



OPIOID CRISIS AND COMPLIANCE

Virtual Ann Arbor Regional Healthcare Compliance Conference
June 2020

Internal Audit, Risk, Business & Technology Consulting

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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

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U.S./MICHIGAN UPDATE ON THE OPIOID CRISIS

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

Michigan saw it's 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>



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WHAT DO WE KNOW ABOUT THE OPIOID CRISIS?

Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.⁵

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.⁷

The Midwestern region saw opioid overdoses increase 70 percent from July 2016 through September 2017.¹⁰

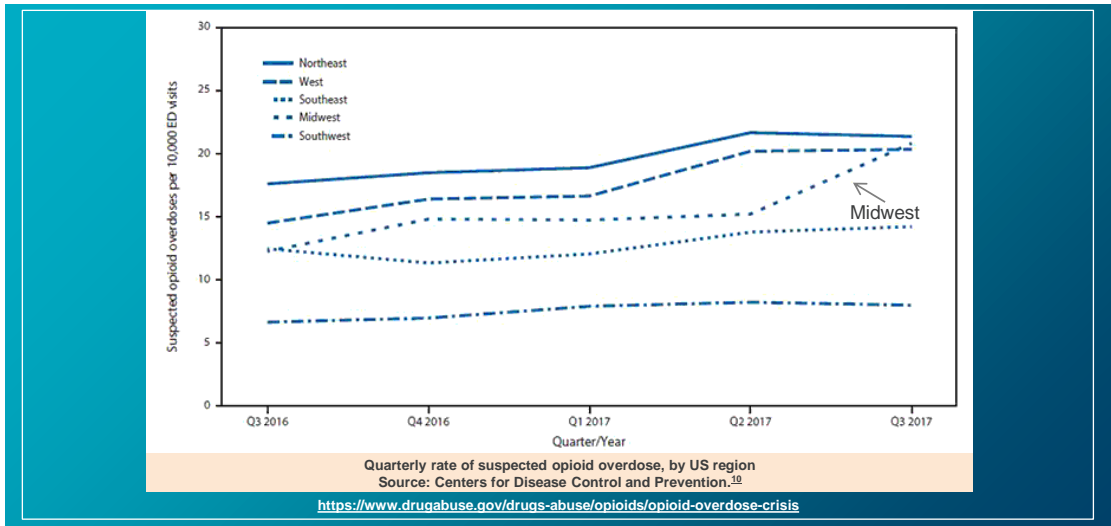
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OPIOID OVERDOSES BY REGION

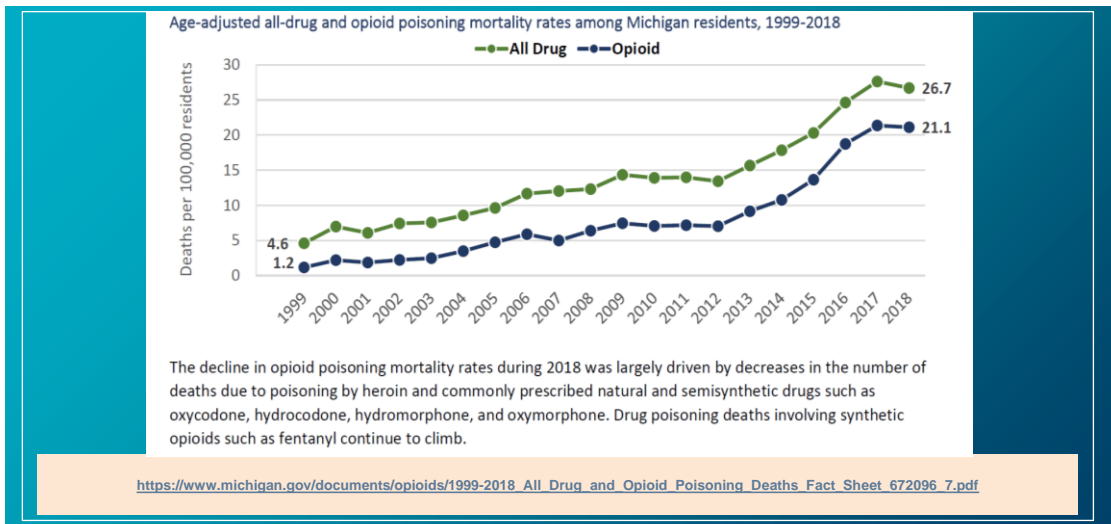


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MICHIGAN OPIOID DEATH DECLINE

