

Universal Precautions

Preventing Misuse and Diversion of Medications



*Balancing Safety with Effective Symptom
Management in the Context of Serious Illness*

Presenters:

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Ohio's Hospice Inc.

Hospice of Central Ohio

Palliative Care of Central Ohio

Today's Discussion

Describe the current epidemic of drug misuse and diversion and how it compels providers to provide effective management of scheduled medications

Describe the state and federal regulations with which medication protocols and policies must be compliant

Describe the components of an effective toolkit for medication management in serious illness care and techniques for proper medication disposal

Describe how adopting a policy of Universal Precautions for medication management improves safety, compliance and engagement for patients, families and staff

Opioid Crisis continues



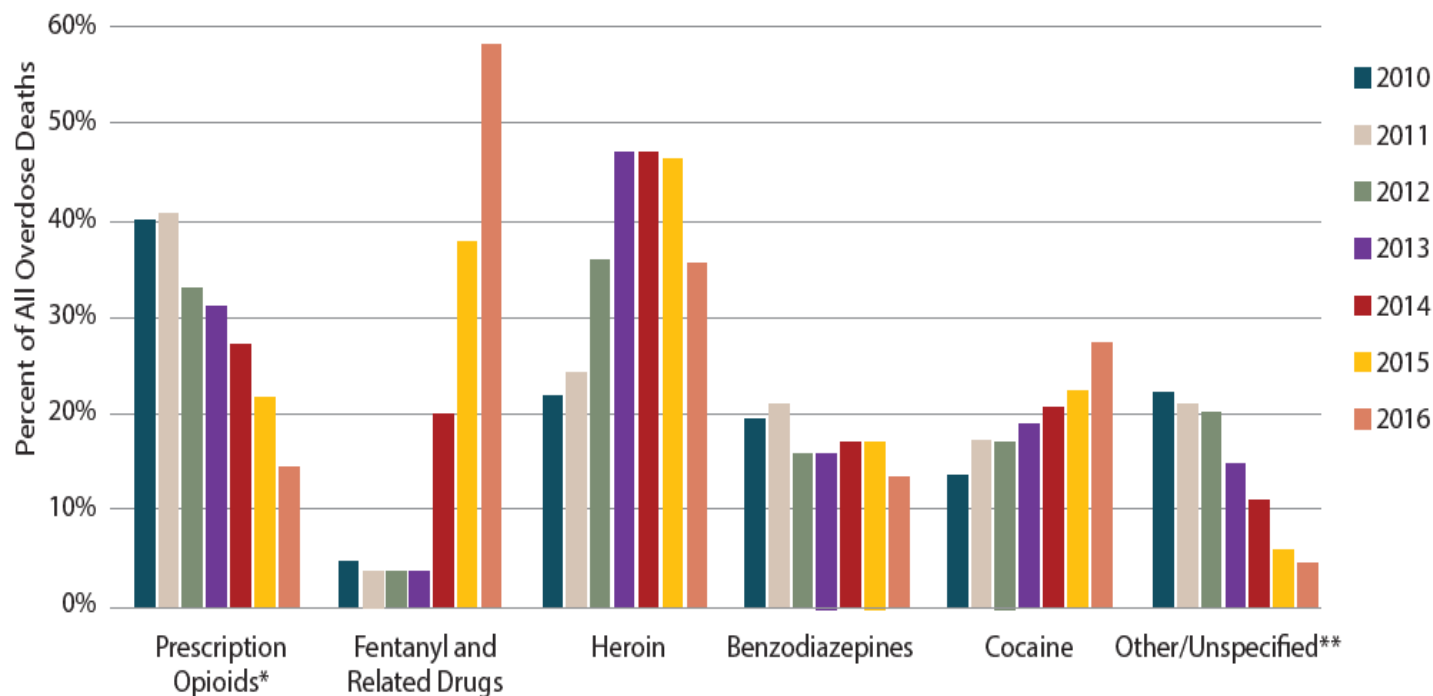
Recognized as a national crisis in the early 2000s with 40% of all unintentional opioid deaths being connected to prescription opioids by 2010

In 2017 there were 4,854 opioid related deaths in Ohio. 20% increase since 2016

13 people per day

2017 Ohio ranked third in the top 4 states in regards to deaths due to drug overdose

Figure 2. Percentage of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, 2010-2016



Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.

Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).

* Excludes deaths involving fentanyl and related drugs.

** No specific drug was identified.

Where are the drugs?

