July 25, 2022

Controlled Substances—Establishing Opioid Stewardship & Drug Diversion Prevention Programs

Meghan Ha, PharmD & Kim Harris, RPh

Disclosures

- The presenters have no real or perceived conflicts of interest related to this presentation

Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.

Learning Objectives

At the end of this session, participants should be able to:

1. Recognize the need for opioid stewardship implementation at acute care hospitals
2. Identify the key components of a successful opioid stewardship program
3. Recall essential components to developing a drug diversion prevention program

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Introduction to Opioid Stewardship

Meghan Ha, PharmD

Wolters Kluwer Health/ Community Health Systems Fellow

Preceptors: Dawn Scott, PharmD, MBA & Steve Mok, PharmD, MBA, BCPS, BCIDP

Opioid Stewardship

Background

10.1 million people

In the U.S. aged 12 or older misused opioids in 2019

100,306 deaths

…related to drug overdose from April 2020-2021

Synthetic opioids

…contribute to the majority of opioid overdose deaths

Source: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm
Source: https://www.cdc.gov/opioids/data/index.html

Opioid Stewardship

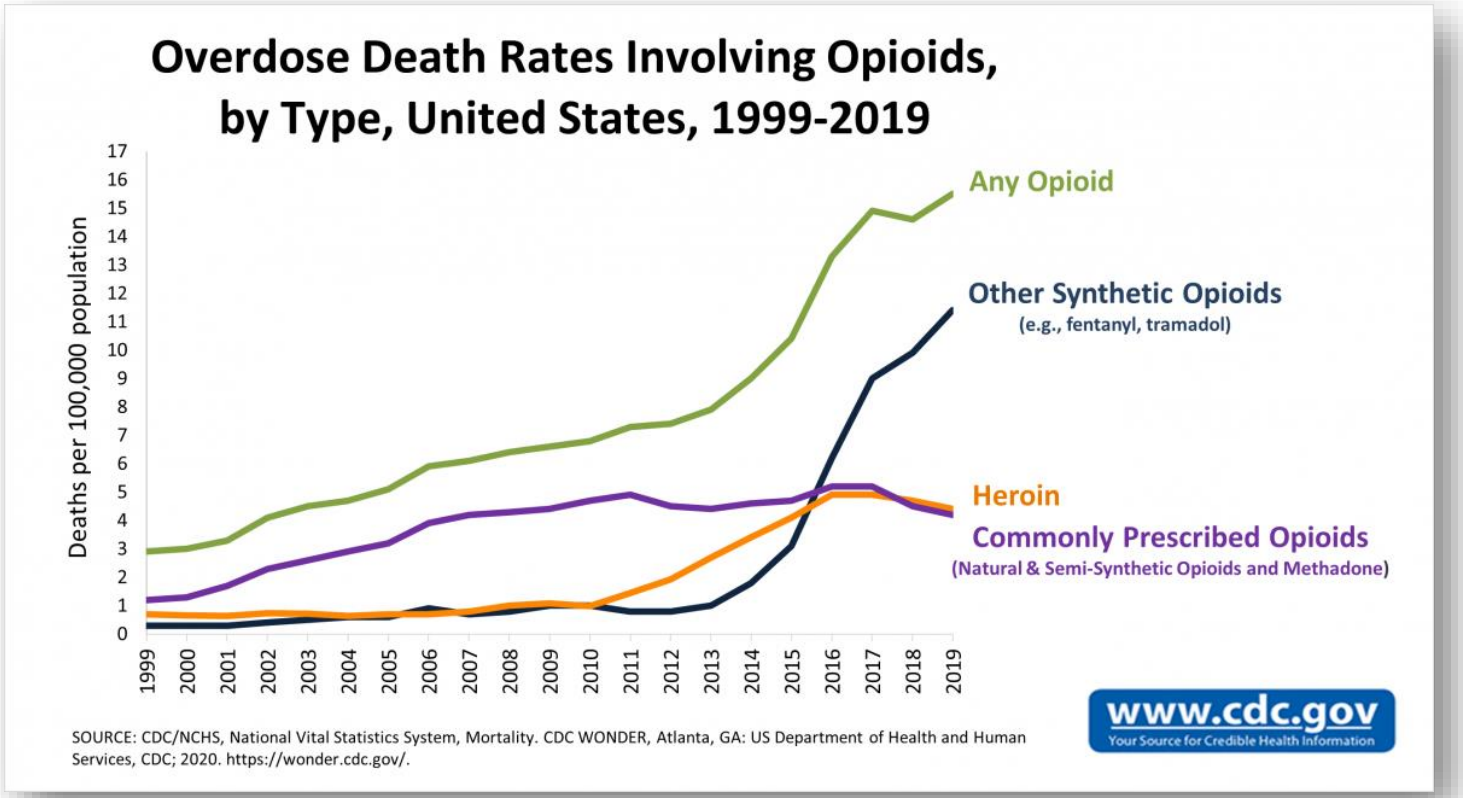
Background

Safe Opioid Use + ALTOs

Harm Reduction

Treating Opioid Use Disorder

ALTOs = alternatives to opioids



Source: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm
Source: https://www.cdc.gov/opioids/data/index.html

Opioid Stewardship

Resources for Opioid Stewardship Programs

The Joint Commission: Pain Assessment and Management Standards for Hospitals

2018

National Quality Forum: National Quality Partners Playbook: Opioid Stewardship

2018

American Hospital Association: STEM THE TIDE

2020

CDC: Guidelines for Opioid Prescribing

2022

Sources:

- National Quality Partners Playbook: Opioid Stewardship: https://www.qualityforum.org/National_Quality_Partners_Opioid_Stewardship_Action_Team.
- R3 Report, Issue 11: Pain Assessment and Management Standards for Hospitals: https://www.jointcommission.org/standards/r3-report/r3-report-issue-11-pain-assessment-and-management-standards-for-hospitals/
- American Hospital Association: https://www.aha.org/guidesreports/2017-11-07-stem-tide-addressing-opioid-epidemic-taking-action

Facility Implementation of an Opioid Stewardship Program

Opioid Stewardship

Useful Tools for an Opioid Stewardship Program

Facility-Level Approach

- Partner with other departments and service-lines to increase buy-in & commitment
- Consider evening meetings to improve attendance
- First meeting should include introductions & agreement on program goals
- Incorporate opioid stewardship initiatives into P&T Meetings

P&T: Pharmacy and Therapeutics, MME: morphine milligram equivalents

Opioid Stewardship

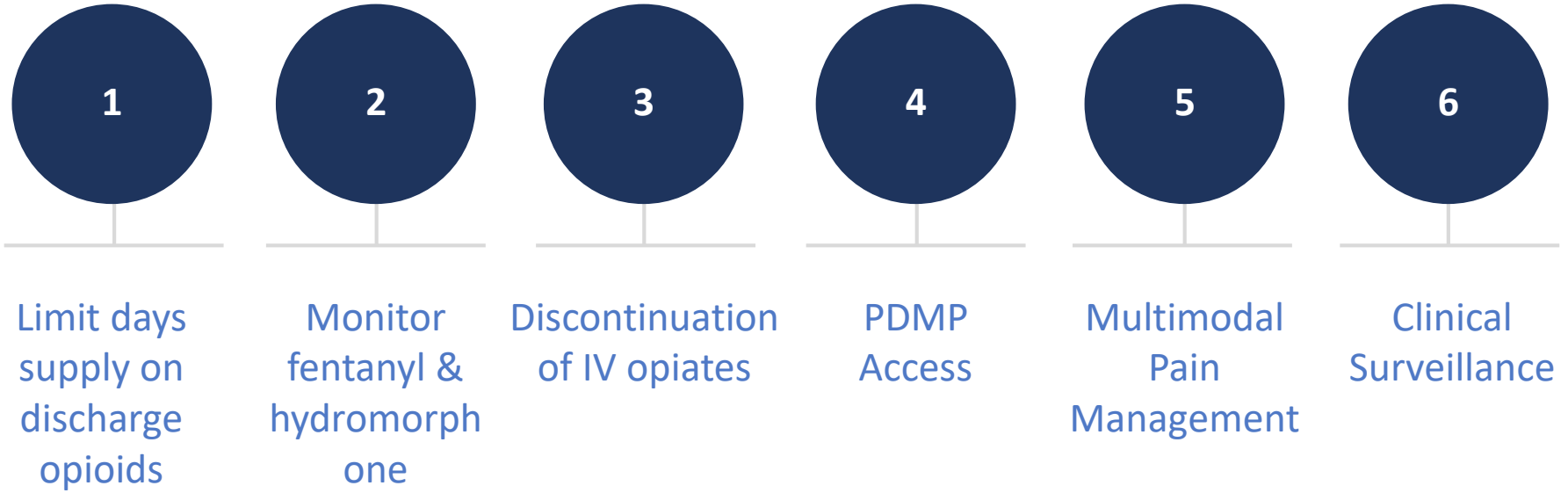
Fundamentals at the Facility Level

Leadership, Culture & Accountability	• Engage leaders for support • Establish culture for opioid stewardship • Develop accountability
Policies & Guidelines	• Support opioid stewardship culture • Hardwire best practices
Education	• Providers • Co-workers • Patients, families & caregivers
Tracking, Monitoring & Reporting	• Identify opportunities • Share with organization • Celebrate successes

Source: National Quality Partners Playbook: Opioid Stewardship: https://www.qualityforum.org/National_Quality_Partners_Opioid_Stewardship_Action_Team.

