

The Current Opioid Epidemic: A National Crisis

Moderator: Michele V. Davidson, R.Ph., NSC, Senior Manager, Pharmacy Technical Standards, Development & Policy, Government Relations, Walgreen Co.

Speakers:

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Darren K. Townzen R.Ph. MBA, Director of Billing, Reconciliation, & Healthcare Data, Walmart

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Moderator:

Michele V. Davidson, R.Ph., NSC

Michele Vilaret Davidson, R.Ph., Senior Manager, Pharmacy Technical Standards, Development & Policy, Government Relations, Walgreen Co. Davidson graduated from the University of Florida with a B.S in Pharmacy. Before joining Walgreens in 2009, she served as the Director of Telecommunication Standards for the National Association of Chain Drug Stores (NACDS) where she led the chain pharmacy industry's effort in the implementation of the NPI. Before NACDS, Michele had over 25 years' experience with Eckerd Drugs in which she held various positions of increasing responsibility from Store Pharmacist to Director of Government Programs. She has been very active in NCPDP over the past 16 years.



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Jennifer Pielsticker Steger

Director, Operations & Government Affairs, Horizon Government Affairs. She joined Horizon Government Affairs in June 2014. Prior to joining Horizon, Jennifer spent seven years on Capitol Hill handling both operations and policy issues. First, serving as the Scheduler and then Legislative Assistant in the office of Representative Jean Schmidt (OH-02) for five years where her portfolio included Agriculture, Financial Services, and Judiciary issues. She then spent the last two years in the office of Representative Jim Gerlach (PA-06) managing operations as the Executive Assistant as well as the Financial Services legislative portfolio. University.



Anthony Schueth, M.S.

CEO & managing partner of Point-of-Care Partners (POCP), a health information technology (HIT) strategy and management consulting firm specializing in the evolving world of electronic health records. A 25-year healthcare veteran, he is an expert in HIT, in general, and one of the nation's foremost experts in ePrescribing and eMedication Management. In addition, he currently serves as a co-leader of the National Council for Prescription Drug Programs (NCPDP) Specialty ePrescribing Task Group and leads the NCPDP Electronic Prior Authorization Task Group.

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Darren K. Townzen R.Ph., MBA

Director of Billing, Reconciliation, & Healthcare Data for Wal-Mart Stores, with responsibility of the billing and reconciliation of pharmacy transactions, industry standards, and the long term health care data strategy. He has been a member of NCPDP since 2001 and is active in work group 2 Product Identification, standardization committee, and has served on the board of trustees for NCPDP and as past chair in 2014-2015



Faculty Disclosure

- Moderator: Michele V. Davidson, R.Ph. Senior Manager, Pharmacy Technical Standards, Development and Policy, Government Relations, Walgreen, Co., has no conflict of interest to declare for this presentation.
- Jennifer Steger, Senior Director Government Affairs, Horizon Government Affairs, has no conflict of interest to declare for this presentation.
- Anthony Schueth, M.S., CEO and Managing Partner, Point of Care Partners, has no conflict of interest to declare for this presentation.
- Darren K. Townsend, R. Ph., MBA, Director of Billing, Reconciliation, & Healthcare Data, Walmart, has no conflict of interest to declare for this presentation.



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Initial release date is 11/7/2017.

Learning Objectives

- Describe three methods currently proposed by States to address the Opioid Crisis.
- Explain what quantity limitations are being placed on controlled substance prescriptions at the state level.
- Describe how integrated PDMP data supports more informed clinical decision-making.
- Identify at least three initiatives the Government is spearheading to resolve the Opioid Crisis.

Agenda

- Introduction
- Pre-Test
- Background
- Federal initiatives
- State initiatives
- The role of PDMP's
- Post-Test Questions
- Questions from moderator and audience

Pre-Test Questions

1. How do most pharmacists access their state's collected prescription drug information?
2. Do all states require prescribers to access PDMP data before prescribing controlled substances?
3. Approximately how many people die each year due to a prescription or illicit drug overdose?
4. What happens when the President declares a National Health Emergency?