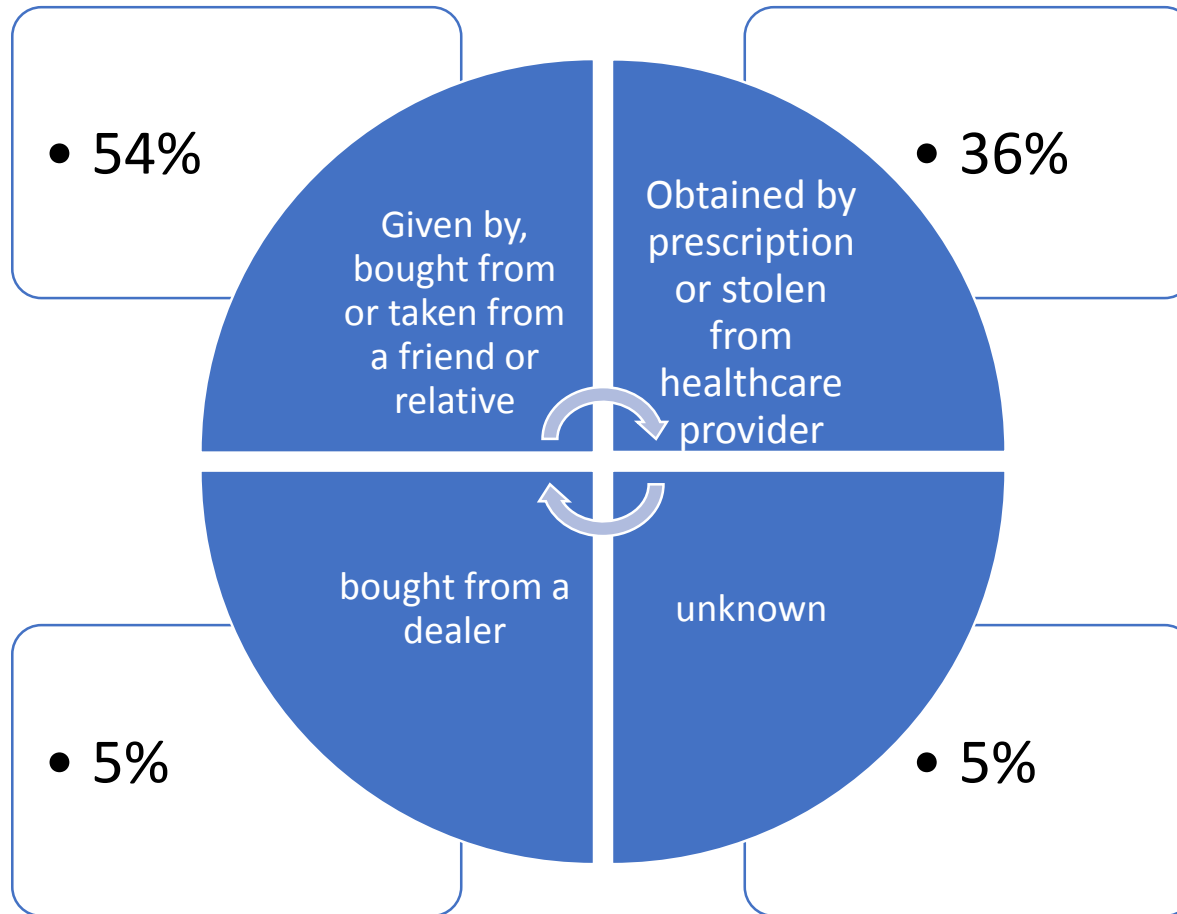
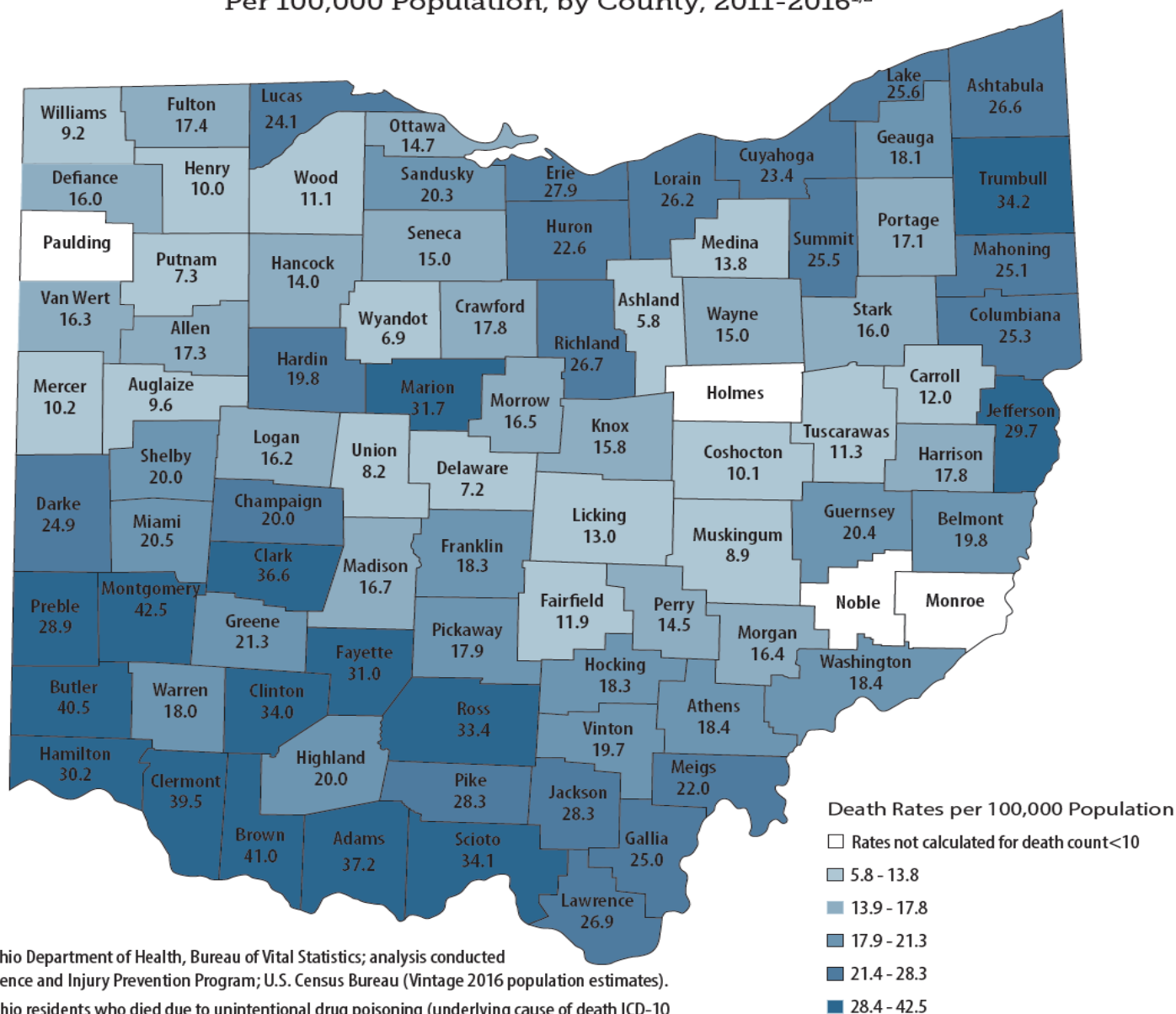


Figure 9. Average Age-Adjusted Unintentional Drug Overdose Death Rate
Per 100,000 Population, by County, 2011-2016^{1,2}



¹ Sources: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program; U.S. Census Bureau (Vintage 2016 population estimates).

² Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).

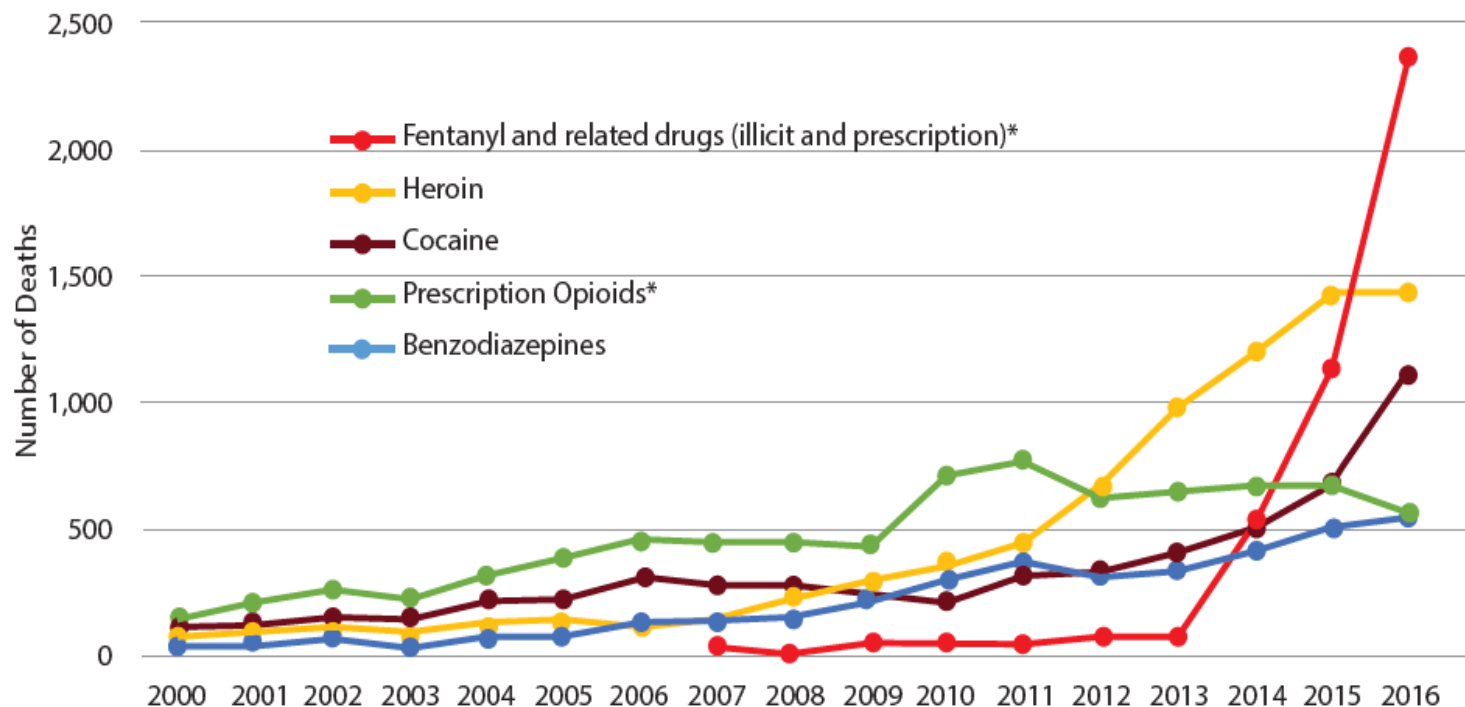
Rate suppressed if < 10 total deaths for 2011-2016.

