Josie Cesear Medina – Sinola Cartel
Miami Valley Bulk Smuggling Task Force - Dayton, Ohio
15 lbs. of pure fentanyl
7 lbs. heroin
\$450,000 in U.S. Currency



On 9/16/15 TF Agents observed criminal indicators while observing Medina at a Bus Station. After conducting surveillance on the subject for several hours, numerous houses were identified as potential stash houses. TF Agents decided to continue surveillance for several weeks on multiple individuals. A traffic stop was conducted on 11/16/15 and \$300,000 in U.S. currency was located.

Subsequent search warrants on multiple residences result in the seizure of an additional \$125,000, 22 lbs of fentanyl/heroin, and 3 handguns.

Medina was sentenced to 9 years in prison.

Christian M. Gonzalez – Sinola Cartel
Miami Valley Bulk Smuggling Task Force - Dayton, Ohio
22 lbs. of heroin
\$250,000 in U.S. Currency



TF Agent observed a 2003 Ford Ranger, bearing California license plates, parked in the parking lot of Extended Stay. "criminal indicators" were observed that led him to believe the vehicle had a "trap" inside the vehicle. The vehicle bed appeared to be separated from the cab and had overspray on the bottom of the vehicle. A Database check revealed the registered owner, Christian Gonzalez, had prior arrests for smuggling illegal Aliens.

TF Agents established surveillance as he drove around Dayton to various locations. During the course of his travels, he went to US Post Office and picked up several boxes. Agents watched Gonzalez go back to his hotel room. Surveillance was continued and Agents observed Gonzales carrying out several boxes that were being covered up by a jacket.

Juan Carlos Nunez & Clemente Delgado – Sinola Cartel
Central Ohio Bulk Currency Task Force - Columbus, Ohio
28 lbs. of methamphetamine
11 lbs. of heroin
15 stolen firearms
\$74,000 in U.S. Currency



TF Agents received a tip, followed up with all-day surveillance, traffic stops, and search warrants leading up to this seizure.

Nunez was in the country illegally and had been working in the narcotics trade for the last 12 years in the Chicago, IL area. He had been directed by Cartel bosses to travel to Columbus to watch over a stash house.

Delgado was not a U.S. citizen but was in the U.S. legally on a B-2 visa. He resided in Tijuana, Mexico and had numerous, legal, border crossings and was in Columbus to watch over the guy watching over the stash house. Delgado had decision making power on behalf of the cartel.

Legislative Perspective



Representative Jeffery Rezabek



COMBATTING DRUG ADDICTION

OHIO ADDICTION STATISTICS



2,482 accidental
overdoses in 2014

Highest number on record,
up 17.6% from 2013



1 death every 4 hours
in 2013



Increase in Fentanyl
abuse in the U.S. from
2013 to 2014



Increase in amount of
opioid grams/100k
people distributed to
Ohio pharmacies from
1998 to 2011

LEGISLATION

HOUSE BILL 4

ENACTED

- Expands access to naloxone, an overdose reversal drug
- Allows pharmacists to provide patients, or their loved ones, with naloxone without a prescription
- Many Ohio pharmacies have begun stocking the popular naloxone drug known as Narcan

HOUSE BILL 64

ENACTED

- Allocates \$11 million over the biennium to expand the creation of the Mediation Assisted Treatment (MAT) drug court program

HOUSE BILL 110

"GOOD SAMARITAN LAW" - EFFECTIVE SEPT. 2016

- Urges individuals to call 9-1-1 in the event of a drug overdose by providing immunity for minor drug possession offenses and connecting individuals with a treatment system
- Recently, many parents have refrained from calling 9-1-1 for fear that both their child and themselves would be prosecuted

HOUSE BILL 197

PENDING SENATE APPROVAL

- Requires individuals to be 18 or older to purchase cough syrups that contain dextromethorphan.
- *Protects unassuming youth from experimenting with a drug that they do not fully understand the danger of, and that can serve as a gateway to even more harmful substances*

HOUSE BILL 230

EFFECTIVE SEPT. 2016

- Updates and modernizes the laws pertaining to the Ohio Chemical Dependency Professionals Board
- Previously, the law stated specific number of hours and certain content that must be covered in order to obtain a chemical dependency counselor's license
- *Given the current demand for counselors, this bill gives the Chemical Dependency Professionals Board the ability to adapt their criteria to fit the demands of Ohioans struggling with addiction*

HOUSE BILL 421

PENDING SENATE APPROVAL

- Allows pharmacists to administer injections of specific drugs if certain conditions are met
- One drug allowed under the bill is an opioid antagonist – a prescription drug that blocks the effects of opioids used to treat drug addiction
- Expands the number of treatment options to individuals that suffer from drug addiction

HOUSE CONCURRENT RESOLUTION 16

ADOPTED

- Urges the federal government to revise survey measures included in the Hospital Consumer Assessment of Healthcare Providers and Systems that relate to patient pain management
- Supports the use of opiate alternatives