Opioid Stewardship

Examples of Facility Program Goals & Initiatives



Targeting Dilaudid: Encourage use of a lower starting dose of IV hydromorphone

- Make low dose easily orderable in the EHR
- Make prefilled syringes available for hydromorphone 0.2 mg
- Set an expected IV initial dose, PRN dose & restrict to severe pain

IV: intravenous; PDMP: Prescription Drug Monitoring Program

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Mercy Health's System Approach to Controlled Substance Stewardship: Opioid Stewardship & Drug Diversion Prevention

Kim Harris, RPh

Manager Controlled Substance Stewardship

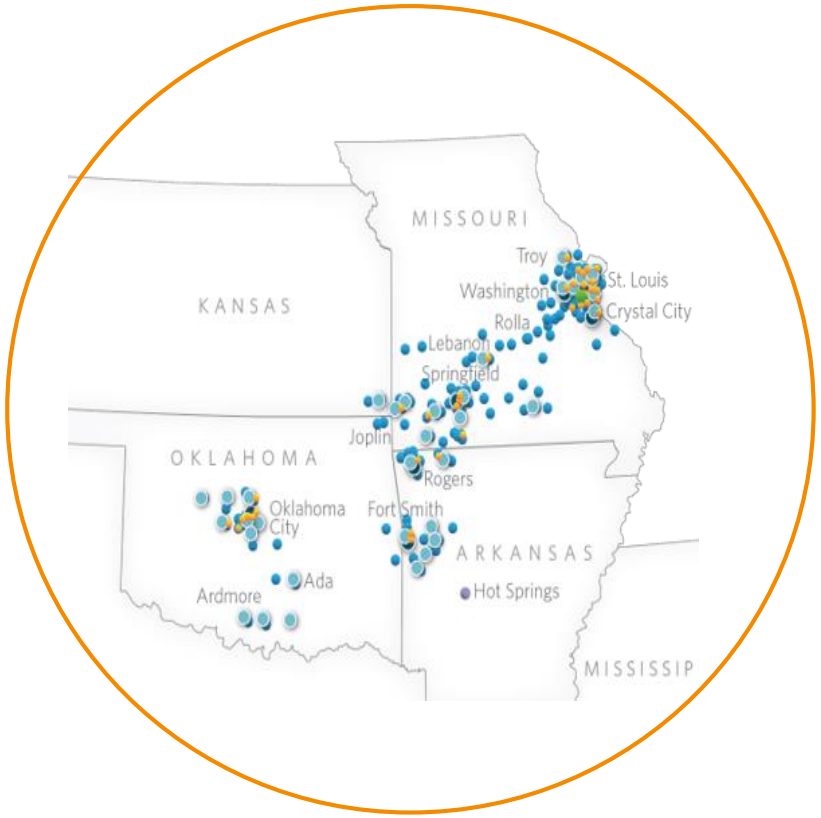
Mercy

Health System Controlled Substance Stewardship Program

Topics covered

1. Opioid stewardship program
2. Drug diversion prevention program
    - Essential components

Mercy Health

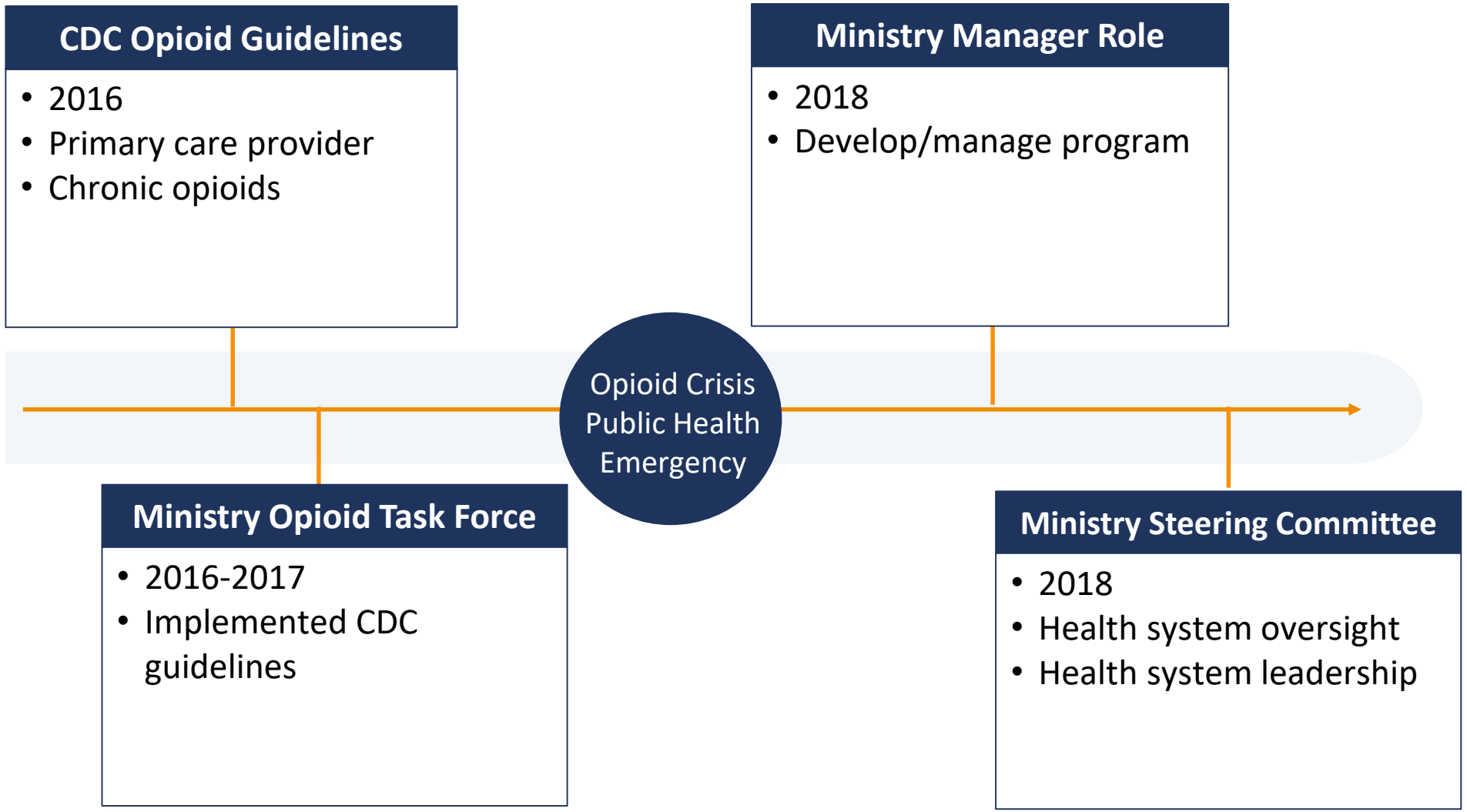


Mercy's Ministry

- Multi-state footprint
- Arkansas, Kansas, Missouri & Oklahoma
- 44 hospitals
- 900 physician practices
- 4,000 integrated providers
- 42,000 co-workers

Mercy's Journey: Health System Controlled Substance Stewardship

Structuring a Health System Controlled Substance Stewardship Program



Health System Controlled Substance Stewardship Oversight

Health System Controlled Substance Operational Task Force

Organization

- Created 2nd quarter CY 2019
- Reports to Controlled Substances Stewardship Committee & Quality Committee of the Board
- Multi-disciplinary
- Health system committee

Membership

- Pharmacy
- Quality
- Nursing
- Behavioral health
- Pain management
- Emergency medicine
- Anesthesia
- Primary care
- Mission
- Executive leadership
- Social services

Health System Controlled Substances Operational Task Force

Collaboration & standardization

Regulatory

- Joint Commission gap analysis on pain and opioid standards

National Quality Forum (NQF)

- NQF Guideline implementation, (e.g., provider education courses)

Drug Diversion Prevention

- Best practices to prevent diversion (e.g., standardized ADC timeout settings)