Prescription related opioid deaths peaked in 2011 and since then have declined by 22%



Unintentional Overdoses Involving Select Drugs and Age-Adjusted Death Rate

Figure 7. Number of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, Ohio, 2000-2016



Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.

Multiple drugs are usually involved in overdose deaths. Individual deaths may be reported in more than one category.

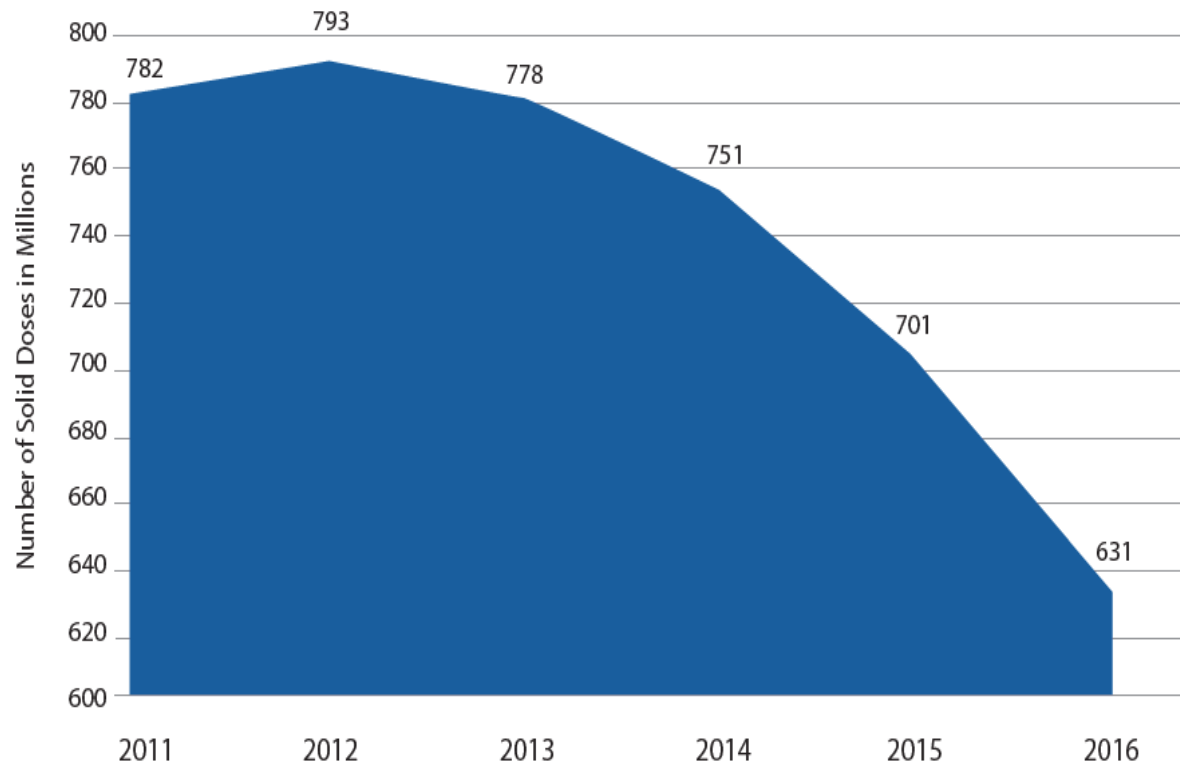
Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).

* Excludes deaths involving fentanyl and related drugs.



Between 2012 and 2016, the total number of opioids dispensed to Ohio patients decreased by 162 million doses or 20.4%

Figure 6. Opioid Solid Doses Dispensed to Ohio Patients, by Year, 2011-2016



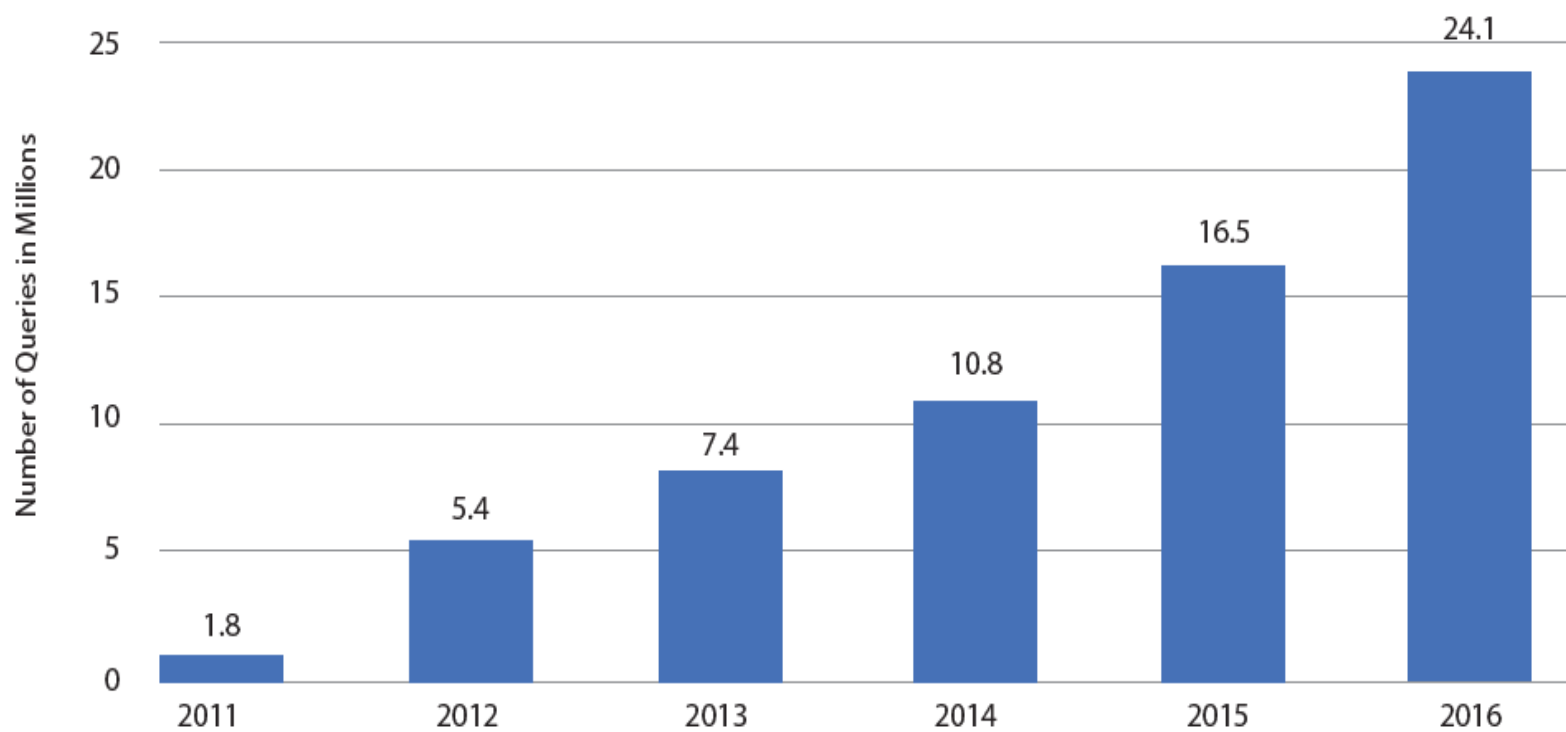
Source: State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System.