Learning Objectives

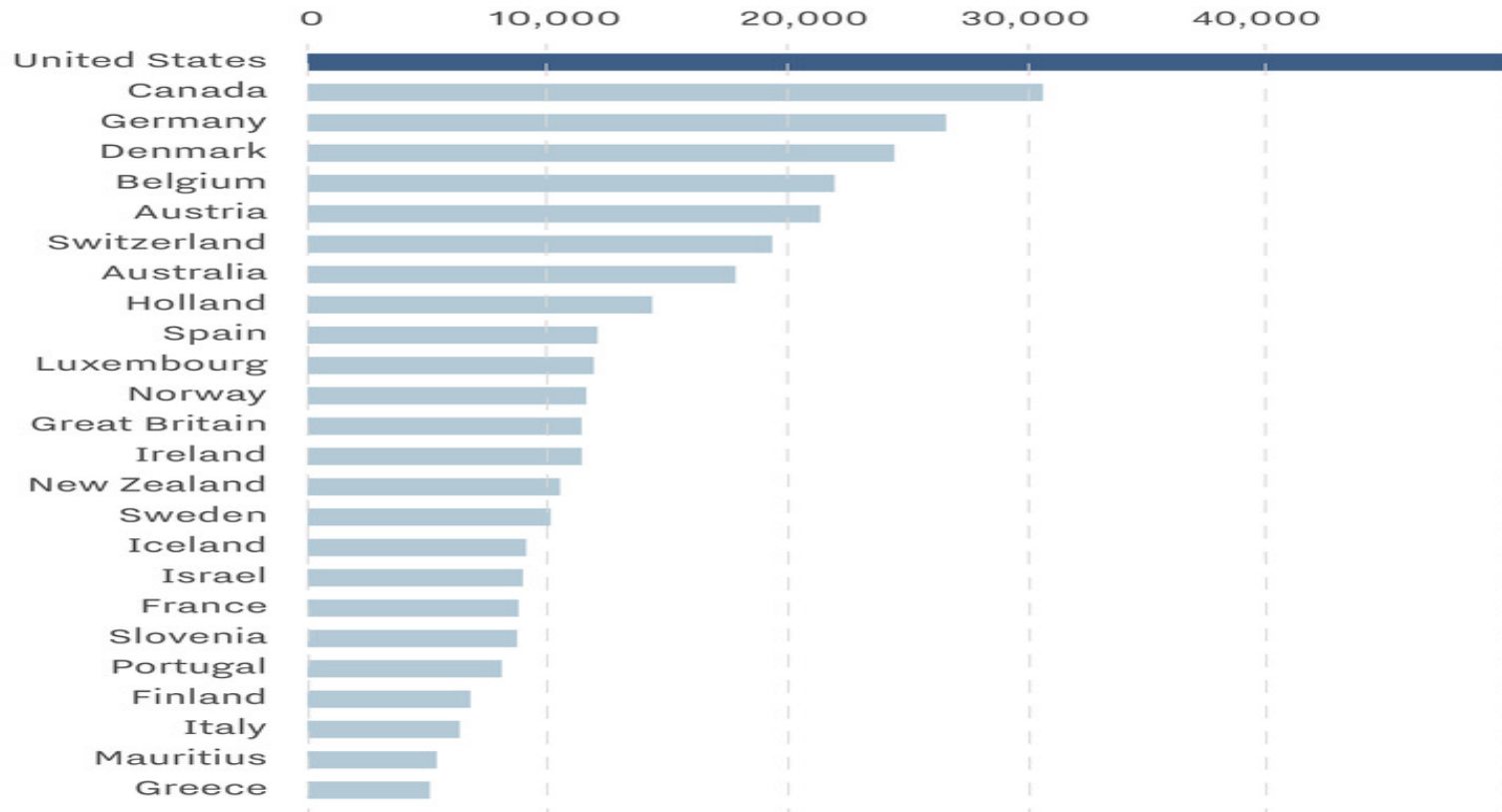
- Upon successful completion of this activity, pharmacists and pharmacy technicians should be able to:
 - Describe three methods currently proposed by States to address the Opioid Crisis
 - Explain what quantity limitations are being place on controlled substance prescriptions at the state level
 - Describe how integrated PDMP data supports more informed clinical decision-making
 - Describe methods currently used for accessing PDMP data at the point of care
 - Identify at least three initiatives the Government is spearheading to resolve the Opioid Crisis

Overview

- Drug overdose deaths have reached epidemic proportions in this country and require a complex, multi-faceted approach.
- CDC estimates over 142 people die daily from a drug overdose.
- Since 1999, the number of American overdose deaths involving opioids quadrupled.
- From 2000 to 2015, more than 560,000 people died of drug overdoses, and opioids account for the majority of those.
- This session will discuss Federal and State initiatives being proposed to resolve the current Opioid crisis including:
 - Federal guidance and Legislation
 - State e-Prescribing and Prescription mandates
 - PDMP's

Americans consume more opioids than any other country

Standard daily opioid dose for every 1 million people



Source: United Nations International Narcotics Control Board
Credit: Sarah Frostenson

Vox

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The Opioid Crisis

In 2016:

- Deaths from drug overdoses reached a record 19.9 per 100,000 population in the third quarter, in-line with the death rates of 18.9 and 19.3 for the first two quarters, according to data released by the National Center for Health Statistics.
- Approximately, six in 10 drug overdose deaths involved opioids. Prescription or synthetic opioid pain relievers were implicated in more than two-thirds of opioid-related overdose deaths
- Providers wrote more than **66 prescriptions for every 100 people** in the United States.

The Opioid Crisis

In 2015:

- **47.7 million people**, which is almost **18 out of 100 Americans**, were said to have used illicit drugs (like marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, or methamphetamine) or misused prescription drugs (like pain relievers, tranquilizers, stimulants, or sedatives).
- A record number of drug overdose deaths happened in 2015, with more than **52,000 Americans dying**. More than 63% of drug overdose deaths involved a prescription or illicit opioid. **2016** estimates range from **59,000 to 65,000** per data from the NYT

In 2014:

- Almost **260,000 Americans were hospitalized** for nonfatal, unintentional drug poisonings.

If nothing is done...

Expect a lot of people to die in the next 10 years

- Forecast by STAT (reporting agency)
- more than the entire city of Baltimore
- Estimated at 650,000

Why?

- It's much easier in America to get high than it is to get help.