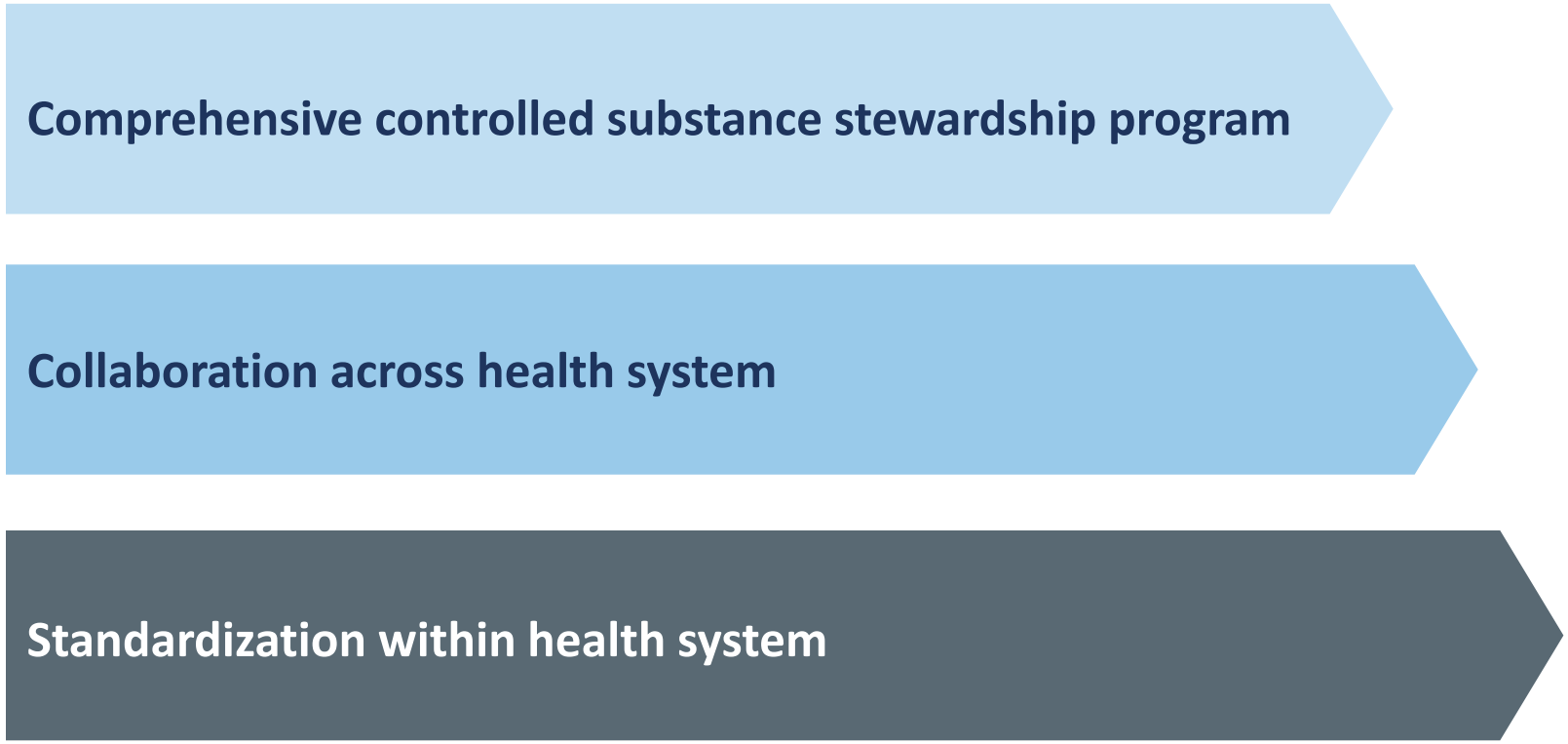
ADC: automated dispensing cabinet

Health System Controlled Substances Operational Task Force

Mercy hospitals connected with health system work

- Hospital controlled substance stewardship committees
- Communication of health system initiatives throughout ministry and to local hospitals
- Template provided to hospitals for agenda items and report monitoring

Framework Established for Health System Controlled Substance Stewardship



Health System Implementation of an Opioid Stewardship Program

Fundamentals of Opioid Stewardship Program

Leadership, Culture & Accountability	• Engage leaders for support • Establish culture for opioid stewardship • Develop accountability
Policies & Guidelines	• Support opioid stewardship culture • Hardwire best practices
Education	• Providers • Co-workers • Patients, families & caregivers
Tracking, Monitoring & Reporting	• Identify opportunities • Share with organization • Celebrate successes

Source: National Quality Partners Playbook: Opioid Stewardship: https://www.qualityforum.org/National_Quality_Partners_Opioid_Stewardship_Action_Team.

Fundamentals: Leadership, Culture & Accountability

Engagement of Organizational Leadership

- Allocate resources
- Establish as organizational priority

Leadership, Culture & Accountability

Mercy's Controlled Substance Stewardship Committee: Ministry Executive Leadership

Culture of quality & safety

Board-level support

Leadership, Culture & Accountability, *continued*

Fundamentals: Policies & Guidelines

Tools to set expectations &
standardize practices

Dignifying Language: Anti-Stigma Awareness Campaign

Use non-stigmatizing language	Don't use stigmatizing language
Patient/person with a substance use disorder	Addict/drug abuser/ drug seeker/junkie/ user/drunk/alcoholic
Drug craving	Drug seeking
Substance Use Disorder (SUD)	Addiction/drug habit/drug problem
Babies/infant born with an opioid dependency (Neonatal Abstinence Syndrome or Neonatal Opioid Withdrawal)	Addicted baby/born addicted
Positive/negative toxicology screen results	Dirty/clean
Use/misuse, risky, unhealthy use	Abuse
Patient/person in recovery/abstinent/not drinking or taking drugs	Former abuser/addict/alcoholic
Treatment/medication/Medication Assisted Treatment (MAT)/medication used for opioid use disorder	Methadone maintenance/opioid replacement/narcotic replacement
Return of symptoms/recurrence of use	Relapse

Cultural policy for dignity

- Co-worker education
- Instructional video
- Promotional flyers
- Co-worker pledge
- Mission formation & training toolkit

Organizational Clinical Practice Guidelines

Mercy Guidelines for Prescribing Opioids for Chronic Pain

Guidelines for Prescribing Opioids for Chronic Pain

- These guidelines provide recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care
- In some settings, these guidelines may be useful for patients in treatment for cancer-related pain, at the judgment of the treating physician.
- In the United States, patients and clinicians have come to view opioids to manage pain as a cultural expectation. To change this cultural expectation, a multimodal, individualized approach to pain management that focuses on the biological, social and psychological components of pain is necessary.
- Chronic pain is a significant medical and social burden. It is our obligation as providers of health care to effectively address this problem with our patients.
- In addition, the misuse and diversion of opioid medications often used in the treatment of chronic pain is a significant medical and societal problem.
- These guidelines seek to address both issues, allowing for the compassionate and appropriate treatment of individual patients, and protecting both the patient and society at large from misuse of prescribed medications.

Definition:
Chronic pain is pain from any source lasting longer than 3 months.

Guidelines:

1. All patients need to have a careful assessment prior to the initiation of chronic opioid therapy. This assessment can be completed by any provider licensed to practice and prescribe opioid medications in the state where the evaluation takes place. Since careful review of history is necessary prior to the initiation of therapy, chronic opioid medication may not necessarily be prescribed at a first patient visit. Office staff should inform patients of this policy when the appointment is made.
2. During the evaluation, a pain history should be conducted. Nature of pain, onset, location, quality, duration and intensity should be documented. A comprehensive medical history should be completed. Include past medications and any history of drug or alcohol abuse or psychiatric disease. Past medication history can be obtained by accessing the patient's insurance records to see where and when narcotic medications were filled. This information may also be obtained through the patient's designated pharmacy and/or the prescription drug monitoring program (PDMP) database, where available, without violation of protected patient information.
3. The Opioid Risk Tool is a valuable instrument that can be used to determine the likelihood of aberrant behaviors associated with chronic opioid use. Patients who score higher than 8 on this assessment may have a higher risk of aberrant behavior. More frequent monitoring may be required in these patients.
4. At minimum, a directed physical exam should be done at every visit.
5. Urine drug screening should be done at initial visit. For patients deemed to be low risk, testing 2 times per year at minimum is adequate. For patients assessed to be of higher risk, testing should be 4 times per year at minimum. Testing can be completed randomly as clinically indicated. Patients are to be informed of this policy in their medication management agreement (pain contract). Failure to give a sample when requested is grounds for dismissal from the practice. No specific frequency of random urine drug tests is mandated, but may be based on the clinician's judgment and assessment of risk.
6. Use of chronic benzodiazepines in conjunction with chronic opioids is dangerous. Clinicians should wean patients being treated with chronic opioids off of benzodiazepines when possible if clinically appropriate.
7. Patients will be informed of the risks and benefits of chronic opioid therapy at initiation of therapy and annually thereafter. Potential risks include hyperalgesia, neuroendocrinologic dysfunction, and possibly immunosuppression. A medication management agreement (pain contract) will be signed at initial visit and annually renewed thereafter. The medication management agreement (pain contract) should include language stating that opioids for chronic pain should be obtained from only one provider and from only one pharmacy.