Ohio Physicians are leading the way

*Ohio Automated Rx Reporting System with an increase from
1.8 million views in
2011 to 24.1 million views in 2016—
far more than any other state*



Figure 5. Prescriber OARRS Queries, Ohio, 2011-2016



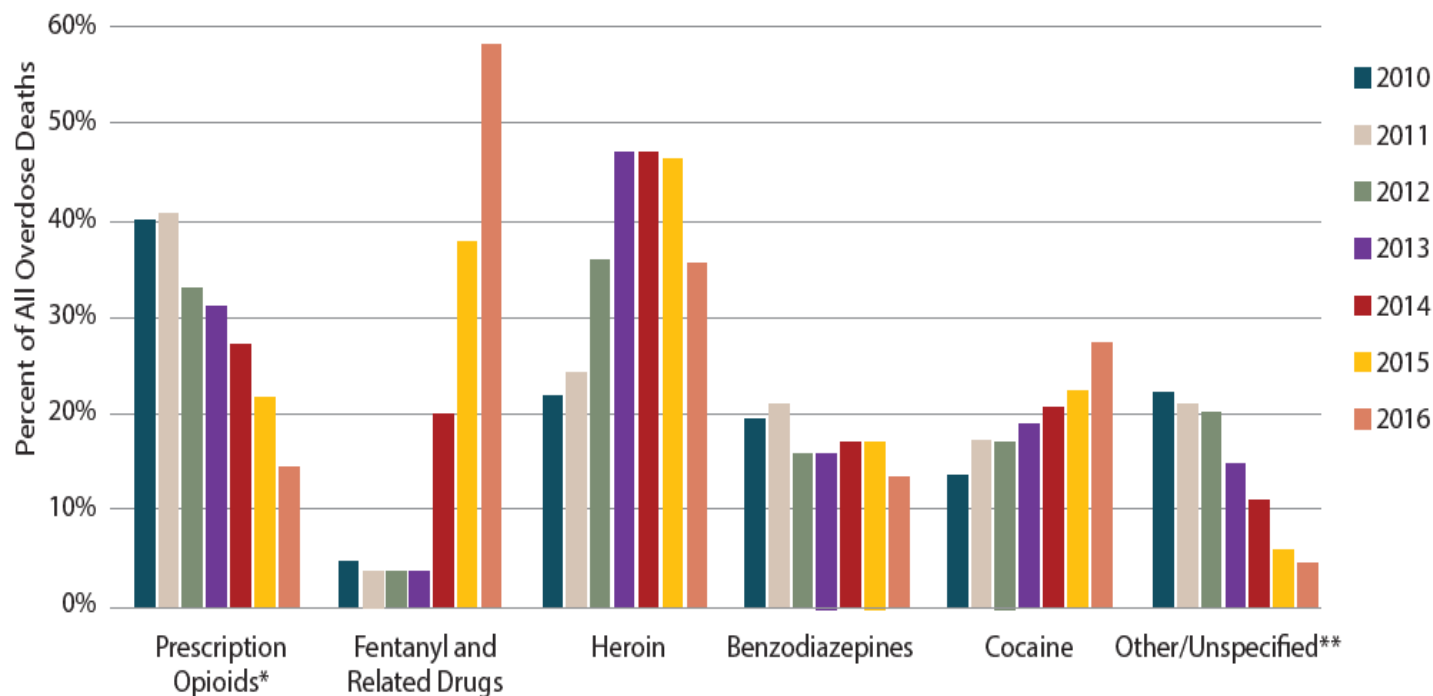
Source: State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System.



*Unfortunately people are now dying
from*

Fentanyl, Heroin and Cocaine
more than ever before.

Figure 2. Percentage of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, 2010-2016



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* Excludes deaths involving fentanyl and related drugs.

** No specific drug was identified.

Conundrum for Hospices:

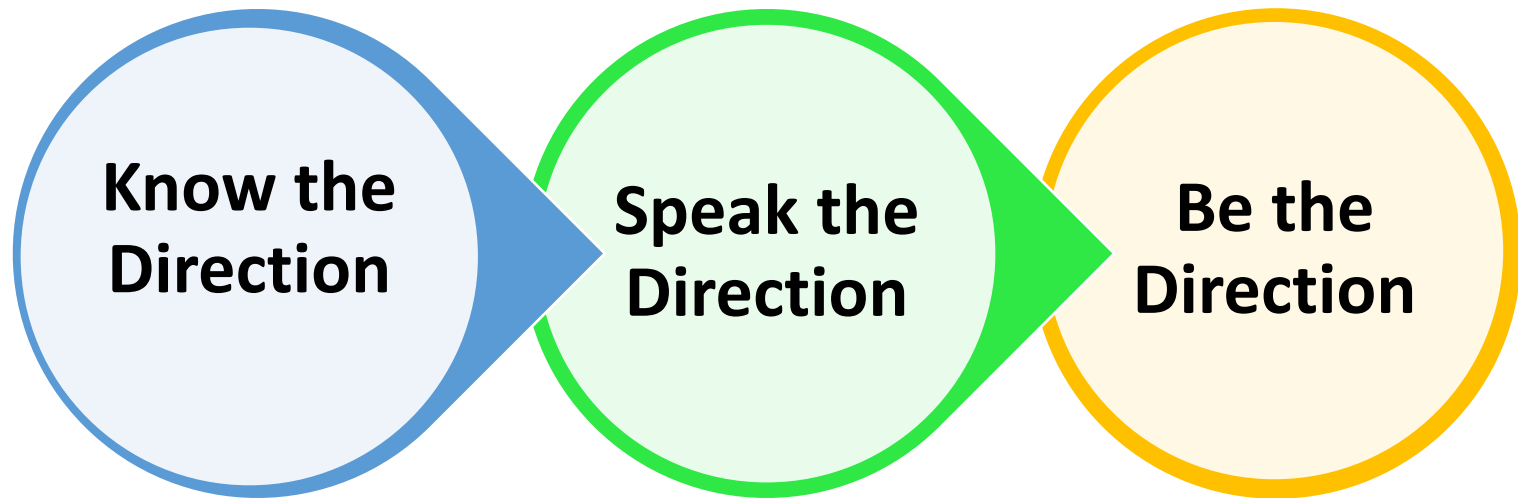
“Twin Serpents in the Caduceus”

To expertly
manage the
symptoms of our
seriously ill
patients...