Ohio Legislative Service Commission

Final Analysis

Elizabeth Molnar

Am. Sub. H.B. 4

131st General Assembly
(As Passed by the General Assembly)

- Reps.** Sprague and Rezabek, Gonzales, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, Ginter, T. Johnson, LaTourette, Lepore-Hagan, Ramos, Sears, Schuring, Sykes, Amstutz, Anielski, Antani, Baker, Blessing, Boose, Brenner, Buchy, Burkley, Celebrezze, Cera, Conditt, Craig, Curtin, Derickson, Dever, Dovilla, Driehaus, Duffey, Fedor, Gerberry, Green, Grossman, Hackett, Hall, Hayes, Henne, Howse, G. Johnson, Koehler, Kraus, Kunze, Landis, Leland, Manning, McClain, M. O'Brien, S. O'Brien, Patmon, Patterson, Pelanda, Perales, Phillips, Rogers, Ruhl, Scherer, Sheehy, Slaby, K. Smith, R. Smith, Stinziano, Strahorn, Sweeney, Terhar, Thompson, Vitale, Zeltwanger, Rosenberger
- Sens.** Hottinger, Jones, Tavares, Brown, Hite, Beagle, Bacon, Balderson, Burke, Cafaro, Coley, Eklund, Gardner, LaRose, Lehner, Manning, Obhof, Oelslager, Patton, Peterson, Sawyer, Schiavoni, Seitz, Skindell, Thomas, Uecker, Widener, Williams, Yuko

Effective date: Emergency, July 16, 2015

ACT SUMMARY

NALOXONE

- Allows a physician to authorize one or more individuals to personally furnish naloxone, pursuant to the physician's protocol, to an individual at risk of an opioid-related overdose or to another in a position to assist that individual.
- Permits a physician or board of health to authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription, in accordance with a protocol developed by the State Board of Pharmacy, to an individual at risk of an opioid-related overdose or to another in a position to assist that individual.
- Requires the Pharmacy Board, after consulting with the State Medical Board and Ohio Department of Health, to adopt rules regarding the authority of pharmacists and pharmacy interns to dispense naloxone without a prescription, including rules specifying the applicable protocol.

- Grants each of the following who acts in good faith immunity from civil liability, criminal prosecution, or professional discipline for the actions or omissions of the person to whom naloxone is furnished or dispensed under a physician or Pharmacy Board protocol: a physician, authorized individual, pharmacist, pharmacy intern, or board of health.
- Allows a board of health that is licensed by the Pharmacy Board as a terminal distributor of dangerous drugs to make occasional sales of naloxone at wholesale to a state or local law enforcement agency.

OPIOID TREATMENT PROGRAMS

- Excepts a physician who personally furnishes buprenorphine, as part of an opioid treatment program where buprenorphine (but not methadone) is distributed, from law that limits the amount of controlled substances a physician may personally furnish, if the program meets specified requirements.
- Requires that the Pharmacy Board and the Director of the Department of Mental Health and Addiction Services annually inspect or review certain opioid treatment programs.

CONTENT AND OPERATION

NALOXONE

The drug naloxone, commonly known by the brand name Narcan, can reverse the effects of an opioid overdose.¹ It counteracts the respiratory depression caused by the overdose, allowing the victim to breathe normally.²

Continuing law establishes for naloxone a limited exception to the requirement that a licensed health professional personally examine the intended recipient of a prescribed drug. A physician (including a podiatrist) or an advanced practice registered nurse (APRN) or physician assistant (PA) authorized to prescribe drugs may personally furnish a supply of naloxone or issue a prescription for the drug to a family member, friend, or another in a position to assist an individual who there is reason to believe is at

¹ U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection*, available at www.nlm.nih.gov/medlineplus/druginfo/meds/a612022.html.

² United Nations Office on Drugs and Crime and World Health Organization, *Opioid overdose: preventing and reducing opioid overdose mortality*, available at www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1.



risk of experiencing an opioid-related overdose.³ Physicians, APRNs, PAs, and others who act in good faith in accordance with this law are not subject to criminal prosecution. Physicians, APRNs, and PAs acting in good faith are also immune from civil liability and professional discipline for the actions or omissions of the individual to whom the naloxone is furnished or the prescription is issued.⁴

Naloxone access

The act permits a physician to authorize one or more individuals to personally furnish naloxone in accordance with a protocol the physician establishes. It also allows a physician or a local board of health to authorize one or more pharmacists and pharmacy interns to dispense naloxone without a prescription in accordance with a protocol established by the State Board of Pharmacy.⁵

Physician-authorized individuals

The act permits a physician who establishes a protocol that meets specified requirements to authorize one or more individuals to personally furnish a supply of naloxone to either of the following:⁶

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist such an individual.

The authorized individual must comply with the physician's protocol and must instruct the individual to whom the naloxone is furnished to summon emergency services as soon as practicable either before or after administering the drug.⁷

The act specifies that the actions of an authorized individual in personally furnishing naloxone in accordance with a physician protocol do not fall within the legal definition of pharmacy or constitute the unauthorized practice of pharmacy.⁸

³ R.C. 4723.488, 4730.431, and 4731.94.