Mercy *Your life is our life's work.*

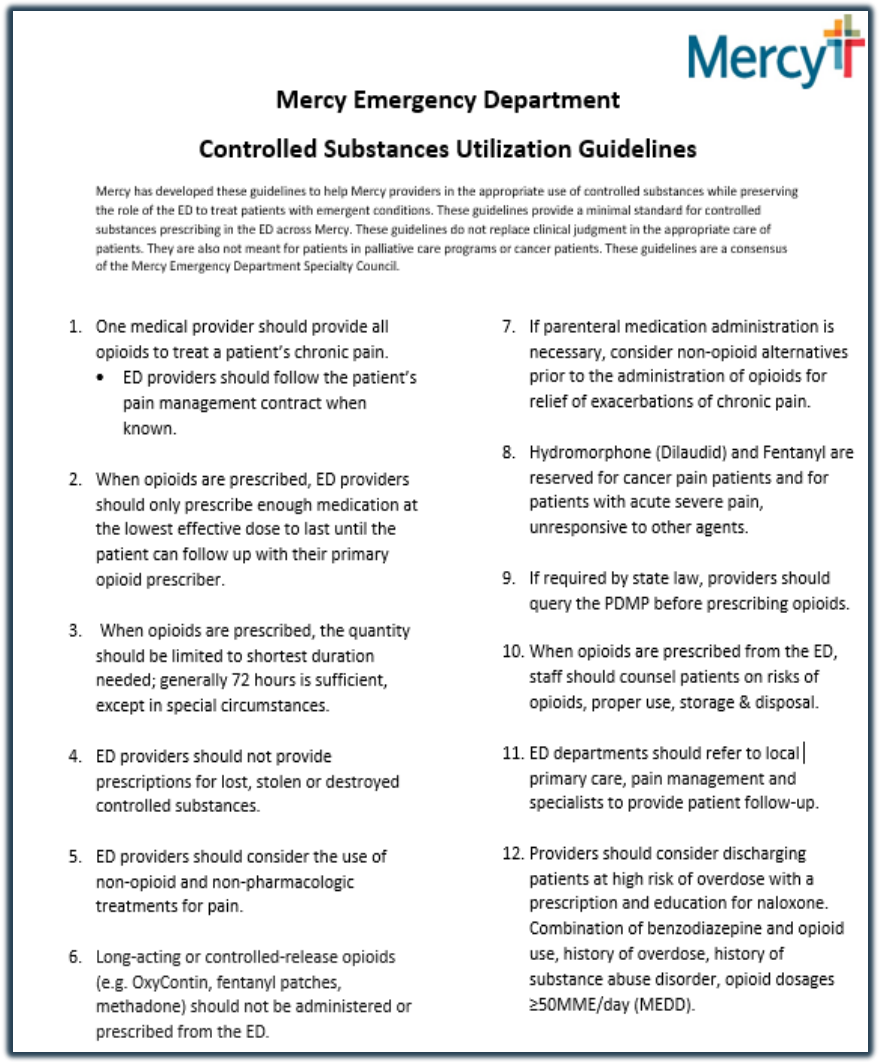
Mercy Opioid Prescribing Guidelines v03.24.2017

1. Identifies best practices
2. Sets expectations
3. Addresses:
   - Assessments
   - Monitoring
   - Pain agreements
   - Prescribing
   - Patient education

Organizational Clinical Practice Guidelines

Emergency Department Controlled Substance Utilization Guidelines

- Establishes standards for controlled substance stewardship
- Addresses administering & prescribing controlled substances from emergency department
- Encourages use of evidence-based alternatives to opioids (ALTO) protocols
- Promotes PDMP checks & naloxone co-prescribing
- Supports non-pharmacologic therapy



Mercy

Mercy Emergency Department

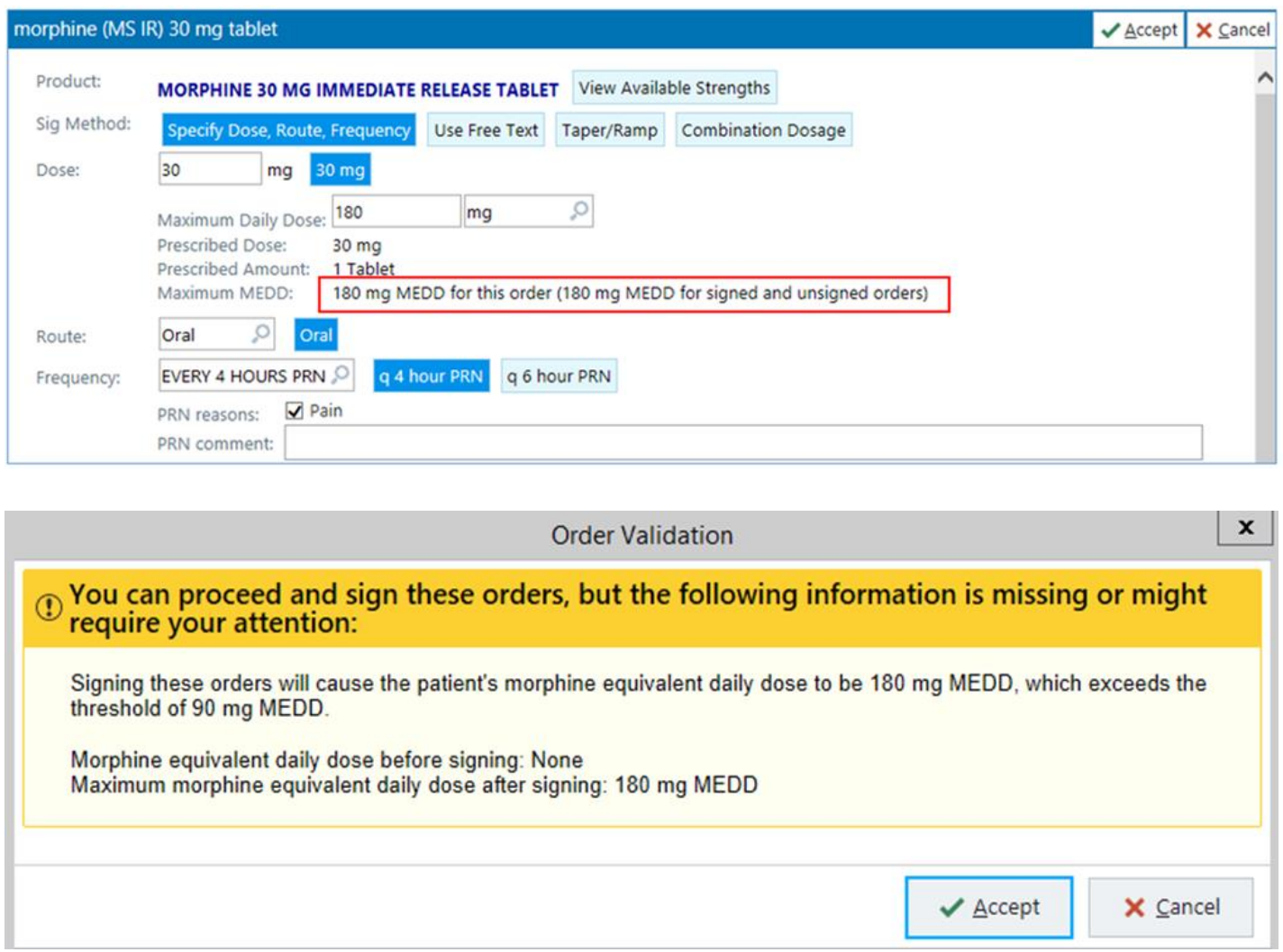
Controlled Substances Utilization Guidelines

Mercy has developed these guidelines to help Mercy providers in the appropriate use of controlled substances while preserving the role of the ED to treat patients with emergent conditions. These guidelines provide a minimal standard for controlled substances prescribing in the ED across Mercy. These guidelines do not replace clinical judgment in the appropriate care of patients. They are also not meant for patients in palliative care programs or cancer patients. These guidelines are a consensus of the Mercy Emergency Department Specialty Council.

1. One medical provider should provide all opioids to treat a patient's chronic pain.
   - ED providers should follow the patient's pain management contract when known.
2. When opioids are prescribed, ED providers should only prescribe enough medication at the lowest effective dose to last until the patient can follow up with their primary opioid prescriber.
3. When opioids are prescribed, the quantity should be limited to shortest duration needed; generally 72 hours is sufficient, except in special circumstances.
4. ED providers should not provide prescriptions for lost, stolen or destroyed controlled substances.
5. ED providers should consider the use of non-opioid and non-pharmacologic treatments for pain.
6. Long-acting or controlled-release opioids (e.g. OxyContin, fentanyl patches, methadone) should not be administered or prescribed from the ED.
7. If parenteral medication administration is necessary, consider non-opioid alternatives prior to the administration of opioids for relief of exacerbations of chronic pain.
8. Hydromorphone (Dilaudid) and Fentanyl are reserved for cancer pain patients and for patients with acute severe pain, unresponsive to other agents.
9. If required by state law, providers should query the PDMP before prescribing opioids.
10. When opioids are prescribed from the ED, staff should counsel patients on risks of opioids, proper use, storage & disposal.
11. ED departments should refer to local primary care, pain management and specialists to provide patient follow-up.
12. Providers should consider discharging patients at high risk of overdose with a prescription and education for naloxone. Combination of benzodiazepine and opioid use, history of overdose, history of substance abuse disorder, opioid dosages ≥50MME/day (MEDD).