.....not contribute to
the rising number of
diverted opioids
available on the
streets.

Part of the process
Part of the solution
Responsible and safe prescribing



Federal vs. State Regulation



Although federal laws and regulations set some parameters for pain management, it is at the state level where the most important policies reside.”

“State legislators and regulators have tremendous ability to promote or inhibit the provision of good pain care through the policies they set.”

- State Pain Policy Advocacy Network



Standards for the practice of medicine, nursing, pharmacy, & other healthcare professions

Define legal use of medications & other pain treatments

Basic and continuing education requirements for healthcare professionals

Coverage requirement for Medicaid & private insurance

<http://sppan.aapainmanage.org/legislation-and-regulations/>



How Does State Legislation affect Patient Care?

Access to medication for
symptom management

Fewer providers are willing to
prescribe certain medications

Burden of prescribing opioids
is sometimes greater than the
benefit of serving the patient

*For those of us still willing to prescribe for the seriously ill
We need to understand the rules.
Make the rules work for the patient and the prescriber.
Be the leaders on the front line.*



Ohio House Bill 366 passed in 2018

OH HB 366 developed in response to prescription opioid abuse epidemic in Ohio (along with 12 additional opioid related Bills)

Legislators cited anecdotal reports that opioid prescriptions originating from Hospice programs were contributing to the problem

ORC 3712.062 Policies to prevent diversion of opioids in hospice care programs

<http://codes.ohio.gov/orc/3712.062v1>



HB 366



Requires hospices to develop policies to prevent diversion of opioids in the home

Requires hospices to provide copies of policies to patients at time of admission

Requires risk assessment before prescribing

Requires that hospice perform pill counts

Requires proper witnessed disposal of medications no longer needed in the home

Requires reporting of suspected diversion and misuse to law enforcement

Legislation Advocacy

Ohio's Hospice Inc. practices a proactive approach to partner with Legislators in efforts to:

Make real the possible impact of new legislation on access to medications for terminally ill patients

Be recognized as excellent stewards to the community

Bring to the table expertise in medication management

Maintain certain level of immunity for Hospice programs



Prescription Monitoring Programs

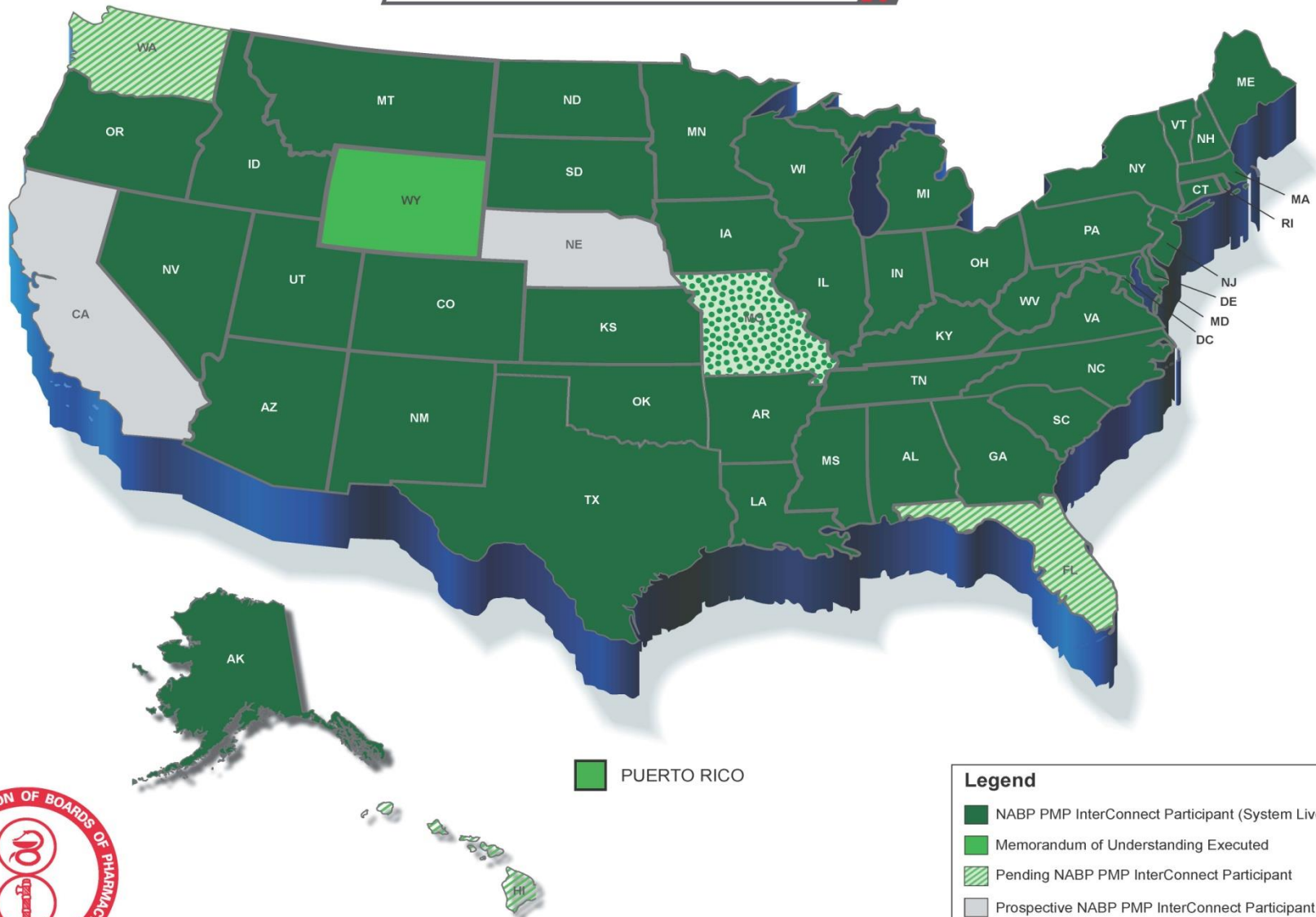
Prescription Monitoring Programs

- Prescription (Drug) Monitoring Program (PMP/PDMP)
- Each state designates a state agency to oversee its PMP
- Pharmacies report all controlled substances, II through V, dispensed as specified by your state
- Each state controls who will have access and for what purpose

States with a PMP

- 50 states either have an operating PMP, or have passed legislation to implement one
- Currently, more than 45 states connect and share data
- PMP Interconnect hosted by the National Association of the Boards of Pharmacy

PMP INTERCONNECT®



When am I required to Check OARRS?

- Medical Board Rule 4731-11-11 “Standards & Procedures for Accessing Ohio’s Automated Rx Reporting System”
- Before prescribing or personally furnishing a controlled substance
- If patient exhibiting signs of drug abuse or diversion
- When treatment will continue past 90 days and every 90 days thereafter (non-hospice patient)

For more information...