⁴ R.C. 2925.61, 4723.488, 4730.431, and 4731.94.

⁵ R.C. 4729.44(B) and 4731.941.

⁶ R.C. 4731.941(A)(1).

⁷ R.C. 4731.941(B).

⁸ R.C. 4729.29.



Physician protocol

A protocol established by a physician must be in writing and include the following:⁹

- (1) A description of the clinical pharmacology of naloxone;
- (2) Precautions and contraindications concerning the furnishing of naloxone;
- (3) Any limitations the physician specifies concerning the individuals to whom naloxone may be furnished;
- (4) The naloxone dosage that may be furnished and any variation in the dosage based on circumstances specified in the protocol;
- (5) Labeling, storage, record-keeping, and administrative requirements;
- (6) Training requirements that must be met before an individual will be authorized to furnish naloxone;
- (7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished.

Pharmacists and pharmacy interns

The act permits a pharmacist, or a pharmacy intern supervised by a pharmacist, to dispense naloxone without a prescription.¹⁰ For this to occur, a physician or a local board of health must have authorized the use of a protocol established by the Pharmacy Board.¹¹ In accordance with the protocol, the pharmacist or pharmacy intern may dispense naloxone without a prescription to either of the following:¹²

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other person in a position to assist such an individual.

⁹ R.C. 4731.941(C).

¹⁰ R.C. 4729.44(B).

¹¹ R.C. 3707.56, 4729.44(G), and 4731.942.

¹² R.C. 4729.44(B).



A pharmacist or pharmacy intern who dispenses naloxone must instruct the individual to whom it is dispensed to summon emergency services as soon as practicable either before or after administering the drug.¹³ A pharmacist may document the dispensing of naloxone by the pharmacist or pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.¹⁴

The act specifies that it does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for naloxone.¹⁵

Pharmacy Board rules and protocol

The act requires the Pharmacy Board to adopt rules implementing its provisions authorizing the dispensing of naloxone without a prescription. The rules must specify a protocol under which pharmacists and pharmacy interns may dispense naloxone without a prescription. Before adopting these rules, the Board must consult with the State Medical Board and the Ohio Department of Health. The rules must be adopted in accordance with the Administrative Procedure Act.¹⁶

Conditions for authorization by boards of health

Under the act, a board of health may authorize pharmacists and pharmacy interns to dispense naloxone without a prescription in accordance with the Pharmacy Board's protocol, if both of the following conditions are met: (1) the authorization is through a physician serving as the board's health commissioner or medical director and (2) the pharmacists and pharmacy interns work in the board's jurisdiction.¹⁷

The act applies to a board of health of a city or general health district and to an authority having the duties of a board of health in a city that has not established a board.¹⁸

Immunity

Each of the following who acts in good faith and in accordance with the act is not liable for or subject to damages in any civil action, prosecution in any criminal

¹³ R.C. 4729.44(C).

¹⁴ R.C. 4729.44(D).

¹⁵ R.C. 4729.44(E).

¹⁶ R.C. 4729.44(G) and Chapter 119.

¹⁷ R.C. 3707.56(B).

¹⁸ R.C. 3707.56(A).



proceeding, or professional discipline for any action or omission of the person to whom the naloxone is furnished or dispensed without a prescription:

- (1) A physician;
- (2) A physician-authorized individual;
- (3) A pharmacist or pharmacy intern;
- (4) A board of health.¹⁹

The act makes two changes to the law governing immunity from criminal prosecution for those in a position to assist an individual at risk of an overdose. It allows a family member, friend, or other person to also obtain naloxone from (1) an individual authorized by a physician to personally furnish the drug or (2) a pharmacist or pharmacy intern authorized by a physician or board of health to dispense it without a prescription. With respect to summoning emergency services, it specifies that the individual attempt to do so as soon as practicable before or after administering naloxone.²⁰

Naloxone administration

Continuing law authorizes a physician or an APRN or PA with prescriptive authority to personally furnish a supply of naloxone or issue a prescription for the drug to a family member, friend, or other individual in a position to assist a person who there is reason to believe is at risk of experiencing an opioid-related overdose. Under prior law, this authorization applied only to naloxone administered intranasally or through an autoinjector. The act eliminates the intranasal and autoinjector limitations; as a result, the foregoing prescribers may furnish or prescribe to the individual any form of naloxone.²¹

Sales of naloxone to law enforcement agencies

The act allows a licensed terminal distributor of dangerous drugs to make occasional sales of naloxone at wholesale to a state or local law enforcement agency if the terminal distributor is any of the following:

- (1) A board of health of a city or general health district;

¹⁹ R.C. 4729.44 and 4731.941.

²⁰ R.C. 4723.488, 4730.341, and 4731.94.

²¹ R.C. 4723.488, 4730.431, and 4731.94.