Federal Initiatives & Perspectives

Jennifer Steger
Horizon Government Affairs

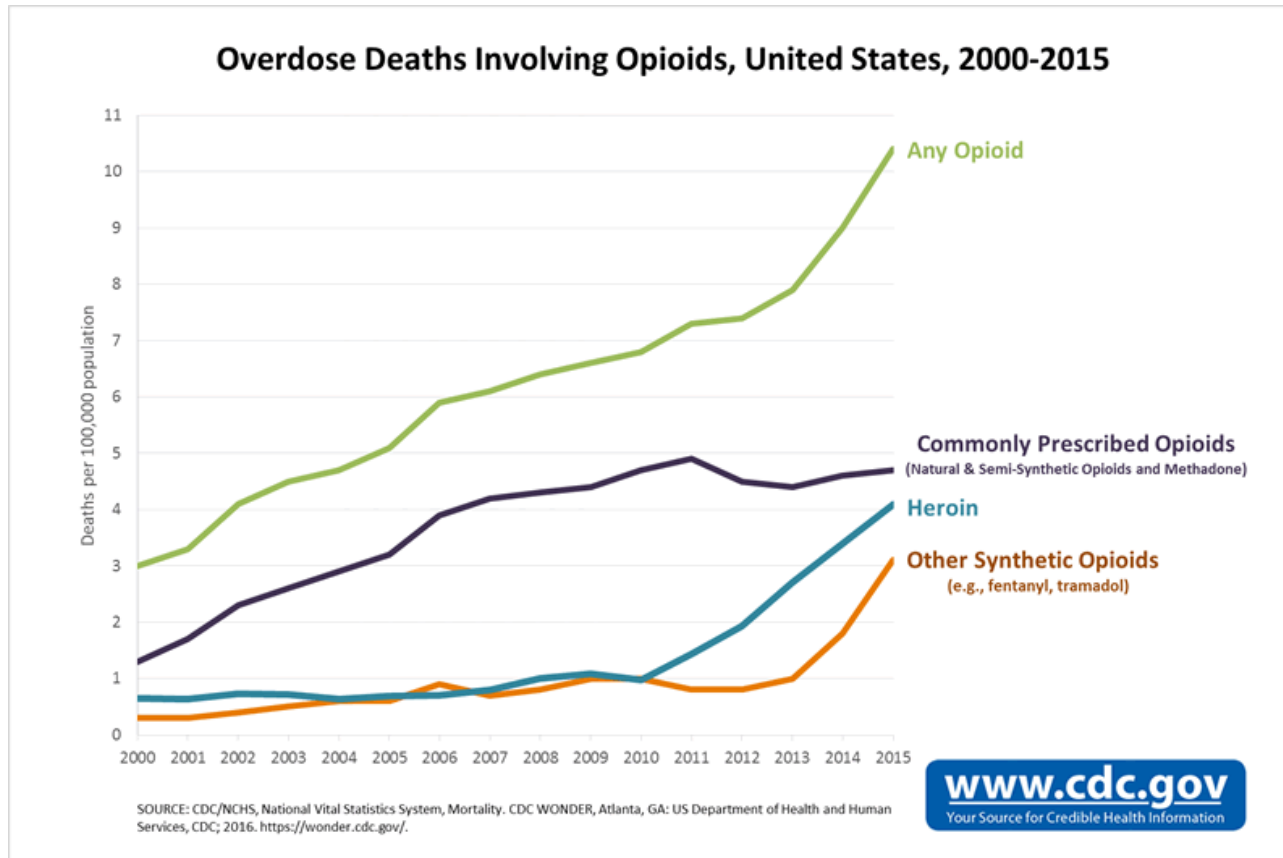
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By the Numbers



<https://www.cdc.gov/drugoverdose/data/>

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By the Numbers



The Opioid Epidemic in the U.S.

In 2015...



12.5 million
People misused prescription opioids¹



2.1 million
People misused prescription opioids for the first time¹



33,091
People died from overdosing on opioids²



2 million
People had prescription opioid use disorder¹



15,281
Deaths attributed to overdosing on commonly prescribed opioids^{2,3}



828,000
People used heroin¹



9,580
Deaths attributed to overdosing on synthetic opioids^{2,5}



135,000
People used heroin for the first time¹



12,989
Deaths attributed to overdosing on heroin^{2,4}



\$78.5 billion
In economic costs (2013 data)⁶

Sources: ¹2015 National Survey on Drug Use and Health (SAMHSA). ²MMWR, 2016; 65(50-51):1445-1452 (CDC). ³Prescription Overdose Data (CDC). ⁴Heroin Overdose Data (CDC). ⁵Synthetic Opioid Data (CDC). ⁶The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Florence CS, Zhou C, Luo F, Xu L. Med Care. 2016 Oct;54(10):901-6

Updated May 2017. For more information, visit: <http://www.hhs.gov/opioids/>

HHS.gov/opioids

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By the Numbers

- In 2015, the five states with the highest rates of death due to drug overdose were:
 - West Virginia (41.5 per 100,000)
 - New Hampshire (34.3 per 100,000)
 - Kentucky (29.9 per 100,000)
 - Ohio (29.9 per 100,000), and
 - Rhode Island (28.2 per 100,000).
- Opioids were involved in 33,091 deaths in 2015. That equates over 90 deaths per day in 2015.
- Overdose deaths have quadrupled since 1999.
- Every day, over 1,000 people are treated in emergency departments for misusing prescription opioids.

CARA Basics

- Culmination of over three years of work by bipartisan sponsors
- Passed the Senate, 92-2 and the House, 407-5
- With President Obama's signature, CARA became P.L. 114-198 on July 22, 2016
- Includes:
 - Prevention
 - Education
 - Treatment
 - Law Enforcement
 - Recovery
 - State Incentives
 - Authorizing funding language
- For PDMPs, meant to address core challenges:
 - Interoperability
 - Information in workflow and
 - Real time information

CARA

Legislative Language

- Section 109: Reauthorization of NASPER for “controlled substances monitoring systems”
- Section 201: Comprehensive Opioid Abuse Grant Program including “developing, implementing, or expanding” a PDMP
- Section 601: State Demonstration Grants for Comprehensive Opioid Abuse Response including PDMPs
- Section 911: Improvement of Opioid Safety Measure by VA

Goals

- Provide resources to states to establish, maintain and improve PDMPs
- Promote data sharing/interoperability
- Encourage more timely data and regularly updated PDMPs

Authorizing Funds

- Section 109: Authorizes \$10 million annually for FY 2017 - 2021
- Section 201: Authorizes \$103 million annually for FY 2017 – 2021
- Section 601: Authorizes \$5 million annually for FY 2017-2021 for Comprehensive Opioid Abuse Response Programs



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Federal Legislation

- 21st Century Cures
 - HHS funds to carry out grant programs for training, PDMPs and access to health care
- Every Prescription Conveyed Securely Act (EPCSA)
 - Mandate EPCS for Part D prescriptions
- Prescription Drug Monitoring Act of 2017
 - Provides for a “Data-Sharing Single Technology Hub”
 - Requires certain notifications and actions by prescribers and dispensers of controlled substances

Congressional Priority

- Hearings
 - House Energy & Commerce
 - Senate Health, Education, Labor & Pensions
- Funding/ Appropriations
 - Included in failed ACA Repeal and Replace proposals
 - \$500 million included in the annual funding bill for FY2017
 - Senate proposed \$816 million for programs to combat opioid abuse in the FY 2018 measure – represents a 440% increase since FY2016
- Congressional Member Organizations
 - Bipartisan Heroin Task Force
 - Addiction, Treatment and Recovery Caucus
 - Caucus on Prescription Drug Abuse