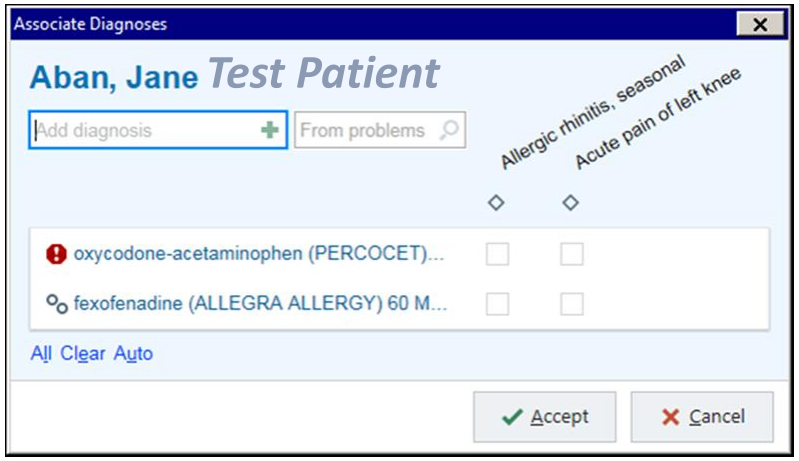
Policies & Guidelines

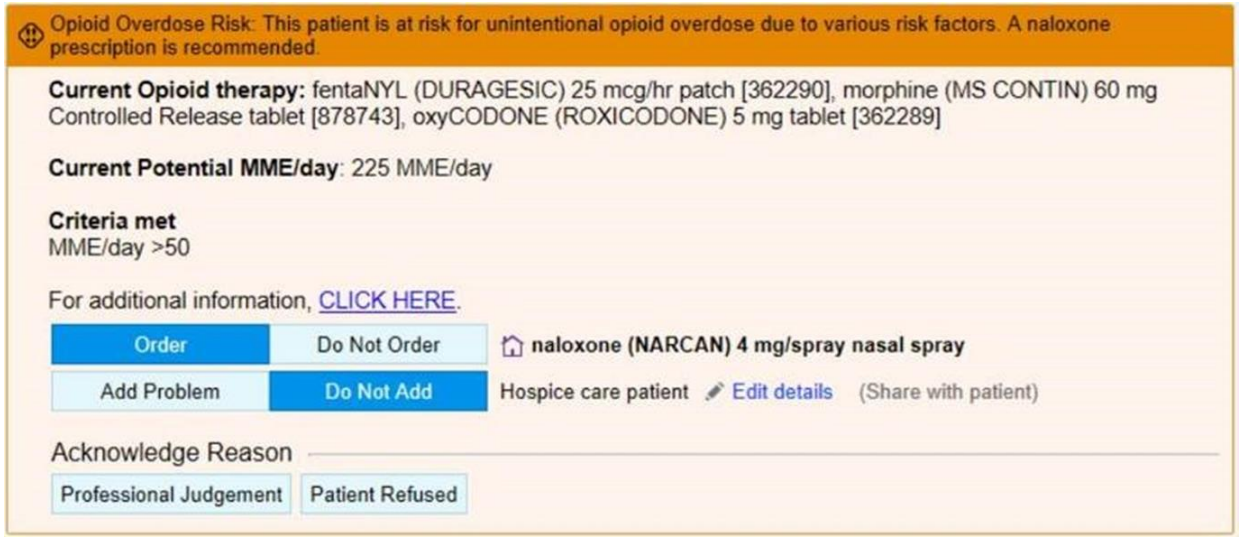
Electronic medical record clinical decision support tools to hardwire clinical practice



Policies & Guidelines

Electronic medical record clinical decision support tools to hardwire clinical practice





Fundamental: Education

Provider, co-worker, patient &
family/caregiver

Provider Education

Continuing education, required annual education, newsletters & tip sheets

MyEducation sponsored by

MercyUniversity

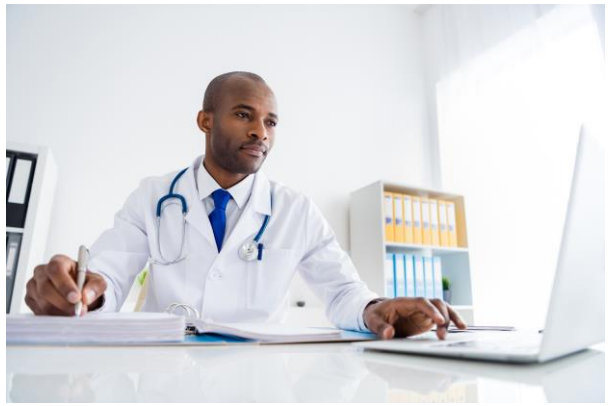
The Opioid Challenge - CLIN2460

COURSE **ACTIVITIES:** Test, Evaluation, Course Attachment, Video

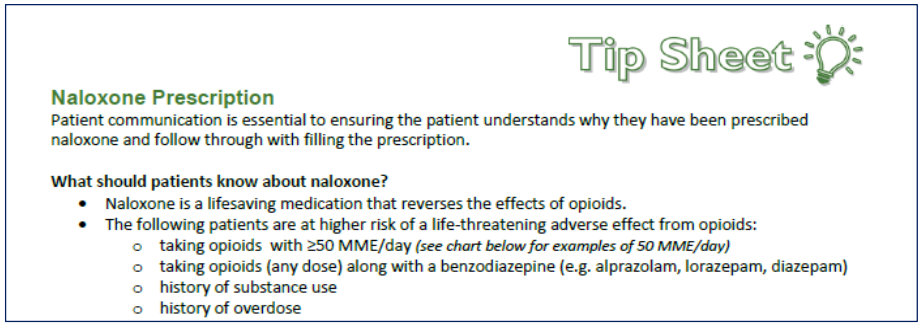
Chronic Pain and Opioid Prescribing Best Practices Course - CLIN3582

COURSE **CE:** 1.00 Hour(s) **ACTIVITIES:** Test, Evaluation, Course Attachment, Online

Required Annual Education



Mercy Provider Newsletters



Tip Sheet

Naloxone Prescription

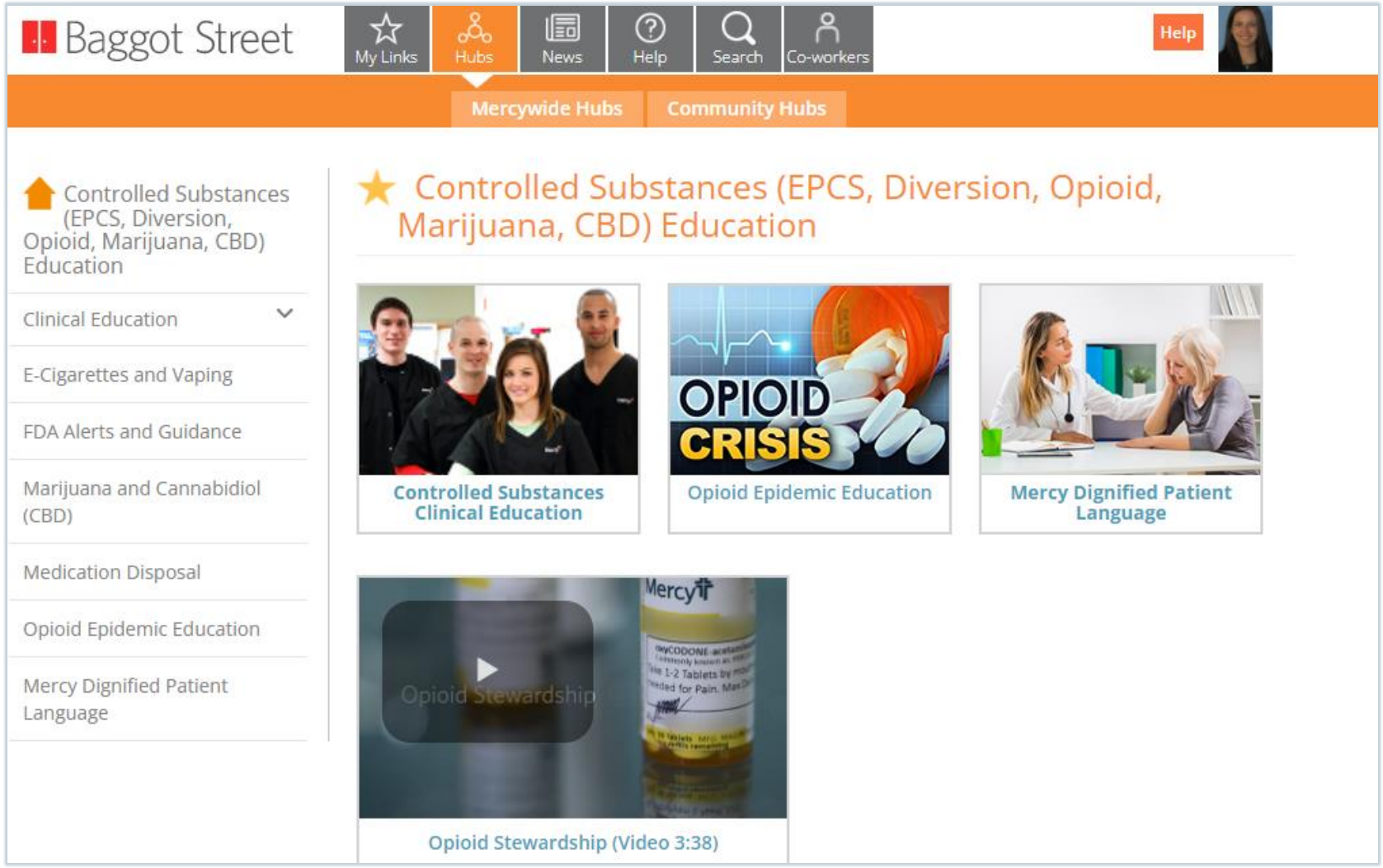
Patient communication is essential to ensuring the patient understands why they have been prescribed naloxone and follow through with filling the prescription.

What should patients know about naloxone?