- (2) An authority having the duties of a board of health;
- (3) A health department of such board or authority.²²

It also clarifies that when a registered wholesale distributor of dangerous drugs sells naloxone at wholesale to a law enforcement agency or its peace officers, the registered wholesaler does not need to obtain from the agency or officer a certificate indicating that the purchaser is licensed as a terminal distributor of dangerous drugs.²³ Under continuing law not modified by the act, a registered wholesaler may sell naloxone at wholesale to law enforcement agencies and their peace officers.²⁴

Definition of "prescription"

Ohio law defines "prescription" as a written, electronic, or oral order for drugs or combinations of drugs to be used by a particular individual, issued by a prescriber. For purposes of the act, "prescription" also includes a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.²⁵

OPIOID TREATMENT PROGRAMS

Limits on personally furnishing controlled substances

Continuing law limits the amount of controlled substances a prescriber may personally furnish to the following:²⁶

- In any 30-day period, 2,500 dosage units for all of the prescriber's patients taken as a whole;
- In any 72-hour period, the amount an individual patient needs for that period.

²² R.C. 4729.51.

²³ R.C. 4729.60(A).

²⁴ R.C. 4729.51(B)(1)(n).

²⁵ R.C. 4729.01(H).

²⁶ R.C. 4729.291(C).



Buprenorphine exceptions

Buprenorphine furnished to patients to treat drug dependence or addiction as part of an opioid treatment program is not counted in determining whether a prescriber has exceeded the limits on personally furnished controlled substances if the opioid treatment program (1) is certified by the U.S. Substance Abuse and Mental Health Services Administration (SAMSHA) and (2) distributes both buprenorphine and methadone.²⁷

The act modifies the foregoing exception by requiring that the opioid treatment program not only be SAMSHA-certified, but also be licensed as a terminal distributor of dangerous drugs by the Pharmacy Board.²⁸

The act also establishes a new exception from the controlled substances limits for an opioid treatment program that has physicians who personally furnish buprenorphine but not methadone. For this exception to apply, the program must meet all of the following conditions:

(1) Be accredited by a national accrediting organization approved by SAMHSA;

(2) Maintain a copy of the physician's signed and dated written order for buprenorphine in the record of each patient to whom the drug was administered or personally furnished;

(3) Be certified by the Ohio Department of Mental Health and Addiction Services (ODMHAS) regarding personally furnishing buprenorphine.²⁹

ODMHAS review

The act requires that the ODMHAS Director conduct annual on-site reviews of opioid treatment programs whose physicians (1) personally furnish buprenorphine but not methadone and (2) are excepted from the law that limits the amount of controlled substances a physician may personally furnish.³⁰

The act authorizes the ODMHAS Director to inspect both pharmacy and patient treatment records as part of the annual review. If the Director has reason to believe that

²⁷ R.C. 4729.291(D).

²⁸ R.C. 4729.291(D)(2).

²⁹ R.C. 4729.291(D)(2)(b).

³⁰ R.C. 5119.372.



a violation of local, state, or federal drug law has occurred, the act requires the Director to report that information to the Pharmacy Board.³¹

Associated with authorizing the Director to inspect pharmacy records, the act requires that persons who must keep files or records under Ohio's controlled substances law³² make them available for inspection and copying by an employee designated by the Director, upon that employee's written request. The documents must be made available at all reasonable hours and the ODMHAS employee must be given an opportunity to check the documents' accuracy.³³

The act specifies that the Director's authority to conduct an on-site review of a community mental health services provider or community addiction and mental health services provider for cause does not affect the Director's duty to also conduct the annual review of a community mental health services provider or community addiction and mental health services provider that is an opioid treatment program.³⁴

The act authorizes the ODMHAS Director to adopt rules, in accordance with the Administrative Procedure Act, implementing its provisions regarding on-site reviews.³⁵

Pharmacy Board inspection

The act requires that the Pharmacy Board also conduct annual on-site inspections of opioid treatment programs whose physicians (1) personally furnish buprenorphine but not methadone and (2) are excepted from the law that limits the amount of controlled substances that a physician may personally furnish.³⁶ Continuing law authorizes the Pharmacy Board to inspect pharmacy and other drug-related records.³⁷

³¹ R.C. 3719.13 and 5119.372.

³² R.C. Chapter 3719.

³³ R.C. 3719.27(B).

³⁴ R.C. 5119.371(C)(2).

³⁵ R.C. 5119.372 and Chapter 119.

³⁶ R.C. 4729.292.

³⁷ R.C. 3719.13 and 3719.27.



HISTORY

| ACTION | DATE |
|---|----------|
| Introduced | 01-28-15 |
| Reported, H. Health & Aging | 02-25-15 |
| Passed House (98-0) | 03-04-15 |
| Reported, S. Health & Human Services | 05-27-15 |
| Passed Senate (33-0) | 06-16-15 |
| House concurred in Senate amendments (98-0) | 06-24-15 |

15-HB4-131.docx/ks



**State of Ohio Board of Pharmacy and Ohio
Medical Board Perspectives**



Cameron McNamee
Jonithon LaCross



Ohio's Opioid Epidemic: Legislation, Rule-Making and Enforcement

Cameron McNamee
Director of Policy and Communications

Goals and Objectives

- Briefly review trends in opioid and other controlled substance prescribing and drug overdose data.
- Review new laws and regulations for the use of OARRS.
- OARRS enforcement actions.
- New laws for the distribution of naloxone.
- Ohio's Opiate MBR – Senate Bill 319



Drug Overdose Statistics

- 3,050 Ohioans died of an unintentional drug overdose in 2015.
 - 21.9% involved prescription opioids (narcotic painkillers).
 - 16.5% involved benzodiazepines (anti-anxiety).
- Of those, 2,265 (74.2%) of those had a record of receiving a prescription controlled substance.