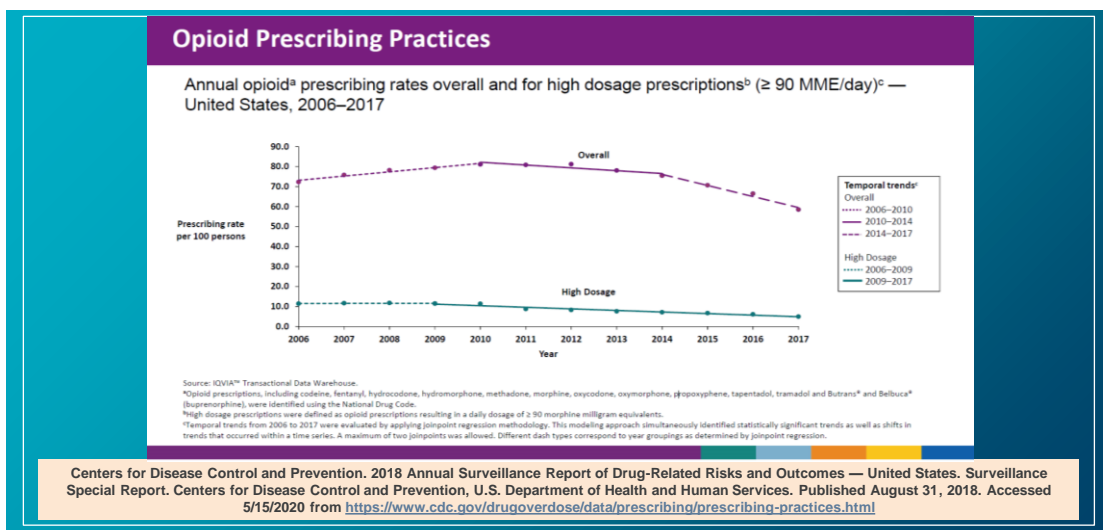


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CURRENT STATS – MAKING PROGRESS

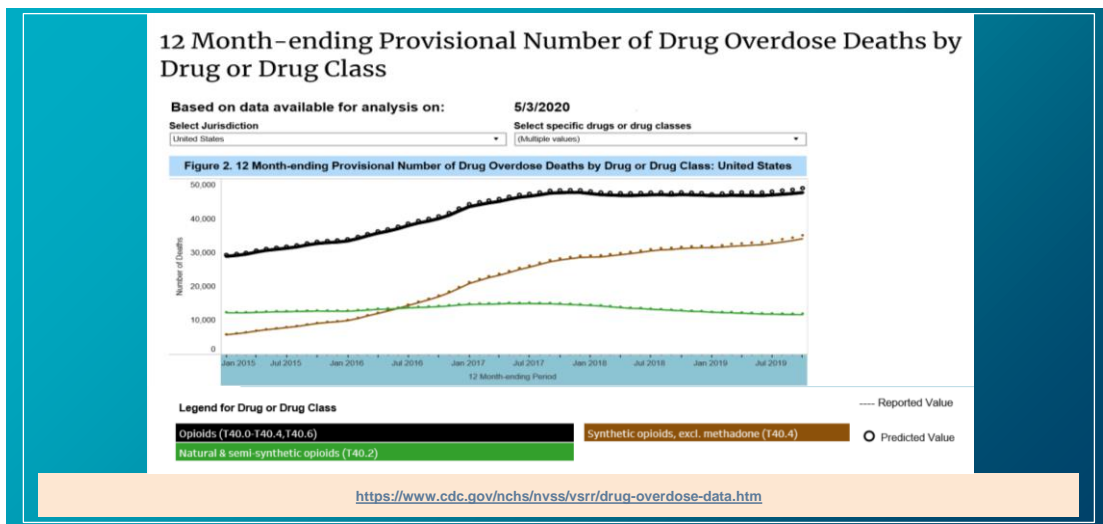


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COMPLIANCE REQUIREMENTS

“
 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)*

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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?