Administration Initiatives

Declared a
“Public
Health
Emergency”

Appointed
Opioid
Commission
Chaired by
Gov. Christie

- Four meetings have been held
- Final recommendations are due out in early November

Food and Drug
Administration

- REMS Authority
- Safe Use of Medications

Centers for
Disease
Control

- Support state responses to epidemic; prevention efforts and better track overdoses

The
Department of
Veterans
Affairs (VA)

- Engaged in comprehensive approach aimed at reducing the use of opioids among veterans using VA healthcare

Centers for
Medicare &
Medicaid
Services (CMS)

- Released its opioid management strategy
- Outlines the agency’s plan to address the national opioid epidemic

Opioid Commission Recommendations

- Final Report released on November 1st
- Included 56 specific recommendations including a section of five on “PDMP Enhancements”. Recommendations included:
 - Support for the Prescription Drug Monitoring Act
 - Establish and maintain a data-sharing hub through the Department of Justice
 - Data integration with EHRs
 - Increase utilization of e-prescribing of controlled substances

Other Initiatives

- **National Governors Association (NGA)**
 - Released a resource for state governments to address the opioid epidemic, titled *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States. A Road Map for States*
 - Letter to Congressional Leadership requesting federal action and assistance in certain areas including funding.

State Initiatives

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State Responses: “All Over The Map”

CLINICAL PREVENTION

- Prescriber Education
- Patient Risk Advisories
- Prescribing Limits
- PDMP mandates

DIVERSION PREVENTION

- EPCS mandates
- PDMP Monitoring
- Penalties
- Identify bad actors

ADDICTION TREATMENT

- Treatment programs
- Overdose reversal
- “No prescribe” designation

Each state independently enacts laws and rules to address state-specific and federal demands.

New Mandates on Prescribers

- **Before** they prescribe “To Dos”
- **How** to prescribe mandates
- **What** they are allowed to prescribe
- **Where** they can prescribe

Before Prescribing

- Opiate Directive Forms
 - Patient forms that indicate no opiates are to be prescribed
 - Typically must be filed in medical record
 - Prescriber needs to know if on file
- Required discussions with patient
 - Severity of pain, reason for pain
 - Warnings regarding addiction risks
 - Consent forms
- Contraindications
 - Taking Benzodiazepine?
- Reviewing PDMP history



Reason for
pain

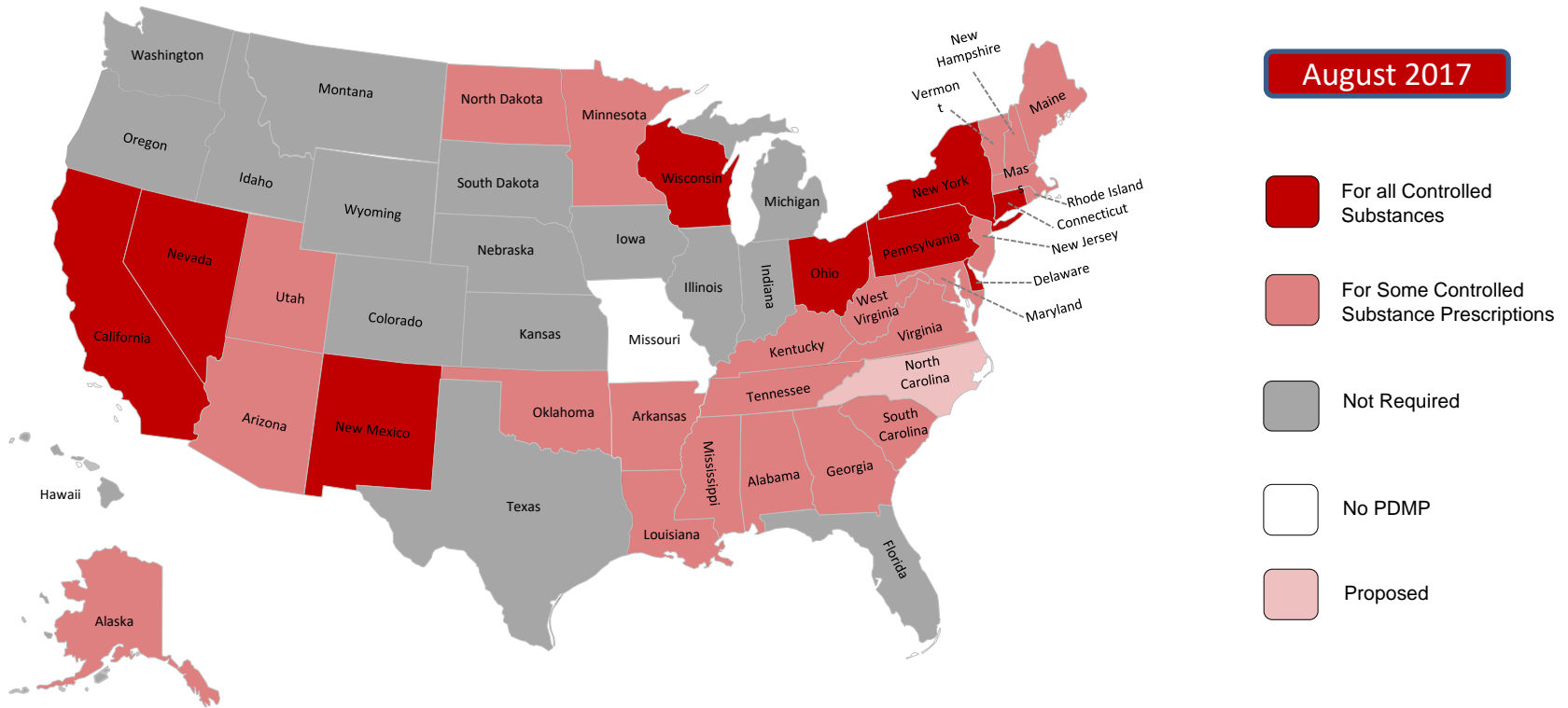


On Xanax?