Heroin and Prescription Opioids

- A study of young, urban injection drug users interviewed in 2008 and 2009 found that 86 percent had used opioid pain relievers nonmedically prior to using heroin, and their initiation into nonmedical use was characterized by three main sources of opioids: family, friends, or personal prescriptions.
- Of people entering treatment for heroin addiction who began abusing opioids in the 1960s, more than 80 percent started with heroin. Of those who began abusing opioids in the 2000s, 75 percent reported that their first opioid was a prescription drug.



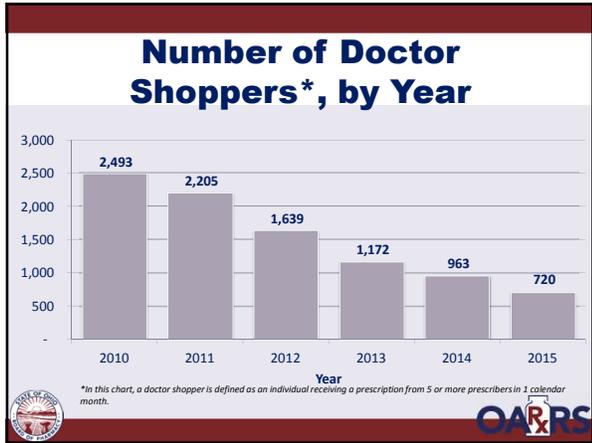
Opioids Dispensed to Ohio Patients for Pain, by Year

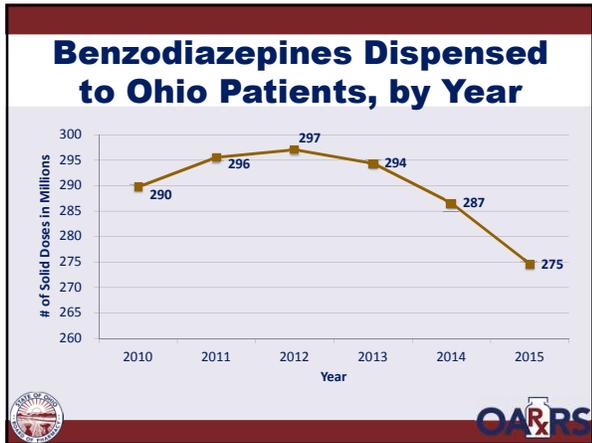


Opioids Dispensed to Ohio Patients for Pain, by Year

In 2015, enough pills were dispensed to provide 59 pills to every Ohio resident.







Ohio Automated Rx Reporting System (OARRS)

- Ohio's Prescription Monitoring Program (PMP)
 - A system which collects prescription information from pharmacies, stores it in a secure database, and produces patient-specific reports for healthcare professionals and law enforcement officers.
 - 49 states, the District of Columbia, and the territory of Guam have a PMP.
 - Missouri is the only state without a PMP.

What is OARRS?

- Web-based system authorized by ORC 4729.75.
- In operation since October 2, 2006.
- Collects approximately 25 million Schedule II-V controlled substance transactions each year.
- All pharmacies licensed by OSBP and prescribers who personally furnish controlled substances (except veterinarians) must submit data within 24 hours.
- VA facilities report outpatient prescriptions to OARRS within 24 hours.



What is OARRS?

- 3 years of identifiable patient data maintained (ORC 4729.82).
- De-identified information kept for research purposes.
- More than 79,000 patients' prescription reports are queried daily.
- 99.9% of reports are generated automatically within 3-4 seconds.



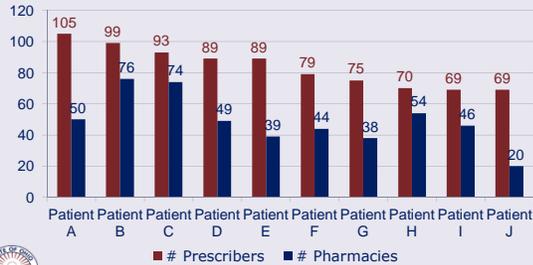
Why OARRS?

- OARRS is designed to monitor this information for suspected abuse or diversion (i.e., the transfer of legally prescribed drugs for illegal use).
- Provides a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history.
- This information can help prescribers and pharmacists identify high-risk patients who would benefit from early interventions.



Why OARRS?