- National Association of Boards of Pharmacy PMP InterConnect <http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect>
- Drug Enforcement Agency http://www.dea.gov/divisions/office_of_diversion/faq/rx_monitor.htm#4
- Alliance of States with Prescription Medication Programs (ASPMP) <http://pmpalliance.org/>
- National Alliance for Model State Drug Laws (NAMSDL) <http://www.namsdl.org/>

Accreditation Standards

Accrediting Agencies

- Joint Commission - JC
- Accreditation Commission for Healthcare – ACHC
- Community Health Accreditation Program - CHAP



CFR 418.106

Hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

1. *Provide copy* of hospice written policies and procedures on the management and disposal of controlled drugs to patient/family
2. *Discuss* hospice policies and procedures for managing the safe use and disposal of controlled drugs with patient/family
3. *Document* in the record that written policies and procedures for managing controlled drugs were provided and discussed

<http://www.gpo.gov/fdsys/pkg/CFR-2013-title42-vol3/pdf/CFR-2013-title42-vol3-sec418-106.pdf>

Universal Precautions

Prevention of Opioid Misuse and Diversion in hospice –

An innovative

PROACTIVE

approach to prevent problems

BEFORE

they occur.

“Just as it is impossible to predict if the body fluids of a patient will harbor infectious agents it is impossible to predict with any certainty which family units might divert or misuse the opioids in their possession.”

*- Scott Fishman,
Responsible Opioid Prescribing*

PROACTIVE

*“Zero Tolerance”
through presentation
and follow through-
supported by policies*



*Encouraging families
to be our partners in
medication
management*

Goals of Universal Precautions



Provide clear written expectations and consequences

Establish partnerships between the IDT and the patient/family/caregiver

Empower staff to effectively manage situations

Continue our tradition of being excellent community partners

Leaders in responsible, effective symptom management

Universal Precautions 3 step Protocol

Opioid Risk Tool for every patient/caregiver unit



Opioid Risk Tool

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[]	1	3
	Illegal Drugs	[]	2	3
	Prescription Drugs	[]	4	4
2. Personal History of Substance Abuse	Alcohol	[]	3	3
	Illegal Drugs	[]	4	4
	Prescription Drugs	[]	5	5
3. Age (Mark box if 16 – 45)		[]	1	1
4. History of Preadolescent Sexual Abuse		[]	3	0
5. Psychological Disease	ADD, OCD, Schizophrenia, Bipolar Disorder	[]	2	2
	Depression	[]	1	1
	TOTAL _____			
Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8				

Reference: Webster LR. (2005)

3 steps or 2 strikes

Step 1-

At time of admission all patients/ families sign a Medication Agreement if low risk



Step 2-

Patient/families with high initial risk assessments and/or clear history of substance abuse/diversion sign Medication Contract



If Medication Agreement is broken- move to step 2



If Medication Contract is broken-move to step 3



Discontinuation of opioids, change in care environment or discharge for cause

Medication Usage Agreement - Step 1

Medications must be taken as prescribed

Illicit/illegally obtained medications will not be consumed

Illegal to share or sell prescriptions

Agree to provide safe storage of medications

Written log of prn medications will be kept and made available to visiting nurse at each visit

Pill counts will be done at each nursing visit

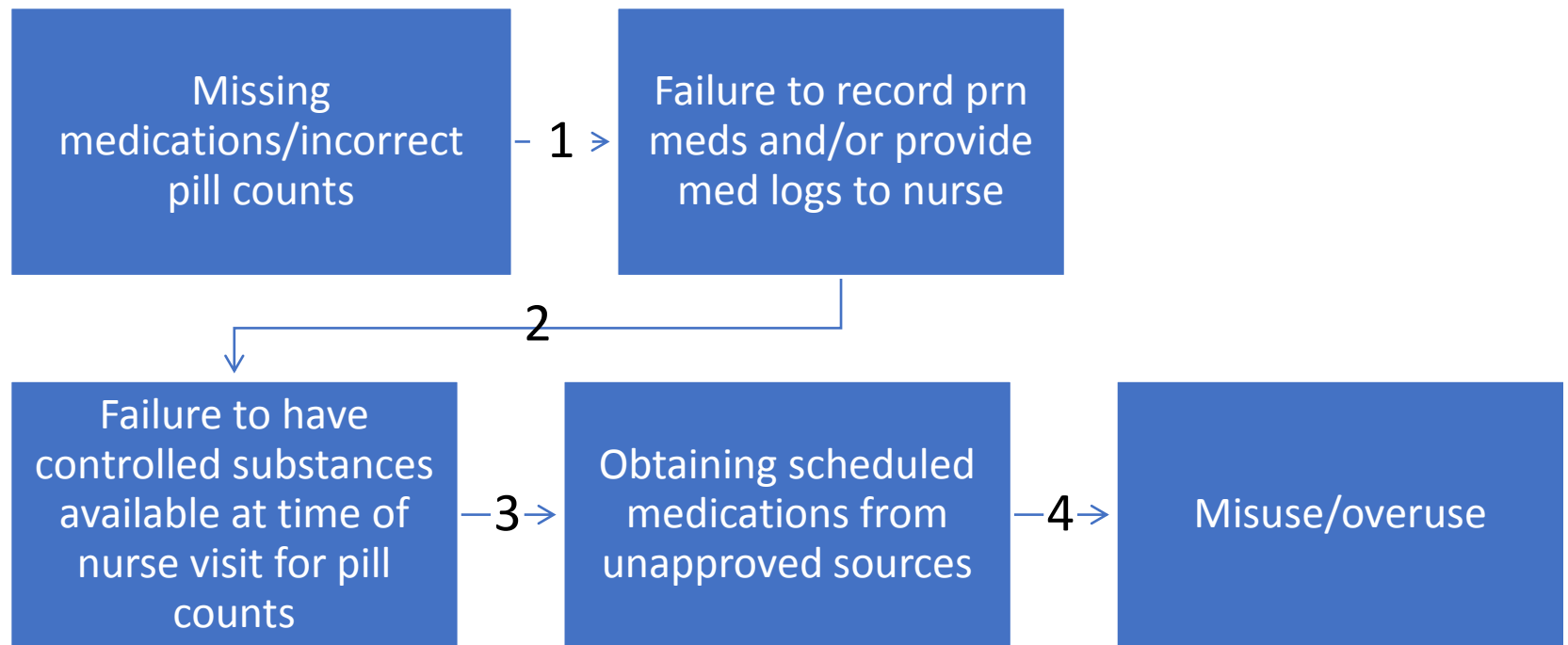
Hospice staff is obligated to witness the disposal of unused opioids

Driving or operating machinery while under the influence is both dangerous and illegal.

Important to notify a member of the IDT if concerned about diversion

Mandatory police report for missing medications

Risk of discharge from the hospice program if agreement is broken



Examples of Failure to Comply
with Step 1

Medication Contract- Step 2

Hospice Medical Director or designee to prescribe/refill

Hospice Medical Director will make changes to regimen

No refills after hours/weekends

Lock box and/or med dispenser required

Small quantities

Urine drug screens

Admission to inpatient unit for pain control if unable to keep medications safe in the home

Failure to comply may result in the “withdrawal of all prescribed medications, termination of the patient/physician relationship and discharge from the hospice program”

Discharge for Cause- Step 3



Requirements per CMS:

Patient must be informed that discharge is a consequence of medication misuse or diversion

Serious effort to resolve problem

Document the problem and efforts made to resolve the problem

Provide for transition of life sustaining equipment/DME

Written discharge order from Hospice Medical Director

Notification of attending physician

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf>

Prevention Strategies

Compassionate vigilance



Family and patient education with open communication



Communication to all staff involved including extended hours teams and all covering providers



Red alert



Collaboration with the attending physician



Family meetings with IDT members present



Pill counts/med reconciliation at every visit

Disposal of Medications



Federal Guidelines for Disposal

Allows ultimate users
to dispose of medications by...