PDMP



Prescriber PDMP Access Required



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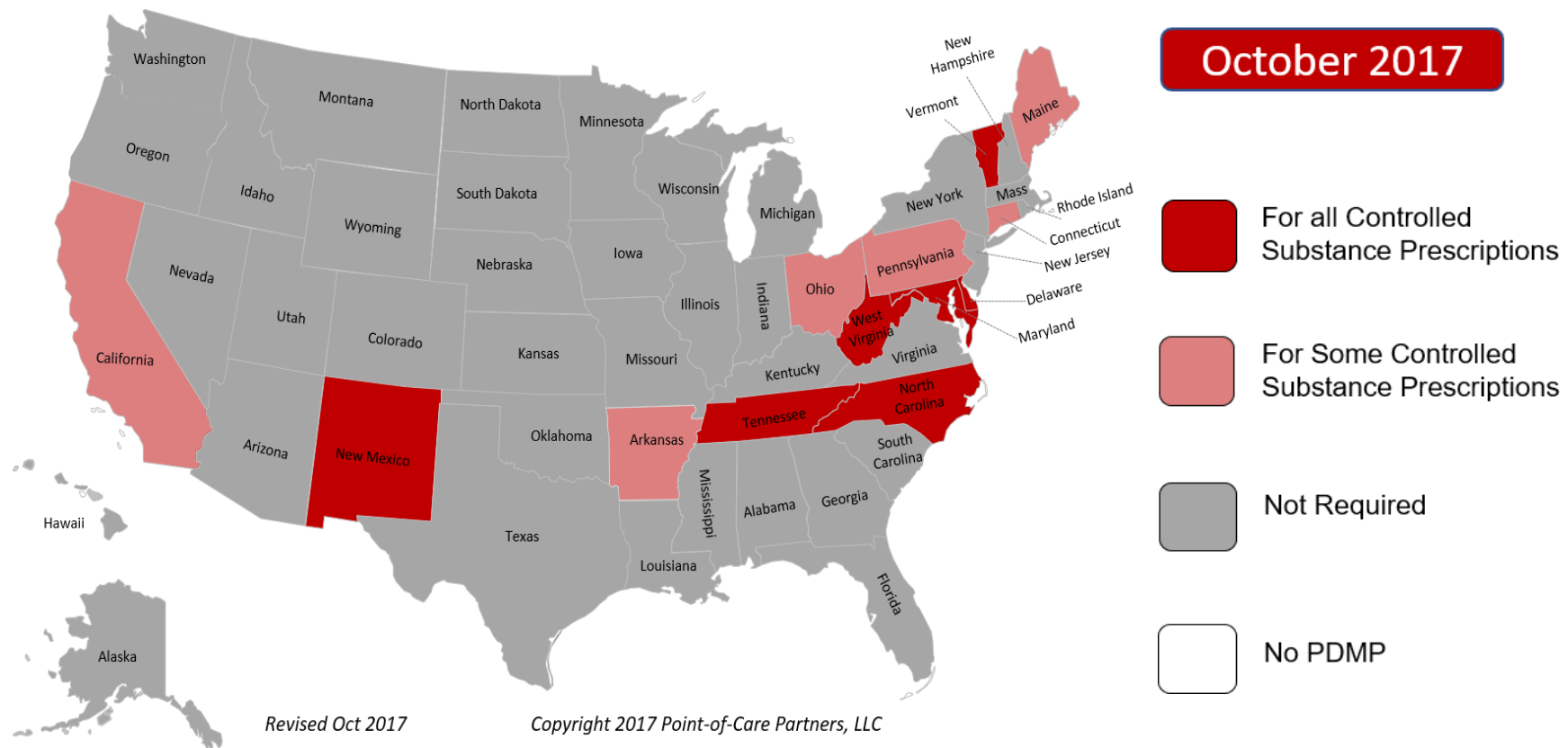


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Dispenser PDMP Access Required



The Challenge: Unintegrated Prescriber Workflow

Navigate to State Website & Manually Login

Manually Enter Patient Identifiers



Navigate to Search

Prescriber Returns to EHR Workflow

Repeat Steps to Navigate to
Neighboring State(s) PDMP as necessary

More Data Needed?

Interpret
Report Data

[View PDMP Report](#)

Wait for
Report to Be
Generated

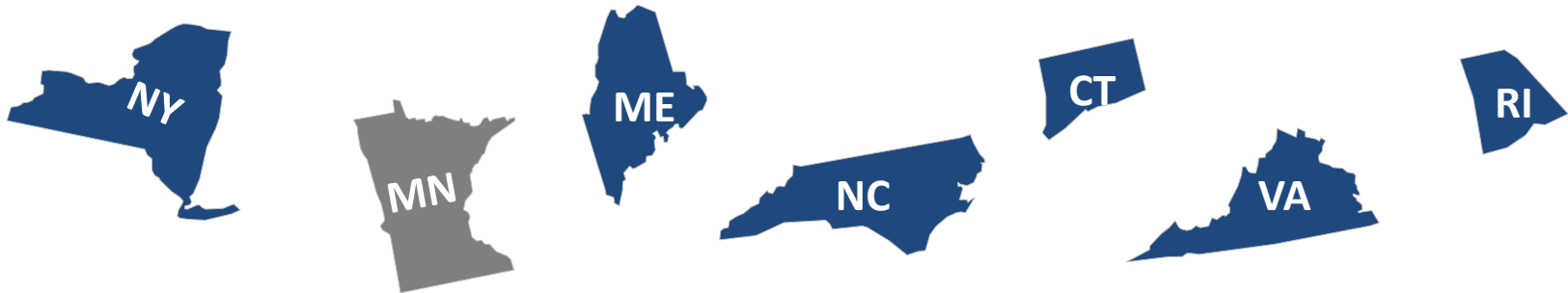
Source: <http://onlinelibrary.wiley.com/doi/10.1111/acem.12905/abstract>

Mandated PDMP Access ***Demands*** Ease of Use

- States are removing regulatory barriers to PDMP access
 - Some are **revising privacy laws** that prevent data assimilation into EHRs
 - Encouraging PDMP **integration** into prescriber workflow
- States are sponsoring 3rd party API solutions that facilitate access within the EHR flow

