OBJECTIVES

1. Compliance Requirements and Beyond: Evaluating the effectiveness of your compliance program and remedial efforts to implement or improve one in the face of the opioid epidemic.

2. Digging into the common findings of opioid compliance and drug diversion reviews.

3. Using analytics to target key risks related to prescribing, drug diversion, and compliance with system and regulatory policies.

4. COVID-19 Considerations
U.S./MICHIGAN UPDATE ON THE OPIOID CRISIS

Every day, 128 people in the United States die after overdosing on opioids.¹

Michigan saw its first decrease (3.2%) in overdose deaths per day in six years between 2017 and 2018

How did this happen?

- Bad Studies/publications — marketing that opioids weren’t addictive
- Overprescribing — Pain as 5th vital sign
- Transition to illicit drugs (heroin and illegally manufactured fentanyl)
- Lack of support for SUD, mental health, and stigma

¹ - https://www.cdc.gov/drugoverdose/epidemic/index.html

WHAT DO WE KNOW ABOUT THE OPIOID CRISIS?

Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.⁶

An estimated 4 to 6 percent who misuse prescription opioids transition to heroin.⁷⁻⁹

Opioid overdoses increased 30 percent from July 2016 through September 2017 in 52 areas in 45 states.¹⁰

Opioid overdoses in large cities increase by 54 percent in 16 states.¹⁰

Between 8 and 12 percent develop an opioid use disorder.⁸

About 80 percent of people who use heroin first misused prescription opioids.²

The Midwestern region saw opioid overdoses increase 70 percent from July 2016 through September 2017.¹⁰
OPIOID OVERDOSES BY REGION

Quarterly rate of suspected opioid overdose, by US region
Source: Centers for Disease Control and Prevention


MICHIGAN OPIOID DEATH DECLINE

The decline in opioid poisoning mortality rates during 2018 was largely driven by decreases in the number of deaths due to poisoning by heroin and commonly prescribed natural and semisynthetic drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone. Drug poisoning deaths involving synthetic opioids such as fentanyl continue to climb.

CURRENT STATS – MAKING PROGRESS


CURRENT STATS – MAKING PROGRESS

COMPLIANCE REQUIREMENTS

"You get no bonus points for having a compliance program."

HHS Inspector General Daniel R. Levinson
Remarks at the Health Care Compliance Association’s Annual Compliance Institute
(Apr. 18, 2016)

DOJ’S FUNDAMENTAL QUESTIONS

Is the corporation’s compliance program well designed?

Is the program being applied earnestly and in good faith? In other words, is the program being implemented adequately resourced and empowered to function effectively?

Does the corporation’s compliance program work in practice?
CONSEQUENCES OF NON-COMPLIANCE

• CIAs
• Settlements
• Examples

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COMPLIANCE STANDARDS

Industry Guidelines
• CDC – Opioid Prescribing Guidelines
• CMS – Limits Conditions of Payment
• TJC – Updated Pain Management and Assessment Guidelines
• AMA – National and State Medical Boards & Associations
• SAMSHA

Federal Regulatory Requirements
• DEA Controlled Substances Act
• BOP, BOM, Medical Licensing Board
• PDMP (MAPS)
• Suspicious Order Monitoring
• Key Performance Indicators of Organization (DOJ)

State Regulatory Requirements
• States’ Limits on Days Supply and Max Daily Dose, Partial Fills
• Michigan Opioid Laws
  – SUD information to patients
  – Minor education and consent
  – Bona-fide relationship
  – MAPS review for CS over 3 days

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KEY CONTROLS/AREAS TO AUDIT FOR DIVERSION

| Procurement | • Authorized Orderer – Utilization of CSOS  
|             | • SOC between Ordering and Receiving |
| Receiving   | • Security upon Receipt  
|             | • Two individuals count received drugs and compare to invoice and sign |
| Inventory Management (including storage and security) | • Utilize Automated Dispensing Machine (Pyxis, Omnicell, etc.)  
|             | • Perpetual Inventory |
| Transfers / Restocking | • Secure carts  
|             | • Inventory count and retrieval of returned drugs |
| Ordering / Prescribing | • Authorized order required for dispense (and review of overrides) |
| Preparation and Dispensing | • CS in single pockets  
|             | • Blind counts and review of discrepancy reports |
| Administration (including Waste and Return) | • Retrieve one patient at a time, and as close to administration time as possible  
|             | • Return / Waste Witness required for CS |
| Monitoring | • Testing of wasted CS  
|             | • Utilization of ADM CS reports |
| Investigation and Response | • Hotline for reporting suspected diversion  
|             | • Multidisciplinary Drug Diversion Response Team |
| Education | • Diversion education is given to all staff and is ongoing  
|             | • Education signage in Med Rooms for what to look for and how to report diversion |

DIVERSION MONITORING REPORTS

1. Missing Admin/Waste/Return
2. Discrepancy Reports and Trending (Buddy Waste Reports / Not Involved in Wasting)
3. Outlier Reports by Drug / Area
4. Override Trending Report
5. Dispense after Discharge (or too close to discharge)
6. Removal after Death/Transfer
7. Dispense Outside of Working Hours
COMMON FINDINGS AS DIVERSION INDICATORS