Top 10 "Doctor Shoppers" 2006



Required Use Of OARRS

- House Bill 341 (2014) – 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 days 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.
- Law change allows OARRS report to be included in patient's medical record.

www.pharmacy.ohio.gov/341FAQ



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 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



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



Monitoring the Data

Board Required to Review the System for Potential Violations of Ohio's Drug Laws (ORC 4729.81)

- Improper Prescribing
 - High instances of known drug cocktails (i.e. opioids and benzodiazepines)
 - Prescribing outside of scope of practice
 - Prescribing levels statistically outside of "norm"
- Internet Pharmacies
- Doctor Shopping

- ORC Chapter 2925: DRUG OFFENSES



Drug Overdose Investigations

- Investigations of prescribers linked to drug overdose decedents has also increased demands on Board investigators.

- In 2014, OARRS staff identified 85 prescribers who prescribed controlled substances to five or more of the overdose decedents:
 - Four cases have been referred to the Board of Pharmacy for administrative action.
 - Two have been referred to county prosecutor's offices for possible criminal charges.
 - One physician has already agreed to permanently surrender their medical license.

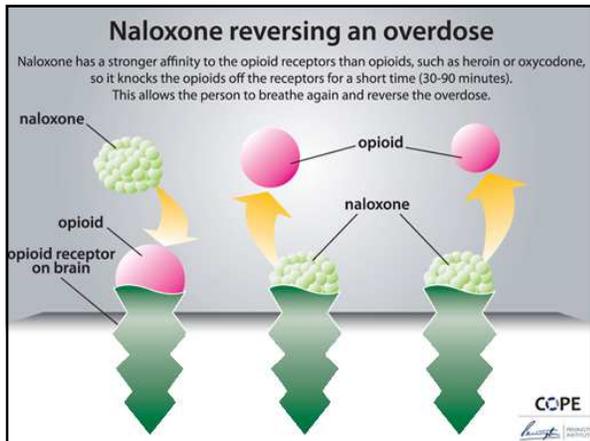


About Naloxone

- Naloxone (Narcan®) is a safe medication that can reverse an overdose that is caused by prescription opioids, heroin and fentanyl.

- When administered during an overdose, naloxone blocks the effects of opioids on the brain and can restore breathing in a matter of minutes.





Naloxone – HB 4

HB 4 (Rezabek & Sprague) 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.
- Permits a local board of health, through a physician serving as the board's health commissioner or medical director, to authorize the protocol for pharmacists and pharmacy interns working in that board of health's jurisdiction.
- Permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol.

Naloxone – HB 4

- Naloxone can be personally furnished or dispensed to the following:
 1. An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or
 2. A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

www.pharmacy.ohio.gov/naloxone

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.
- The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for a number of pharmacy locations.
- **1,374 Ohio retail pharmacies (65%) in 85 counties offer naloxone without a prescription.**



Naloxone at Pharmacies

www.pharmacy.ohio.gov/stopoverdose



**STATE OF OHIO
BOARD OF PHARMACY**

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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: All

| License Number | Business Name | Phone | Address | County |
|----------------|--------------------|----------------|--|--------|
| 020961050 | CVS/PHARMACY #4445 | 4199910010 | 2620 W. BREESE RD. LIMA, OH 45805 | 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 | 4192231200 | 2366 HARDING HWY LIMA, OH 45805 | Allen |

Opiate Mid-Biennium Review (MBR) – SB 319

- Technician registration.
 - More than one-third (36 percent) of all drug theft cases investigated by the Board between 2013 and 2015 involved a pharmacy technician.
 - Ohio is only one of eight states that does not license, register or certify pharmacy technicians (Colorado, Delaware, Hawaii, Michigan, New York, Pennsylvania & Wisconsin).
 - Uniform background checks.
- 90 day supply limit on dispensing opioid analgesic Rx (void after 14 days).



Opiate Mid-Biennium Review (MBR) – SB 319

- Remove all exceptions for TDDD if controlled substances are on-site.
 - Prescribers at 1,035 exempted locations ordered more than 6.5 million doses of controlled substances.
- Naloxone on-site without TDDD for emergency use.
- Licensing of suboxone clinics (30+ patients).



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Opioids and Pain Medicine ... a Regulatory Perspective

Jonithon LaCross
Director of Public Policy & Government Affairs
State Medical Board of Ohio



Legislation in effect

| | |
|-------------------------|--|
| HB93 2011 | Physician ownership and licensure of pain management clinics required |
| SB301 2013 | Medical Board allowed to inspect pain clinics; Medical Board may take action if doctor practices at or owns an unlicensed pain management clinic |
| HB170 2014 | Naloxone Access – Allows Prescriptions to family members or others to assist individual at risk of opioid overdose |
| HB314 2014 | Prescribing Opioids to Minors - Start Talking! Form required |
| HB341 2014 & 2015 | Ohio Automated RX Reporting System (OARRS) License renewal attestation required 1-1-15 Check OARRS before prescribing an opioid or benzodiazepine 4-1-15 |