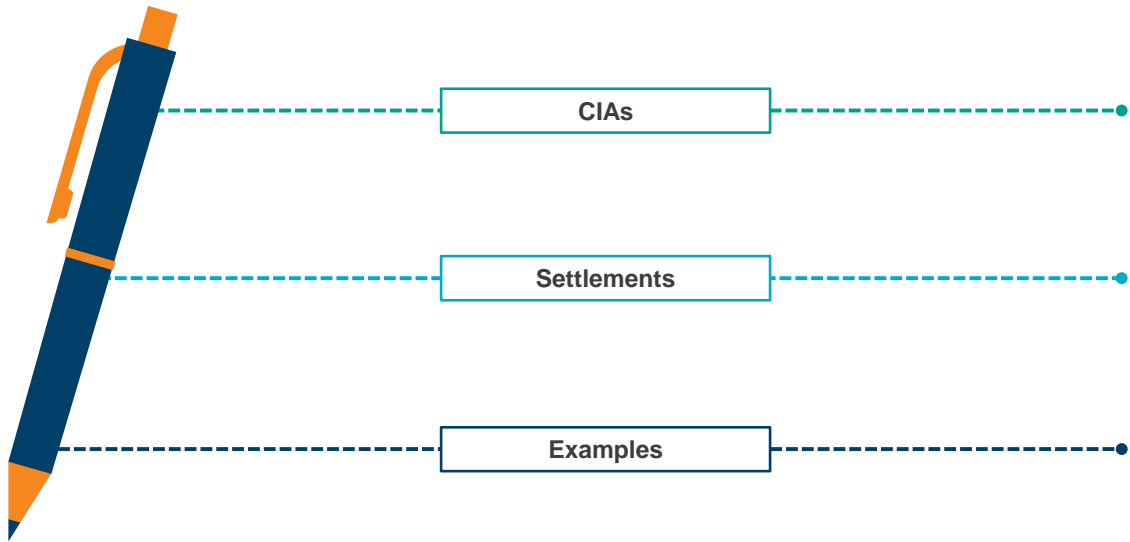
Does the corporation’s compliance program work in practice?

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CONSEQUENCES OF NON-COMPLIANCE






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COMPLIANCE STANDARDS

 Industry Guidelines	 Federal Regulatory Requirements	 State Regulatory Requirements
<ul style="list-style-type: none"> • CDC – Opioid Prescribing Guidelines • CMS – Limits Conditions of Payment • TJC – Updated Pain Management and Assessment Guidelines • AMA – National and State Medical Boards & Associations • SAMSHA 	<ul style="list-style-type: none"> • DEA Controlled Substances Act • BOP, BOM, Medical Licensing Board • PDMP (MAPS) • Suspicious Order Monitoring • Key Performance Indicators of Organization (DOJ) 	<ul style="list-style-type: none"> • States’ Limits on Days Supply and Max Daily Dose, Partial Fills • Michigan Opioid Laws <ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> Authorized Orderer – Utilization of CSOS SOD between Ordering and Receiving
Receiving	<ul style="list-style-type: none"> Security upon Receipt Two individuals count received drugs and compare to invoice and sign
Inventory Management (including storage and security)	<ul style="list-style-type: none"> Utilize Automated Dispensing Machine (Pyxis, Omnicell, etc.) Perpetual Inventory
Transfers / Restocking	<ul style="list-style-type: none"> Secure carts Inventory count and retrieval of returned drugs
Ordering / Prescribing	<ul style="list-style-type: none"> Authorized order required for dispense (and review of overrides)
Preparation and Dispensing	<ul style="list-style-type: none"> CS in single pockets Blind counts and review of discrepancy reports
Administration (including Waste and Return)	<ul style="list-style-type: none"> Retrieve one patient at a time, and as close to administration time as possible Return / Waste Witness required for CS
Monitoring	<ul style="list-style-type: none"> Testing of wasted CS Utilization of ADM CS reports
Investigation and Response	<ul style="list-style-type: none"> Hotline for reporting suspected diversion Multidisciplinary Drug Diversion Response Team
Education	<ul style="list-style-type: none"> 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

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DIVERSION MONITORING REPORTS



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COMMON FINDINGS AS DIVERSION INDICATORS