How to Prescribe

- EPCS mandates dictate the method of prescribing
 - New York paved the way
 - Now there are 7 states
 - Others have been introduced
 - Each state has varied approach
- Diagnosis on Prescription
 - New trend for requiring ICD-10 on specified prescriptions
- Specific wording to include on the prescription
 - Notice to patient and/or pharmacist



What May Be Prescribed

- Legislating prescribing limits
- Quantity limitations
- Duration (Days Supply) limitations
- Restrictive expiration timeframes
- Not to be prescribed with other drugs

QTY: ~~10 30~~

< 7 Days
Supply

~~Benzo~~

Where May Be Prescribed

- Limitations based upon the location
 - Emergency Department
 - Urgent Care Center
 - Long Term Care
 - Telemedicine
- Primarily related to Opioids

PDMP as a tool

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Walmart

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Overview of PDMP Reporting

Data is submitted to various states or processors, for various drug classes, in a variety of formats, within varying time periods, must include reports on stores without sales, as well as any drugs mailed into the jurisdiction. With 52 jurisdictions, changes occur monthly, some with little or no lead time.

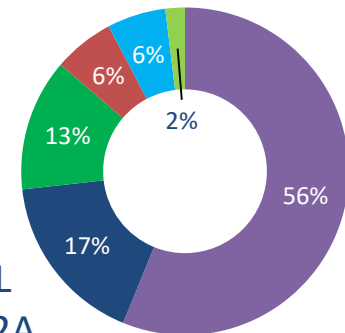
Processor: Jurisdictions

• PMP Clearing House (Appriss)	29
• Health Info Design(Appriss)	9
• State	7
• Optimum (Appriss)	3
• Atlantic Associates	3
• Not Reporting	<u>1</u>
Total Jurisdictions:	52

Variables by Jurisdiction:

- **Drugs:** CII-III-IV-V-DOI-PSE-ALL
- **Formats:** ASAP v4.1, v4.2, v4.2A
- **Times:** 24 hrs, COB, Midnight, Weekly
- **No Sales:** Zero Report Files
- **Mail Order:** Drugs shipped into the state

Processor Split



Timely Submissions

Drilling into submission timelines, the clock starts counting upon sale of a Rx. Oklahoma requires data at time of sale, with other states requiring it within 24 hours of sale (or longer). With stores opening at 8am Eastern, we have obligations to submit prior to 7am Central. This was impossible to hit given prior processes.

Due Time: Jurisdictions

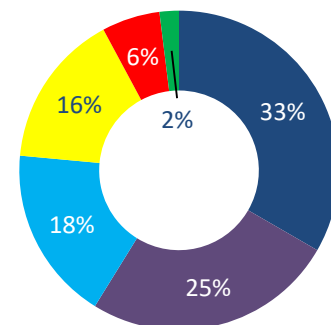
• Real Time (RT)	1
• Within 24 hrs of Sale (NRT)	8
• Close of Business Next Day	9
• Midnight Next Day	17
• Weekly	3
• Other	3
• Not reporting	1

Total Jurisdictions: 52

Typical Errors

- Patient Data - Address, zip code
- Prescriber Data – DEA, phone
- Pharmacy Data – DEA, phone
- Rx Data – Serial Numbers, Pick up data

Split by Due Time



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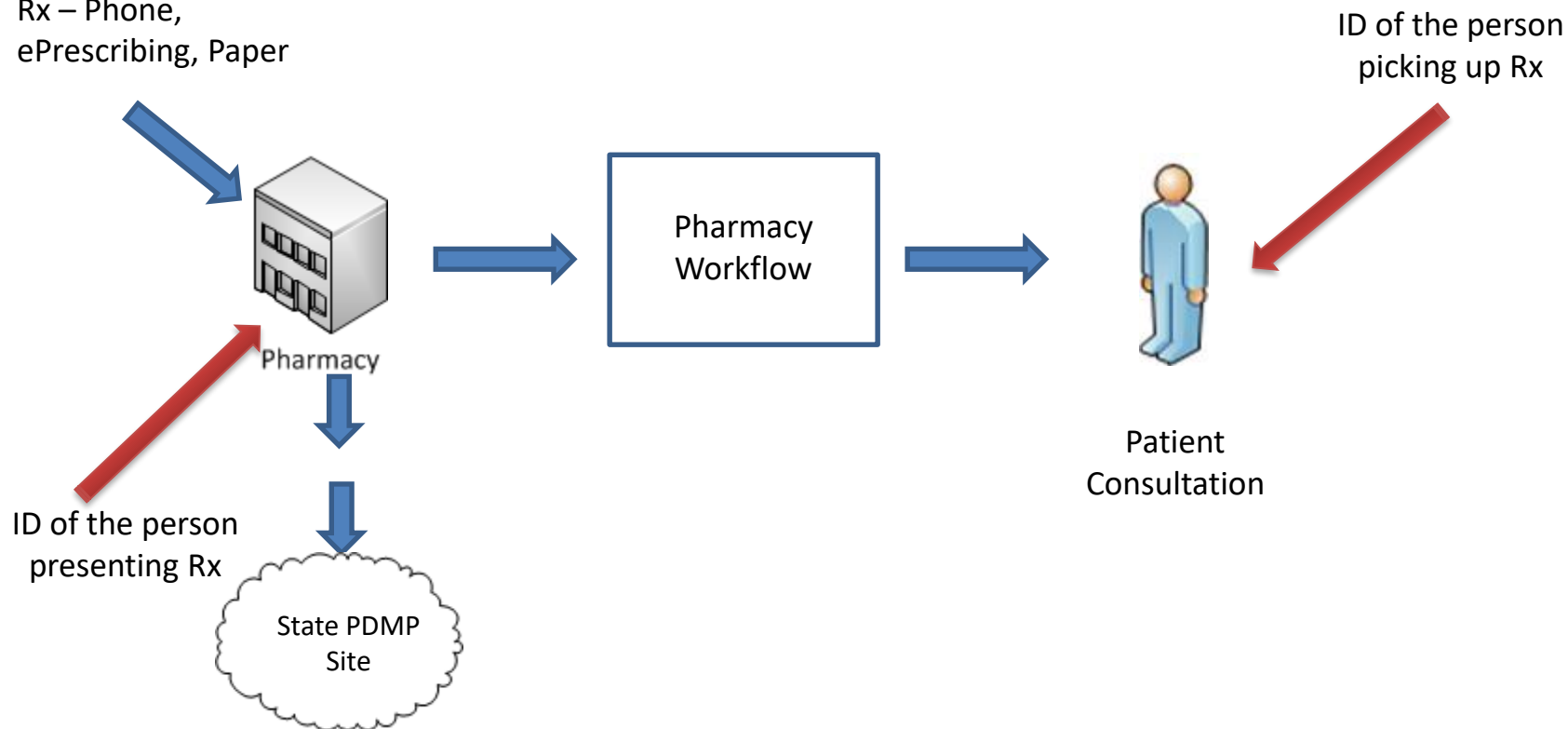
Data Submission