- Naloxone is a lifesaving medication that reverses the effects of opioids.
- The following patients are at higher risk of a life-threatening adverse effect from opioids:
  - taking opioids with ≥50 MME/day *(see chart below for examples of 50 MME/day)*
  - taking opioids (any dose) along with a benzodiazepine (e.g. alprazolam, lorazepam, diazepam)
  - history of substance use
  - history of overdose

Provider Education

Baggot Street: Mercy intranet

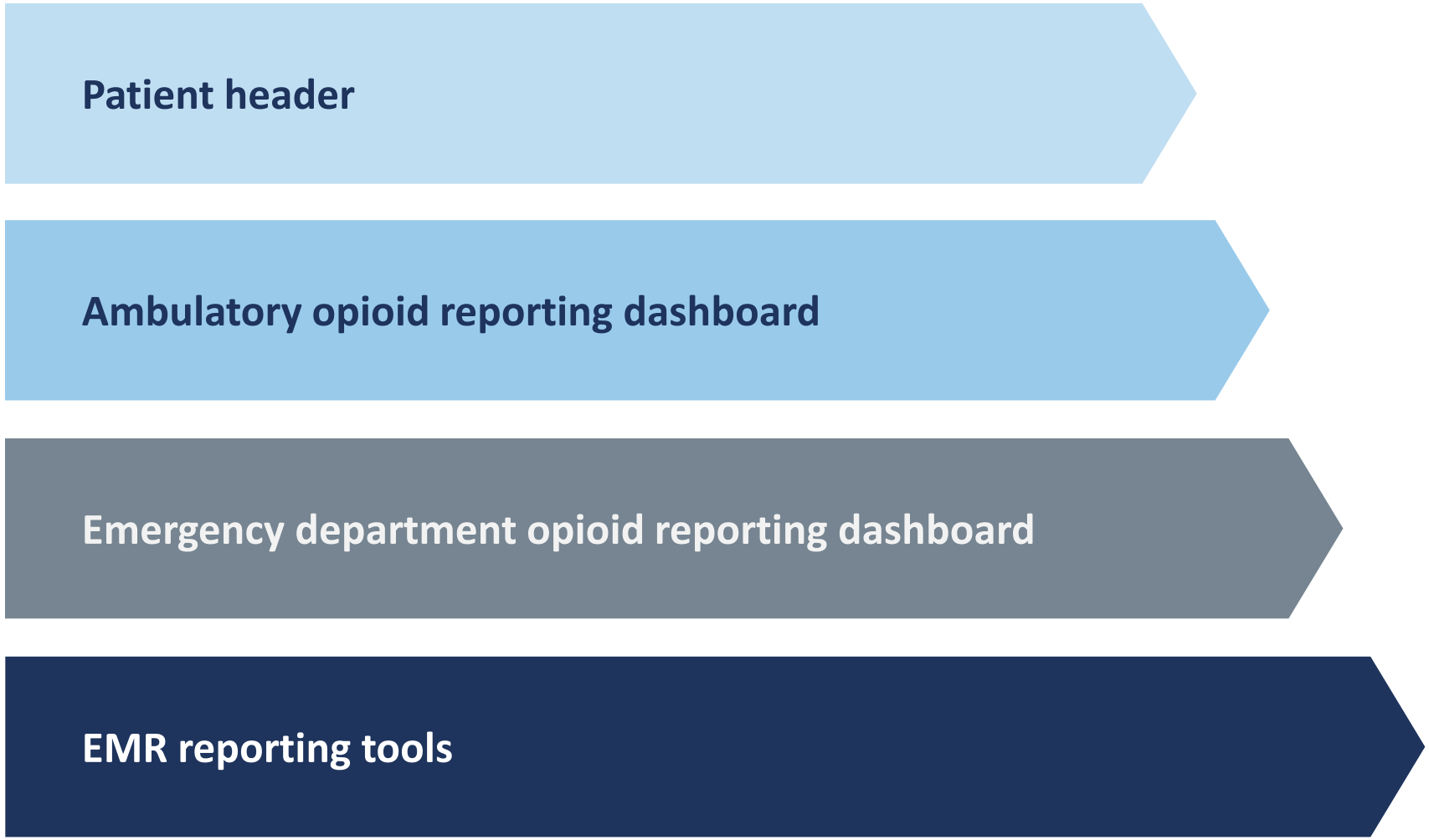


Patient & Family/Caregiver Education

Opioid medication management consents & agreements

- ✓ Educates on side effects & risks of opioid therapy
- ✓ Establishes goals of therapy
- ✓ Captures informed consent
- ✓ Details guidelines for chronic opioid therapy
  - Provider checking Prescription Drug Monitoring Program (PDMP)
  - Patient submitting to urine drug screens
  - Provider referring patient to specialists when indicated

Opioid Medication Management Agreement Integration in Electronic Medical Record (EMR)



Patient & Family/Caregiver Education

Opioid & naloxone patient education tools

- After visit summary (AVS) discharge education

How and when to give naloxone (03:11)

QR Code and weblink to access video

- Patient pamphlets
- Patient flyers
- Mercy.net education powered by Healthwise

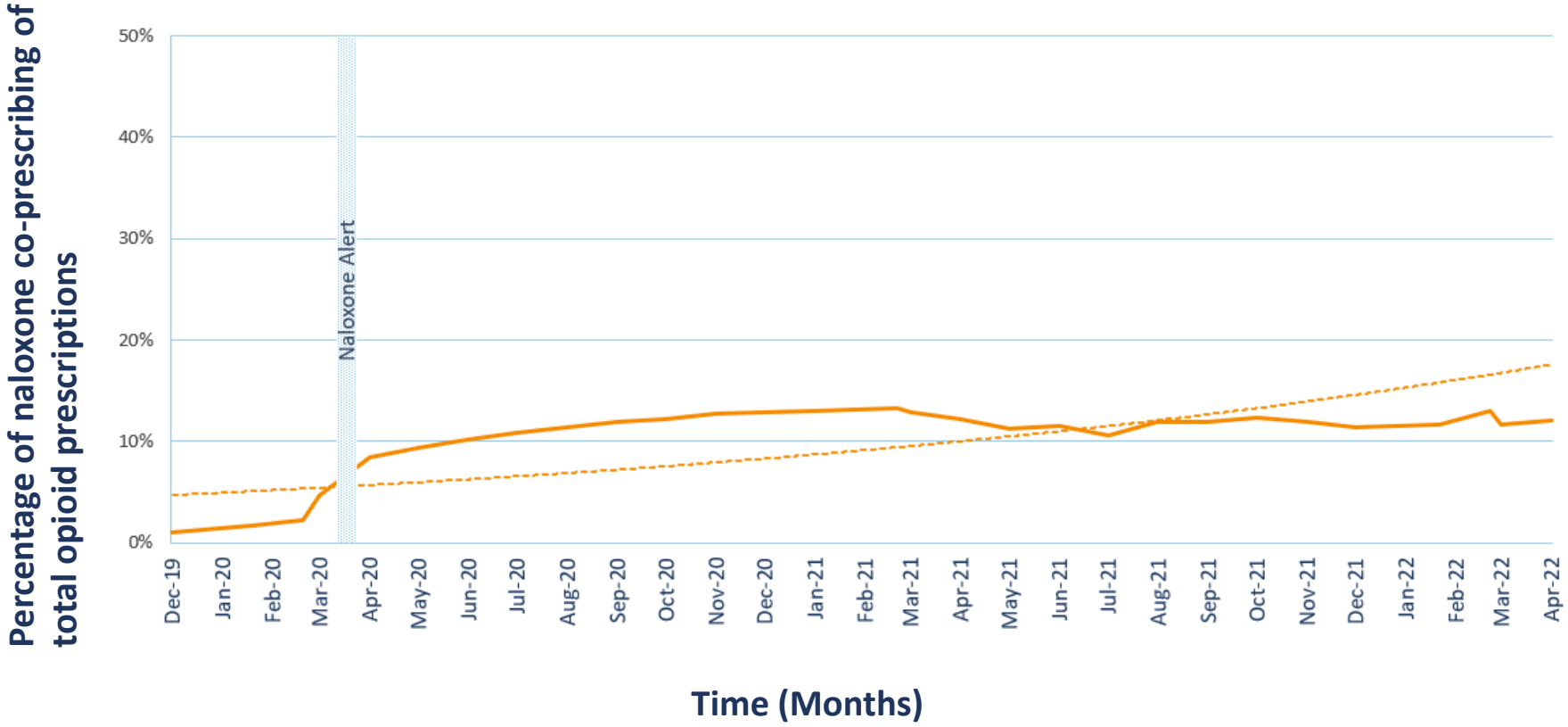
Fundamental: Tracking, Monitoring & Reporting