1. Participating in Community Take-Back Programs
2. Household Disposal
3. Surrendering them to Law Enforcement
4. Seeking assistance from the DEA

Federal Regulation

Home Healthcare Professionals

not authorized to receive
controlled substances
from ultimate users
for the purpose of disposal,
unless state regulation allows it.



Ohio Regulation

- OH HB 366 developed in response to prescription opioid abuse epidemic in Ohio
- Legislators cited anecdotal reports from constituents that opioid prescriptions originating from Hospice programs were contributing to the problem
- ORC 3712.062 Policies to prevent diversion of opioids in hospice care programs

<http://codes.ohio.gov/orc/3712.062v1>

ORC 3712.062

- Written policy establishing procedures preventing diversion
- Provide policy to patient & family
- Assess Risk factors
- Maintain records of opioids dispensed including counts
- Monitor fills & signs of diversion
- Dispose of any opioids included on Plan of Care, when no longer needed
- Suspected diversion must be reported to local law enforcement

Take-Back Programs

- Final Rule – disposal site must be registered & authorized by DEA
- DEA authorized sites to accept and dispose of unused prescription medication
 - Mail-back
 - Collection receptacles
 - Take-back events

Mail-Back Program



https://www.deadiversion.usdoj.gov/drug_disposal/non_registrant/edzuray.pdf

- Fill envelope with medications
- Seal the envelope
- Mail back with prepaid USPS label
- Mailed to reverse distributor or law enforcement agency

Actual envelopes are not branded to meet requirements of the Disposal Act (nondescript packaging)

Collection Receptacles



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION

Controlled Substance Public Disposal Locations - Search Utility

Public Controlled Substance Disposal Locations:

Business Name	Address 1	Address 2	City, State Zip	Distance	Map
OHIO CVS STORES, L.L.C.	3920 LINDEN AVE.		DAYTON, OH 45432	2 miles	Map
MIAMI VALLEY HOSP	DEPT OF PHARMACY	ONE WYOMING ST	DAYTON, OH 45409	4 miles	Map
EQUITAS HEALTH PHARMACY #2	1222 S. PATTERSON BLVD.	SUITE 110	DAYTON, OH 45402	4 miles	Map
MIAMI VALLEY HOSPITAL SOUTH	2400 MIAMI VALLEY DR		CENTERVILLE, OH 45459	5 miles	Map
OHIO CVS STORES, L.L.C.	1331 NORTH FAIRFIELD ROAD		BEAVERCREEK, OH 45432	5 miles	Map
GENOA HEALTHCARE, LLC	1520 GERMANTOWN STREET		DAYTON, OH 45417	5 miles	Map

↶ Search Again

<https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s2>

Collection Receptacles



Map Search

Please enter your location information below.
Results will appear on and below the map.

Find Locations Near:

Street: City: State:

Zip:

Select a distance:



Dayton Police 0.3 miles

335 West Third Street
Dayton, Ohio 45402

Phone: 9373331000
Email:
Gary.lowe@daytonohio.gov

[Get Directions](#)

Montgomery County Sheriff's Office 0.4 miles

345 W Second St
Dayton, OH 45422

Phone: 937-225-6490

[Get Directions](#)

Dayton Police 1.0 miles

248 Salem Avenue
Dayton, Ohio 45406

Phone: 9373331000
Email:
Gary.Lowe@daytonohio.gov

[Get Directions](#)

Dayton Police 1.1 miles

951 Washington Street
Dayton, Ohio 45408

Phone: 9373331000
Email:
garu.lowe@daytonohio.gov

[Get Directions](#)

Dayton Police 2.4 miles

2721 Wayne Avenue
Dayton, Ohio 45420

Phone: 937-333-1000
Email:
gary.lowe@daytonohio.gov

[Get Directions](#)

<http://rxdrugdropbox.org/>

Take-Back Events

- Bi-annual events
- Usually April & October
- Next:
April 2019



<https://takebackday.dea.gov/>

Non-Retrieveable Destruction Standard

Incineration



Chemical Digestion



Methods that Do Not Meet NRDS

- “Landfill” or Household Disposal
- “Sewering” or Disposal by Flushing



<https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-20926.pdf>

Disposal & NRDS

- Only registered sites must meet the NRDS
- Ultimate users/community can dispose of by flushing & household disposal

Household Disposal

- Take medications out of their original containers
- Mix with undesirable substances (kitty litter, coffee grounds) to make less appealing to children and pets, and unrecognizable to people intentionally going through trash
- Put them in a sealable bag, empty can, or other container to prevent leakage or breaking out of the garbage bag

Additional Tips

- Scratch out all identifying information on the prescription label to help protect identity and privacy.
- Do not give medications to friends.
- When in doubt, contact a pharmacist.

Flushing Medications

When a label instructs to flush down the toilet, the FDA working with the manufacturer, has determined this method to be the most appropriate route of disposal that presents the least risk to safety.

<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm107163.pdf>

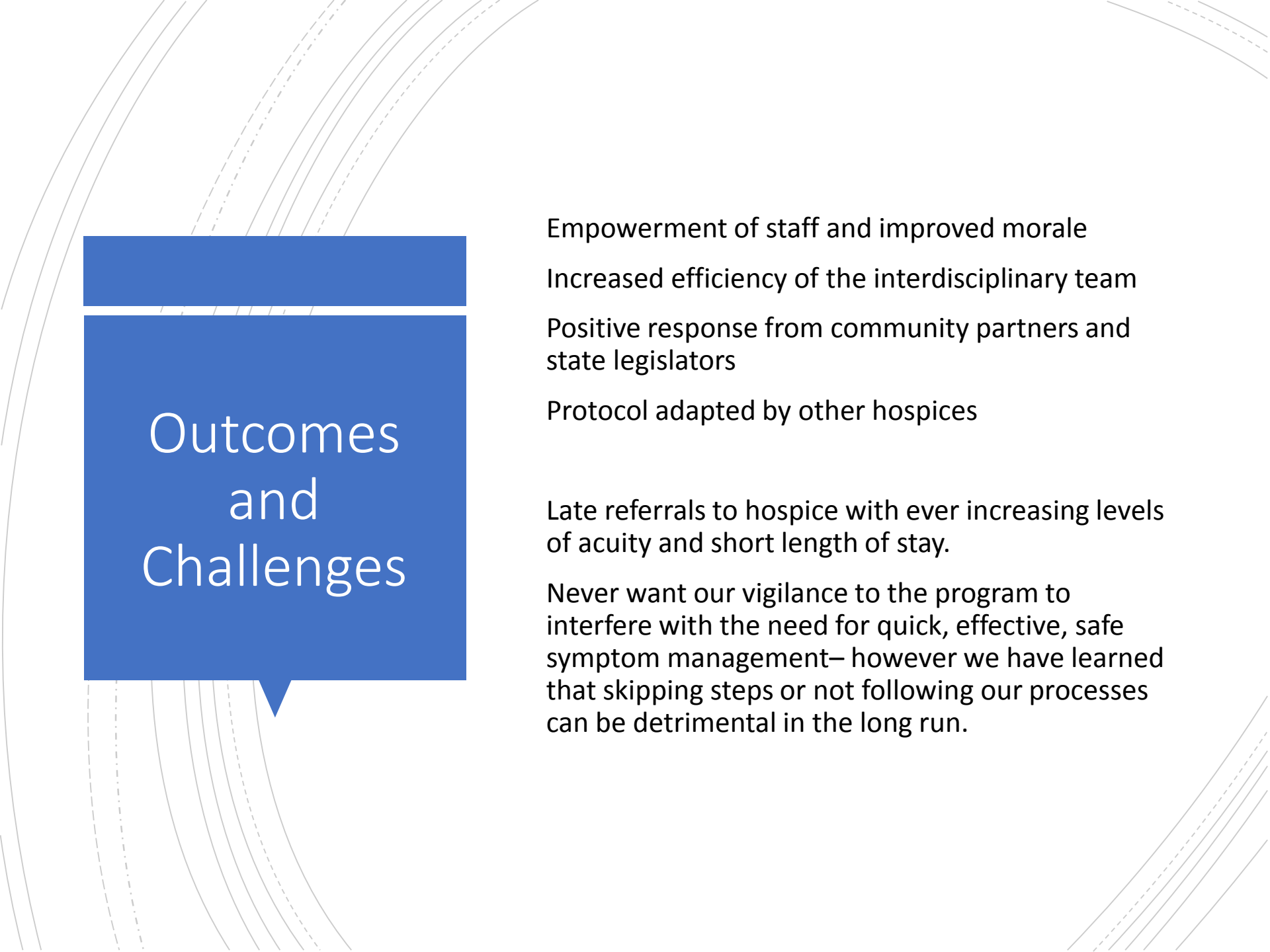
Medicines Recommended for Disposal by Flushing