- Challenges
- Data timing errors – Delay in getting the information posted (Example of state rejecting the entire file for one error)
- Inconsistent drug across states – Different schedules and drugs of concerns
- Validating the submission of data – only licensed professionals have access
- Disconnect between states and PDMP administrators

Operational Perspective

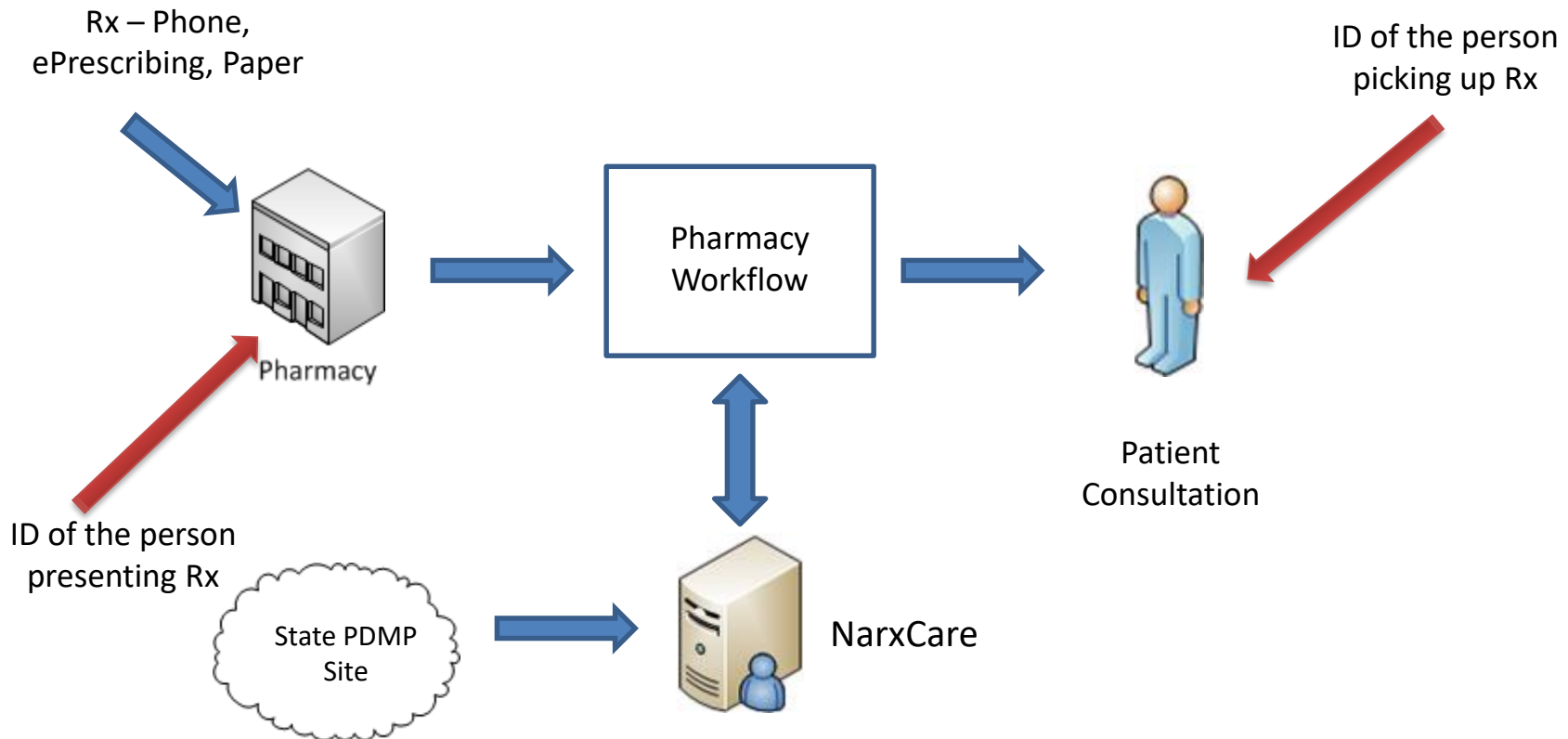
Using standalone PDMP websites

Rx – Phone,
ePrescribing, Paper



Operational Perspective

Using embedded software to access PDMP Data with NarxCare



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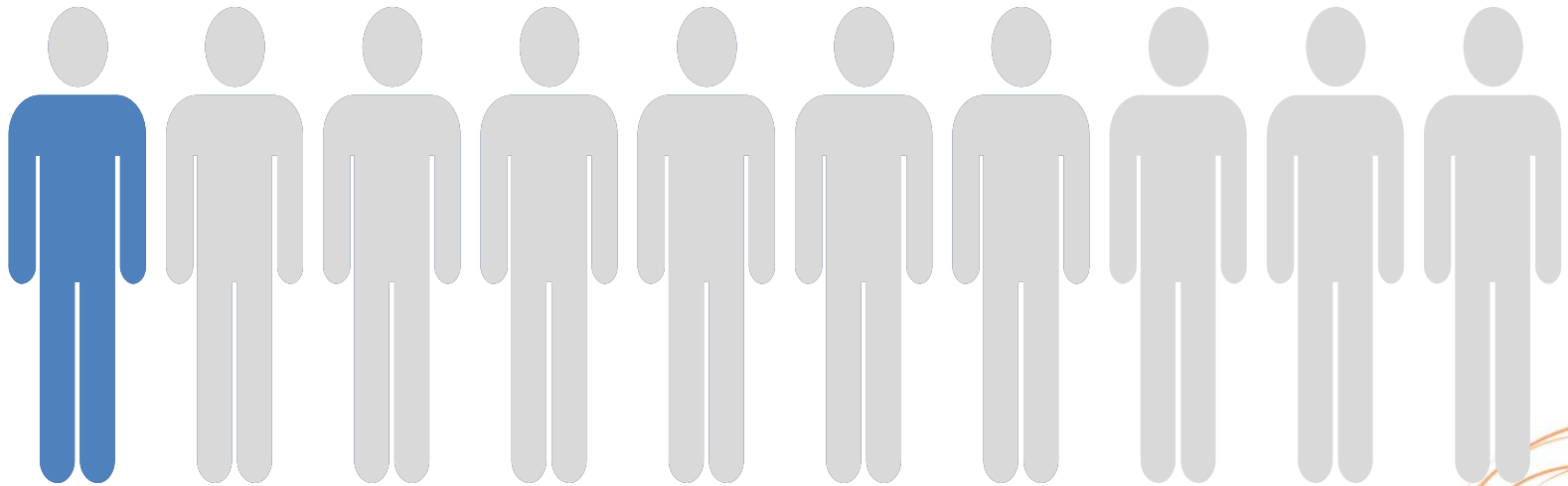
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Identifying the At Risk Population

7%

71 million individual patients
took a controlled Substance

5 million individual patients
exhibited At Risk behavior



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Post-Test Question 1

1. How many states have law enforcement administer the prescription drug information collected by the pharmacies:

- a) 6
- b) 9
- c) 5
- d) 15

Post-Test Answer 1

1. How many states have law enforcement administer the prescription drug information collected by the pharmacies:

- a) 6
- b) 9
- c) 5**
- d) 15

Post-Test Question 2

2. Depending on the state, who would NOT have access to the PDMPs?

- a) Law Enforcement agencies for drug investigations – Often require OPEN investigations
- b) License Regulatory Boards for investigating Health Care professionals who prescribe or dispense prescription controlled substances
- c) State Medicaid programs for Medicaid recipients and provider review
- d) Consumer rights advocates to ensure information is being used responsibly

Post-Test Answer 2

- Depending on the state, who would NOT have access to the PDMPs?
 - a) Law Enforcement agencies for drug investigations – Often require OPEN investigations
 - b) License Regulatory Boards for investigating Health Care professionals who prescribe or dispense prescription controlled substances
 - c) State Medicaid programs for Medicaid recipients and provider review
 - d) **Consumer rights advocates to ensure information is being used responsibly**

Post-Test Question 3

3. Which of the following does the Comprehensive Addition and Recovery Act (CARA) achieve?

- a) Reauthorizes National All Schedules Prescription Electronic Reporting ACT (NASPER)
- b) Provides grants to state PDMPs
- c) Mandates VA facility prescribers to query the PDMP
- d) None of the above
- e) All of the above

Post-Test Answer 3

3. Which of the following does the Comprehensive Addition and Recovery Act (CARA) achieve?