Medical Board Rules

- 4731-11-11 Standards and Procedures for Review of OARRS “Ohio Automated Rx Reporting System”
- 4731-21-02 Chronic (intractable) Pain Rules
- 4731-29-01 Standards and Procedures for Operation of a Pain Management Clinic
- 4731-11-12 Office Based Opioid Treatment



OARRS Access Required

As of January 1, 2015, Physicians, Advanced Practice Registered Nurses, and Physician Assistant's who prescribe opioid analgesics or benzodiazepines have to certify on their license renewal that they have access to OARRS

Required by HB341



OARRS Checks

- Prescribers required to request OARRS information that covers at least the previous 12 months before initially prescribing an opioid analgesic or benzodiazepine
- If treatment continues longer than 90 days, the prescriber has to check OARRS at least once every 90 days until the course of treatment ends
- Prescriber has to document in patient record that OARRS report was assessed and reviewed



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OARRS Check Exceptions

Unless a physician believes a patient may be abusing or diverting drugs OARRS check not required if a drug is prescribed:

- For not more than 7 days
- For treatment of cancer pain or condition associated with cancer
- To hospice patient in a hospice program
- To treat acute pain from surgery, invasive procedure, or delivery
- In a hospital, nursing home, or residential care facility

Rule 4731-11-11 (G); Effective 12-31-2015



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Red Flags – Prescription Drug Abuse

Look for signs of drug seeking behavior

- Appearing impaired or overly sedated during office visit
- Traveling with others to office; requesting controlled substance prescriptions
- Traveling abnormally long distances to the physician's office

Listen for signs of drug seeking behavior

- Comments about sharing medications with friends or family
- Reports of lost prescriptions; early refill requests
- Refusing drug screen

Check for signs of drug seeking behavior

- Drug screen results inconsistent with drugs on treatment plan
- History of chemical abuse or dependency; illegal drug use
- Receiving abused drugs from multiple prescribers



7

Office Based Opioid Treatment

- Medical Board rule 4731-11-12, Ohio Administrative Code - effective January 31, 2015
- Rule provides treatment parameters for physicians treating opiate addiction with Schedule III, IV or V narcotics specifically approved by the FDA for this purpose
- Currently, buprenorphine products are the only approved drugs



Practice Guidelines

- Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain - 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" – May 2013
- Joint Regulatory Statement - Prescription of Naloxone to High-Risk Individuals and Third Parties who are in a Position to Assist an Individual who is Experiencing Opioid-Related Overdose – updated November 2015
- Guidelines for Management of Acute Pain Outside of Emergency Departments – January 2016



80 MED Guidelines

Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" - approved May 2013

Applies to providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than 3 continuous months



Action Steps for 80 MED "trigger point"

- Reestablish informed consent
- Use 4 A's to review functional status
 - activities of daily living; adverse effects; analgesia & aberrant behavior
- Review patient's progress toward treatment objectives
- Run OARRS report
- Consider patient pain treatment agreement
- Reconsider having patient evaluated by specialist



Naloxone Regulatory Statement

Prescription of Naloxone to High-risk Individuals and Third Parties who are in a Position to Assist an Individual who is Experiencing an Opioid-related Overdose

Jointly adopted by Medical Board, Nursing Board and Pharmacy Board - updated November 2015

- Addresses factors to consider before prescribing Naloxone to a patient, or a family member, friend, or other person who can assist a person who may be at risk of an opioid-related overdose



Acute Pain Prescribing Guidelines

Guidelines for the Management of Acute Pain Outside of Emergency Departments

- Developed by Governor's Cabinet Opiate Action Team (GCOAT) released January 19, 2016
- Guidelines supplement – not replace – clinical judgment
- Acute pain normally fades with healing, is related to tissue damage and significantly alters a patient's typical function
- Acute pain is expected to resolve within days to weeks

Link: opioidprescribing.ohio.gov



Prescribing Opioids to Minors

Prescribers must take the following steps before prescribing opioids to minors

- Assess** for mental or substance abuse disorders and whether treatment included prescription drugs
- Discuss** with the minor patient and the parent, guardian or other authorized adult
 - Risks of addiction and overdose associated with the opioid
 - Increased risk of addiction in patients with mental and substance abuse disorders
 - Dangers of taking opioids with benzodiazepines, alcohol or other CNS depressants
- Obtain** written consent from the minor's parent, guardian or other authorized adult on the Start Talking! Form



med.ohio.gov



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 Ohio | State Medical Board of Ohio

Substance Abuse Education



Kristine Carson

Substance Abuse and Mental Health

Kris Carson, MA, LPC
Ohio Lawyers Assistance Program

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What is OLAP?

- In 1979, a group of lawyers and judges in alcohol recovery met in the chambers of then Franklin County Common Pleas Judge Craig T. Wright. This group formed the OSBA Lawyer Assistance Committee
- As the number seeking help increased, the Ohio Supreme Court began to change discipline and admissions rules to take "recovery" into account
- In 1991, the OSBA incorporated Ohio Lawyers Assistance Program, moving it from a volunteer group to a non-profit agency. In 2002, clinicians were added to the staff to address clients' mental health concerns

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What is OLAP?