Identify areas of improvement &

monitor organization's progress

Tracking, Monitoring & Reporting for Improvement

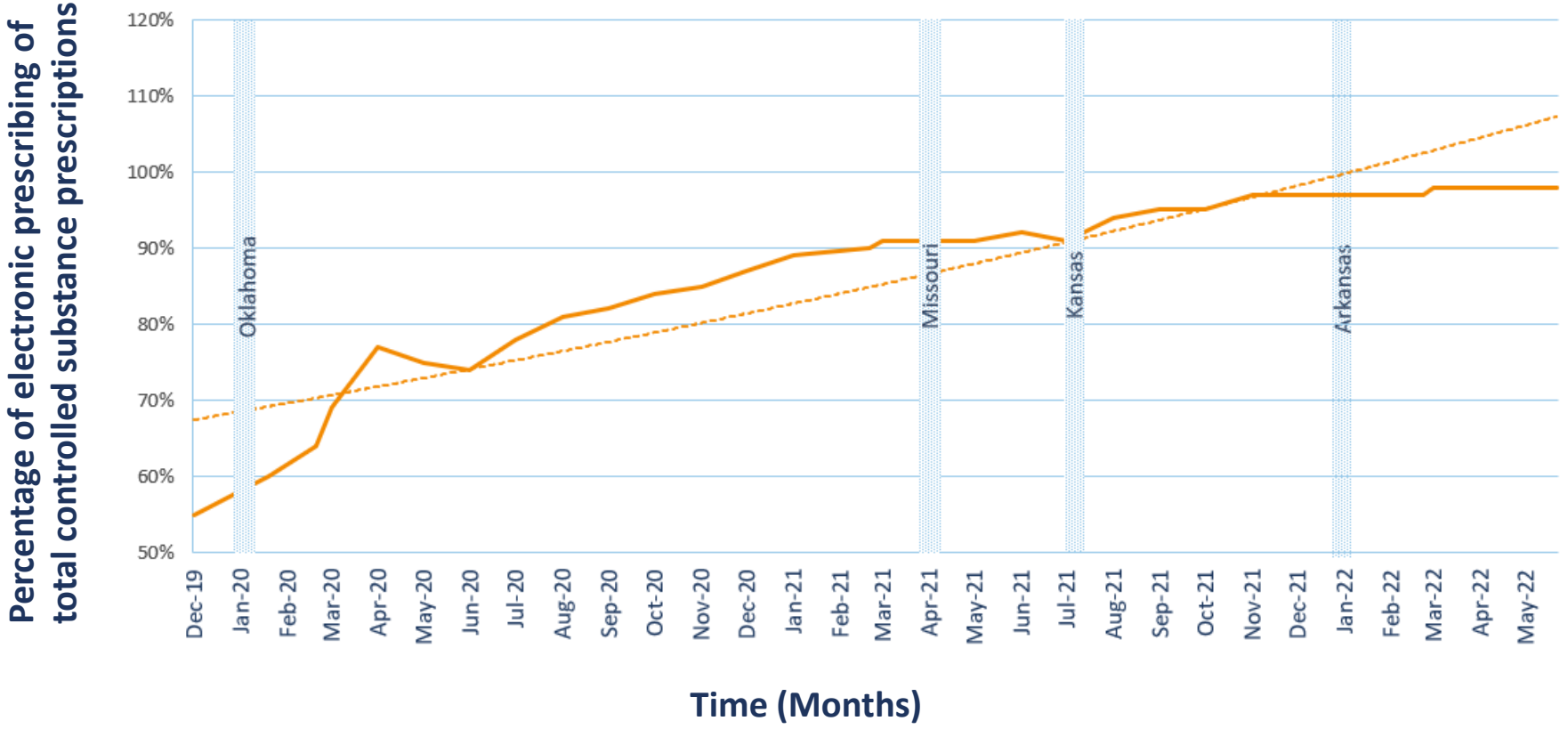
Opioid & naloxone co-prescribing



Source: Mercy Data

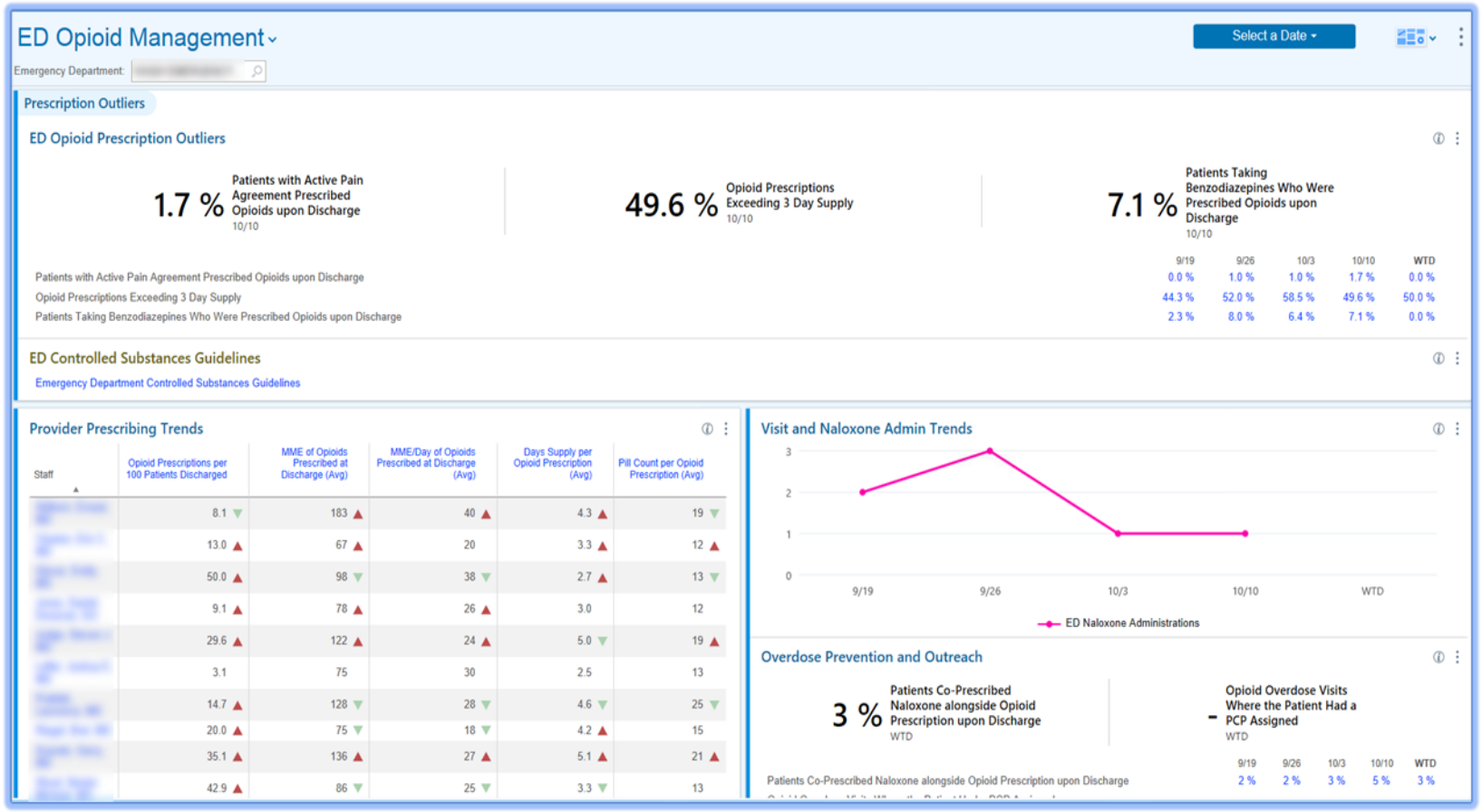
Tracking, Monitoring & Reporting for Improvement

Electronic prescribing of controlled substances (EPCS) promotes safe opioid prescribing



Source: Mercy data

Opioid Dashboards



- Active pain agreement
- Opioid prescription days supply
- MME values
- Naloxone co-prescribing

Source: Mercy data

Implementation of a Drug Diversion Prevention Program

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Healthcare Drug Diversion

Transfer of a medication for illegal distribution or personal use

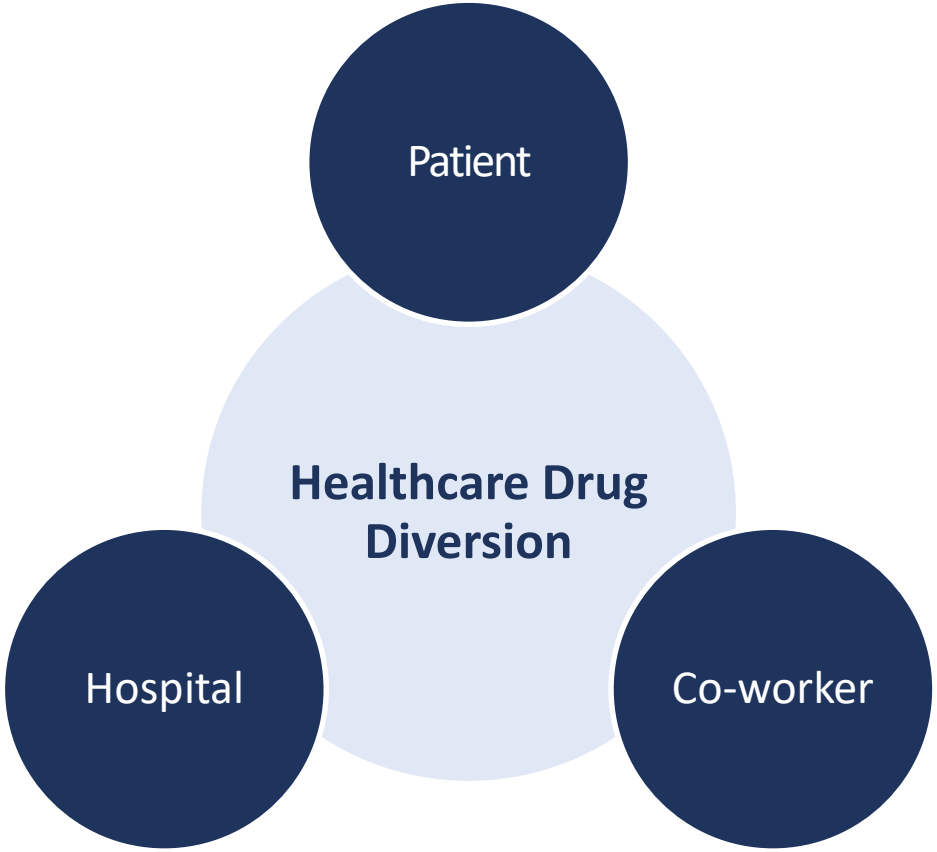
Significant healthcare issue affecting hospitals & health systems