- Fentanyl
- Morphine
- Buprenorphine +/- Naloxone
- Methylphenidate
- Meperidine
- Diazepam
- Hydromorphone
- Methadone
- Tapentadol
- Oxymorphone
- Oxycodone +/- acetaminophen or aspirin
- Buprenorphine
- Sodium Oxybate

Environmental Concerns

“Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants.”

- Raanan Bloom, Ph.D.

The background of the slide features several thin, curved lines in shades of gray, some solid and some dashed, creating a sense of movement and depth. A blue speech bubble shape is positioned on the left side, containing the title text.

Outcomes and Challenges

Empowerment of staff and improved morale

Increased efficiency of the interdisciplinary team

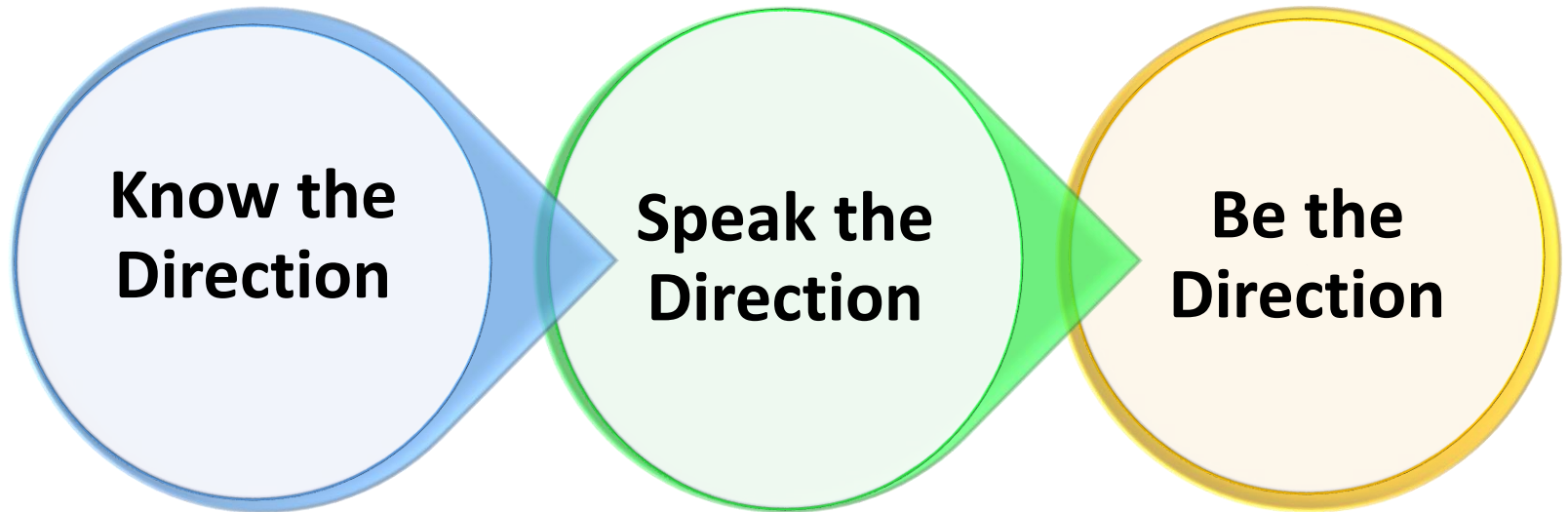
Positive response from community partners and state legislators

Protocol adapted by other hospices

Late referrals to hospice with ever increasing levels of acuity and short length of stay.

Never want our vigilance to the program to interfere with the need for quick, effective, safe symptom management— however we have learned that skipping steps or not following our processes can be detrimental in the long run.

Part of the process
Part of the solution
Responsible and safe prescribing



Thank you!

References

https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm576167.htm#flush_list updated 3/7/2018 accessed 5/15/2018

<https://www.ncbi.nlm.nih.gov/pubmed/28787777>_accessed 5/15/2018

<https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/buyingusingmedicine/safely/understandingover-the-countermedicines/ucm107163.pdf>_accessed 5/15/2018

https://www.deaiversion.usdoj.gov/drug_disposal/index.html accessed 5/15/2018

<https://archive.epa.gov/region02/capp/web/pdf/ppcpflyer.pdf> accessed 5/15/2018

<http://ship.oh.networkofcare.org/ph/library/article.aspx?hwid=d00233a1&search=Chronic%20Condition%20Data%20Warehouse> accessed 5/15/2018

[https://pharmacy.ohio.gov/Documents/Pubs/Newsletter/2012/State%20Board%20Newsletter%20\(Aug%202012\).pdf](https://pharmacy.ohio.gov/Documents/Pubs/Newsletter/2012/State%20Board%20Newsletter%20(Aug%202012).pdf) accessed 5/15/2018

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- Fishman, Scott. (2012). Responsible Opioid Prescribing. Washington, DC: Waterford Life Sciences.
- Moore, T. et al. (2009). Comparison of Screening Methods for Predicting Aberrant Drug-Related Behavior. *Pain Medicine*, 10 (8); 1426-1433.

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- Reid, M. Carrington et al. (2002) Use of Opioid Medications for Chronic Non Cancer Pain Syndromes in Primary Care. *J. of Gen Internal Medicine*. 17(3): 173-179.
- Veteran's Affairs/Department of Defense; Clinical Practice Guidelines Summary Management of Opioid Therapy for Chronic Pain, 2010

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- Webster LR. (2005). Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the opioid risk tool. *Pain Medicine*. 6(6):432-442.