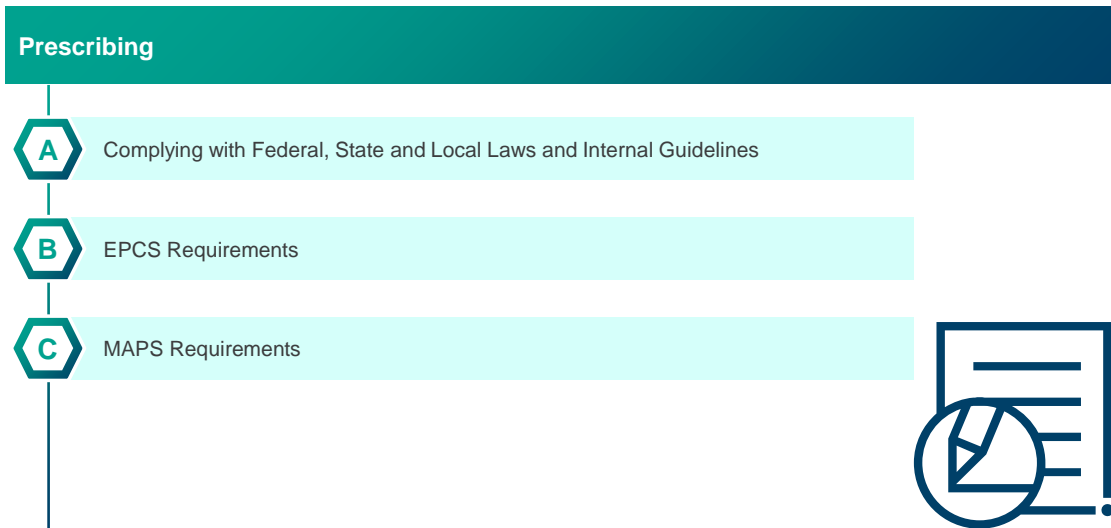


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KEY AREAS TO AUDIT



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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 expediate the currently pending legislature to mirror the Part D requirements.

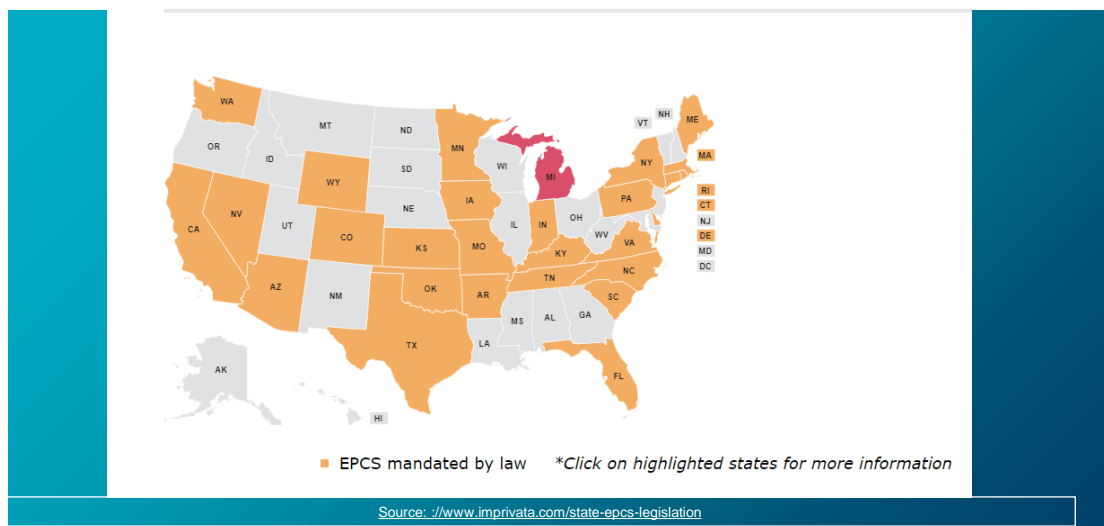


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EPCS MANDATES BY STATE



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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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KEY AREAS TO AUDIT

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.

Monitoring for Compliance with Grant Requirements:

- A** Inpatient/ED identification of SUD
- B** Treatment referrals
- C** Peer recovery
- D** MAT availability



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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.

Program	Budget
Naloxone distribution to high-risk areas and populations	\$4.5 million
Medications to treat opioid use disorder in emergency departments	\$4 million
Medications to treat opioid use disorder in jails	\$3 million
Syringe service programs	\$2 million
Mobile care units	\$1.7 million
Loan repayment for providers beginning or expanding medication-assisted treatment	\$1.25 million
Outreach to increase providers offering medications to treat opioid use disorder	\$410,000
Data-driven overdose response efforts	\$235,000
Start-up costs for new treatment services	\$235,000
Community engagement in majority-minority communities	\$200,000
TOTAL	\$17.5 million