- a) Reauthorizes National All Schedules Prescription Electronic Reporting ACT (NASPER)
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- d) None of the above
- e) All of the above**

Post-Test Question 4

4. To combat the Opioid Crisis all of the following solutions have been proposed **except**:

- a) Quantity restrictions on Opioid prescriptions
- b) Provider mandates on PDMP
- c) A national PDMP solution
- d) Mandatory EPCS
- e) Allowing Naloxone to be dispensed without prescription

Post-Test Answer 4

4. To combat the Opioid Crisis all of the following solutions have been proposed **except**:

- a) Quantity restrictions on Opioid prescriptions
- b) Provider mandates on PDMP
- c) A national PDMP solution**
- d) Mandatory EPCS
- e) Allowing Naloxone to be dispensed without prescription

Post-Test Question 5

5. Which of the following is **not** true about EPCS;
- a) Allows secure transmission of controlled substance prescriptions to a pharmacy
 - b) Would allow for an in-workflow PDMP process
 - c) Reduces the number of “lost” or “stolen” prescriptions
 - d) Is difficult for prescribers to implement since very few EHR vendors are certified
 - e) Mandatory EPCS could improve adoption of e-Prescribing

Post-Test Answer 5

5. Which of the following is **not** true about EPCS;
- a) Allows secure transmission of controlled substance prescriptions to a pharmacy
 - b) Would allow for an in-workflow PDMP process
 - c) Reduces the number of “lost” or “stolen” prescriptions
 - d) Is difficult for prescribers to implement since very few EHR vendors are certified**
 - e) Mandatory EPCS could improve adoption of e-Prescribing

Additional materials for participants on opioids:

- <https://www.cdc.gov/vitalsigns/opioids/index.html> (Opioid Prescribing where you live matters)
- <https://www.cdc.gov/drugoverdose/opioids/index.html> (Opioid Abuse Basics)
- <https://www.cdc.gov/drugoverdose/opioids/index.html> (New today)
- <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwjNqcOwza3XAhUp4oMKHVXHDe4QygQIUzAD&url=https%3A%2F%2Fwww.hhs.gov%2Fopioids%2Fabout-the-epidemic%2Findex.html%23combat&usg=AOvVaw3ZeXvzy-h2RZAY0Z8AyCi1> (Federal plans to Stop Opioid Abuse)

Questions



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Evaluation Weblink

<https://www.surveymonkey.com/r/K638BGZ>

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- This evaluation asks for your CPE Monitor number in order to post CE credit, so have that number ready when you start the evaluation.
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