- Inappropriate waste procedures and virtual witnessing
- Lack of monitoring reports or action taken as a result of review
- Lack of physical security from when drugs are received to when they are checked into inventory
- ADM configuration and access
- Lack of system-wide education on what to look for and how to report potential diversion
- Utilization of single use vials for multiple doses or patients and not securing medication in between doses (Can also lead to inappropriate billing)
- Lack of effective Oversight Committee

KEY AREAS TO AUDIT

Prescribing

A. Complying with Federal, State and Local Laws and Internal Guidelines
B. EPCS Requirements
C. MAPS Requirements
ELECTRONIC CONTROLLED SUBSTANCE PRESCRIBING (EPCS)

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the “SUPPORT for Patients and Communities Act” signed into law on October 24, 2018 requires the following:
  - All prescriptions for all Medicare Part D controlled substances must be e-prescribed starting on January 1, 2021.
  - All Part D drugs requiring prior authorizations must be electronically submitted to Part D by January 1, 2021.
- These new mandates will most likely cause all states to enact new or expedite the currently pending legislature to mirror the Part D requirements.

EPCS MANDATES BY STATE

Source: https://www.imprivata.com/state-epcs-legislation
### KEY AREAS TO AUDIT

#### Licensing

| A | DEA Facility License |
| B | APRN Licenses and User Templates |
| C | Notification/Removal of DEA or state CSR Licenses monitoring |

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#### Grant Compliance

**On September 4th, 2019, HHS announced $1.8 billion in grants available to states to combat the opioid crisis by expanding access to treatment and supporting near real-time data.**

| A | Inpatient/ED identification of SUD |
| B | Treatment referrals |
| C | Peer recovery |
| D | MAT availability |
KEY AREAS TO AUDIT

Grant Compliance - Michigan

The Michigan Department of Health and Human Services (MDHHS) announced the allocation of $17.5 million from the State Opioid Response (SOR) Grant from the U.S. Department of Health & Human Services to respond to the opioid epidemic and help meet Gov. Gretchen Whitmer’s goal of cutting opioid overdose deaths by half within five years.

<table>
<thead>
<tr>
<th>Program</th>
<th>Budget</th>
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<tr>
<td>Naloxone distribution to high-risk areas and populations</td>
<td>$4.5 million</td>
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<tr>
<td>Medications to treat opioid use disorder in emergency departments</td>
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<tr>
<td>Medications to treat opioid use disorder in jails</td>
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<td>Syringe service programs</td>
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<td>Mobile care units</td>
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<td>Loan repayment for providers beginning or expanding medication-assisted treatment</td>
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<td>Outreach to increase providers offering medications to treat opioid use disorder</td>
<td>$410,000</td>
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<td>Data-driven overdose response efforts</td>
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<td>Start-up costs for new treatment services</td>
<td>$235,000</td>
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<tr>
<td>Community engagement in majority-minority communities</td>
<td>$200,000</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$17.5 million</strong></td>
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KEY AREAS TO AUDIT

TJC Pain Management And Assessment Guidelines

A. Discharge Instructions
B. Data Monitoring for Progress
C. Monitoring for Respiratory Depression
D. Appropriate Referrals
**DATA ANALYTICS/MONITORING**

- **A** Compliance Metrics (Opioid Risk Screening, Urine Screen, PDMP check)
- **B** Prescribing Habits/Outliers
- **C** Suspicious Order Monitoring
- **D** SUD Predictive Modeling / Analytics
- **E** Drug Diversion Monitoring Reports

**COVID-19 CONSIDERATIONS**

- Potential increase for Diversion / Opioid Overdoses
- Increased Availability of MAT
- Critical Drug Shortages
- Information Sharing / Privacy Laws
- State and Federal Law Contradictions
ACRONYMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADF</td>
<td>Abuse Deterrent Formula</td>
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<tr>
<td>SUD/OUD</td>
<td>Substance Use Disorder/Opioid Use Disorder</td>
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<td>MAPS</td>
<td>Michigan Automated Prescription System (PDMP)</td>
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<td>MOP</td>
<td>Michigan Opioid Partnership</td>
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<tr>
<td>DATA</td>
<td>Drug Addiction Treatment Act</td>
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<tr>
<td>MED</td>
<td>Morphine Equivalent Dose</td>
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<tr>
<td>MME</td>
<td>Morphine Milligram Equivalents</td>
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<td>MAT</td>
<td>Medication Assisted Treatment</td>
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<td>OCRA</td>
<td>Opioid Crisis Response Act</td>
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<td>Substance Abuse Mental Health Services Administration</td>
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<td>Prescription Drug Monitoring Program</td>
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<td>Subjective Opioid Withdrawal Scale</td>
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<tr>
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<td>The Joint Commission</td>
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<td>CIA</td>
<td>Corporate Integrity Agreement</td>
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<td>SOM</td>
<td>Suspicious Order Monitoring</td>
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APPENDIX – DEA CS PRESCRIBING DURING COVID