- OLAP is a non-profit agency funded by the Ohio Supreme Court to help lawyers, judges and law students who have substance abuse, chemical dependency, process addictions, and mental health concerns
- Main office is located in Columbus
- Mission: Educate the profession about substance abuse, chemical dependency and mental health disorders, perform interventions, conduct assessments and provide recommendations, as well as, provide support and monitoring

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Research

- A 1990 American Bar Association survey showed:
 - One-third of practicing lawyers suffer from depression at some time, making lawyers 5 to 10 times more likely than other professionals to suffer from major depressive disorder
 - 18%-20% of lawyers suffer from alcoholism, compared to 10% of the general population. The rate rises to 25% after 20 years of practice
 - Lawyers are twice as likely as other professionals to commit suicide

(Benjamin, Darling, & Sales, 1990)

Addiction

- Addiction is a primary, chronic neurobiological disease with genetic, psychosocial, and environmental factors
- Characterized by one or more of the following behaviors:
 - Inability to abstain or control use
 - Diminished ability to recognize problems related to use
 - Dysfunctional emotional response
 - Cycles of relapse and remission
 - Chronic, progressive disease that can result in disability or premature death without treatment

American Society for Addiction Medicine (ASAM)

DSM 5 Criteria: Substance Use Disorder

- Using more or longer than intended
- Desire or unsuccessful efforts to cut down
- Great deal of time spent to obtain, use, recover
- Craving or a strong desire to use,
- Recurrent problematic use that negatively impacts work, school, or home
- Continued use despite social or interpersonal problems caused or exacerbated by use
- Important social, occupational, recreational activities given up or reduced due to use
- Continued use in situations in which it is physically hazardous
- Continued use although use exacerbates a psychological/physical problem
- Tolerance
- Withdrawal

Alcohol

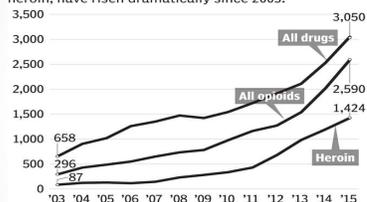
- College Alcohol Study (CAS) conducted by the Harvard School of Public Health define binge drinking as five drinks for men and four drinks for women on a single occasion within the past two weeks
- The 5/4 definition is consistent with findings that consumption at or above this level increases risk for serious alcohol-related problems such as vandalism, fights, injuries, drunk driving, and arrests, as well as the associated negative health, social, economic, or legal consequences

Opioids

- Defined as an opium-like compound that binds to one or more of the three opioid receptors of the body
- Opioids are used to relieve pain by reducing intensity of pain signals reaching the brain. Opioids affect brain areas controlling emotion, which diminishes the effects of a painful stimulus. Medications that fall within this class include hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), morphine (Kadian, Avinza), codeine, and related drugs. Heroin and opium are illicit opiates.
- Physical dependence is a *normal* adaptation to chronic exposure. Withdrawal from opiate use may include symptoms that include restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, cold flashes with goose bumps and involuntary leg movements.
- Overdose: relapse following abstinence is common and dangerous.
- Naloxone: approved by the FDA to prevent opiate overdoses.
- Buprenorphine is used in medication-assisted treatment (MAT) to help people reduce or quit their use of heroin or other opiates. Unlike methadone, buprenorphine can be prescribed or dispensed in a physician's office.

Overdose deaths in Ohio

Overdose deaths caused by opioids, and specifically heroin, have risen dramatically since 2003.



*Individual drugs do not add up to the total deaths because more than one drug was listed for the cause of death in some cases.
Source: Ohio Department of Health

GATEHOUSE MEDIA

Substance Abuse

- Personality characteristics that may be linked to substance abuse
 - Perfectionism
 - Pessimism
 - Independence
 - Competitiveness
- Job-related characteristics that may be linked to substance abuse
 - Social influences in the work environment
 - Heavy workloads
 - Stress associated with working with clients
 - Co-occurring mental health diagnoses

Symptoms of Depression

- Persistent low mood
- Feeling hopeless, guilty, worthless
- Sleep disturbances
- Eating disturbances
- Loss of interest in enjoyable activities
- Difficulty concentrating or making decisions
- Fatigue
- Thoughts of suicide or death

Symptoms of a Panic Attack

- Palpitations or accelerated heart rate
- Sweating
- Trembling or shaking
- Shortness of breath or smothering sensation
- Chest pain or discomfort
- Nausea or abdominal distress
- Feeling dizzy or light-headed
- Chills or heat sensations
- Numbness or tingling sensations
- Fear of losing control or "going crazy"
- Fear of dying

When to call OLAP

- More than two weeks
- DUIs or any legal history related to a substance
- Significant mental health diagnosis
- Call sooner rather than later

Sources

- Benjamin, G. A. H., Darling, E. J., & Sales, B. "The Prevalence of Depression, Alcohol Abuse, and Cocaine Abuse among United States Lawyers." *International Journal of Law and Psychiatry* 13 (1990): 233-46. Print.
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