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KEY AREAS TO AUDIT

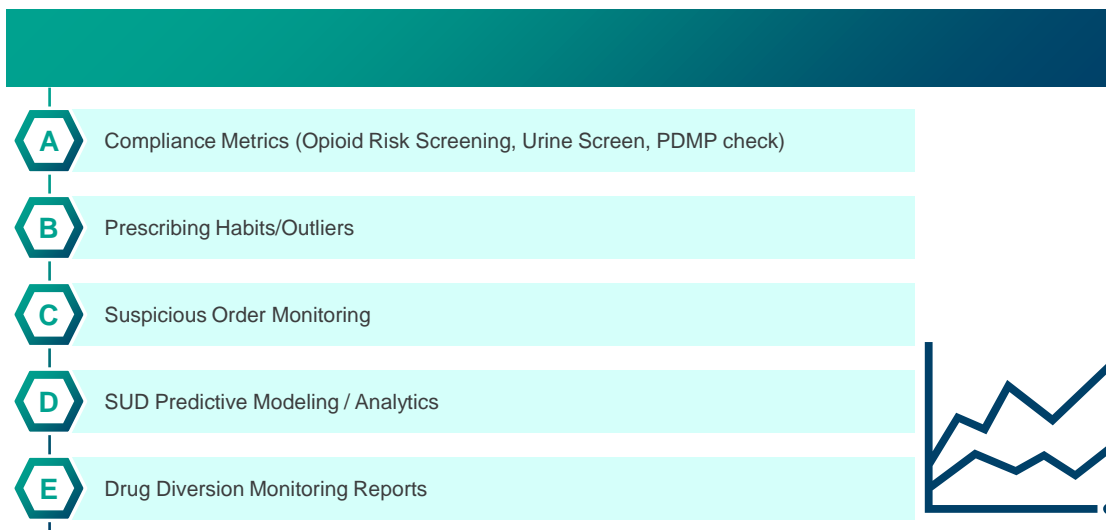
TJC Pain Management And Assessment Guidelines

- A** Discharge Instructions
- B** Data Monitoring for Progress
- C** Monitoring for Respiratory Depression
- D** Appropriate Referrals



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DATA ANALYTICS/MONITORING

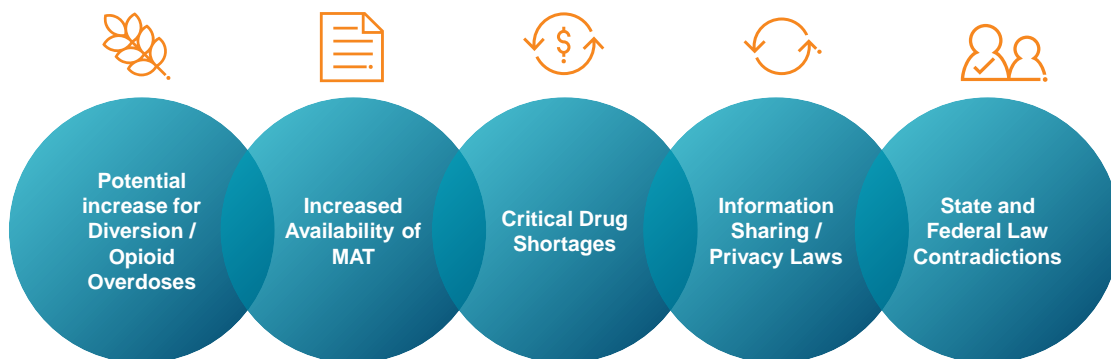


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COVID-19 CONSIDERATIONS



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ACRONYMS AND ABBREVIATIONS

ADF	Abuse Deterrent Formula
SUD/ODU	Substance Use Disorder/Opioid Use Disorder
MAPS	Michigan Automated Prescription System (PDMP)
MOP	Michigan Opioid Partnership
DATA	Drug Addiction Treatment Act
MED	Morphine Equivalent Dose
MME	Morphine Milligram Equivalents
MAT	Medication Assisted Treatment
OCRA	Opioid Crisis Response Act
SAMHSA	Substance Abuse Mental Health Services Administration
DEA	Drug Enforcement Agency
PDMP	Prescription Drug Monitoring Program
SOWS	Subjective Opioid Withdrawal Scale
TJC	The Joint Commission
CIA	Corporate Integrity Agreement
BOP	Boards of Pharmacy
SOM	Suspicious Order Monitoring
MLB	Medical Licensing Board
CDC	Centers for Disease Control
BOM	Boards of Medicine
CSA	Controlled Substances Act

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