10-15% of healthcare workers (HCW) misuse medications

Controlled substances, most frequently opioids

Source: Brummond, P. W., et. al. (2017). ASHP Guidelines on Preventing Diversion of Controlled Substances. *American Journal of Health-System Pharmacy*, 74(5), 325–348

Impact of Healthcare Drug Diversion



Patient Safety Risks & Impact

- **Risk of infection**
  - Tampering
- **Insufficient pain control or untreated pain**
- **Unsafe care**
  - Impaired co-worker

Healthcare Co-worker Risks & Impact

Diverting co-worker

- Loss of license
- Legal charges
- Self harm
    - Increased risk of overdose
    - Increased risk of suicide

Peer co-workers

- Potential legal charges
- Potential license sanctions
- Second victim trauma

Hospitals & Health System Risks & Impact

Required to maintain safety & security of medications

- **Regulatory & legal**
  - Drug Enforcement Agency (DEA)
  - Centers for Medicare and Medicaid Services (CMS)
  - State regulations
  - Lawsuits
- **Accreditation & licensure**
  - Joint Commission
  - Hospital or pharmacy license
- **Financial**
  - Loss of reimbursement
  - Fines (e.g., $7.75 million)
- **Reputation**
  - Loss of confidence

Guides for Developing Drug Diversion Prevention Program

New, Kimberly	Drug Diversion Prevention in Healthcare
ASHP	ASHP Guidelines on Preventing Diversion of Controlled Substances

Source: New, K. (2016). *Drug Diversion Prevention in Healthcare*. HCPro.
Source: Brummond, P. W., et. al. (2017). ASHP Guidelines on Preventing Diversion of Controlled Substances. *American Journal of Health-System Pharmacy*, 74(5), 325–348.

Recommended Structure for Diversion Prevention Program

Oversight Committee: Leadership & ongoing support for program

Diversion Specialist or Manager: Manages daily operations, performs audits, collect data

Diversion Response Team: Small, multidisciplinary group which investigates identified diversion

Source: New, K. (2016). Drug Diversion Prevention in Healthcare. HCPro.

Components of Comprehensive Drug Diversion Prevention Program

Diversion Program Policies, Procedures & Forms

Diversion Program Policies & Procedures

Diversion Program

- Scope of diversion program
- Co-worker diversion education
- Medication audit expectations
- Investigation process
- Diversion response team
- Regulatory reporting of diversion

Human Resources & Diversion Program Collaborative

- Suspected impaired co-worker
- Confidential reporting of diversion
- Co-worker drug screens
- Co-worker searches
- Employee assistance program
- Return to work

Diversion Program Forms

Diversion Program

- Communication templates
- Standard of work for medication audits
- Coaching & documentation
- Nursing risk rounds
- Pharmacy compliance inspection
- Investigation report
- Investigation process map

Human Resources & Diversion Program Collaborative

- Consent for co-worker drug screen
- Consent for co-worker search
- Suspected impaired co-worker screening tool

Diversion Program Education

Organization Diversion Education

Who? All co-workers (clinical & non-clinical)

When? Initial & annual refresher education

Why? Culture of awareness

Organization Diversion Education

Identify	• Prevalence of drug diversion in healthcare • Patient & co-worker safety initiative
Recognize	• Red flags of diversion • Signs of impaired co-worker
Report	• See something, say something • Confidential reporting options

Additional Focused Diversion Education

Clinical co-worker education

- Tampering identification
- Documentation expectations
- Waste & disposal requirements

Leader education

- Diversion program policies
- Diversion program forms
- Diversion investigation process
- Regulatory reporting requirements

Internal Controls & Physical Security

Internal Controls

Physical security for controlled substances

- Electronic medical record (EMR) documentation
- Automated dispensing cabinets (ADC)
- Chain of custody
- Video surveillance
- Access restriction
- Standardize waste solution
- Separation of duties
- Diversion monitoring tools

Diversion Monitoring

Diversion Monitoring: Identify Potential Diversion With ADC & EMR Data

Controlled substance variances
(medication not charted, wasted or returned)

Questionable timing
(medication removal, administration, waste or return)

Questionable documentation
(handoff, pain assessments, undocumented override, zero waste)

Medication scanning issues

Diversion Monitoring Software

Homegrown & commercial options

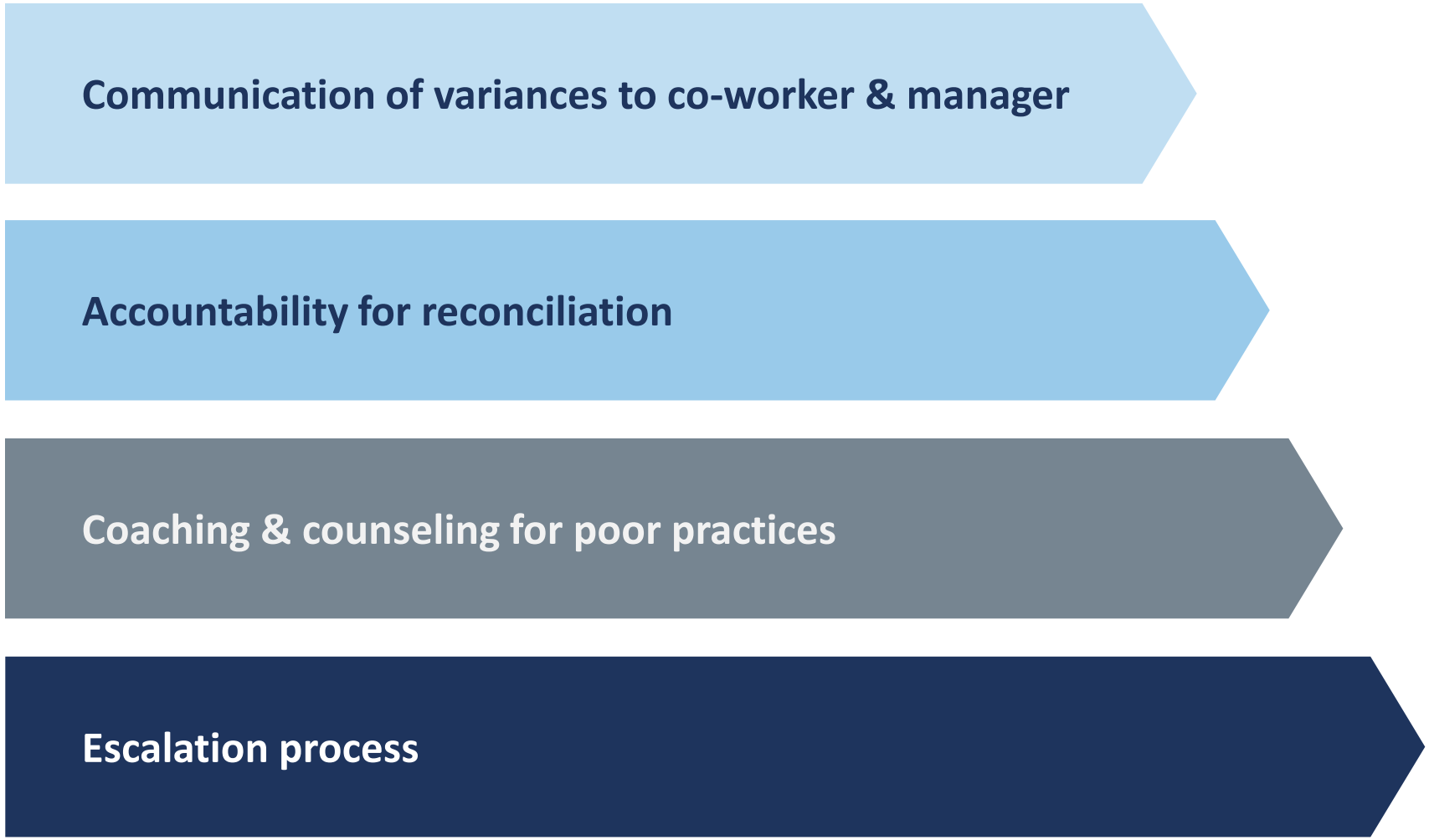
Software Methods for Identifying Diversion Risk:
Variances
Standard deviations
Risk score
Artificial intelligence
Machine learning

Additional Software Features:
Timeclock data
Pharmacy wholesaler data
Non-controlled substance monitoring
Communication module
Case management
Enterprise option (health systems)

Diversion Monitoring With ADC Reports

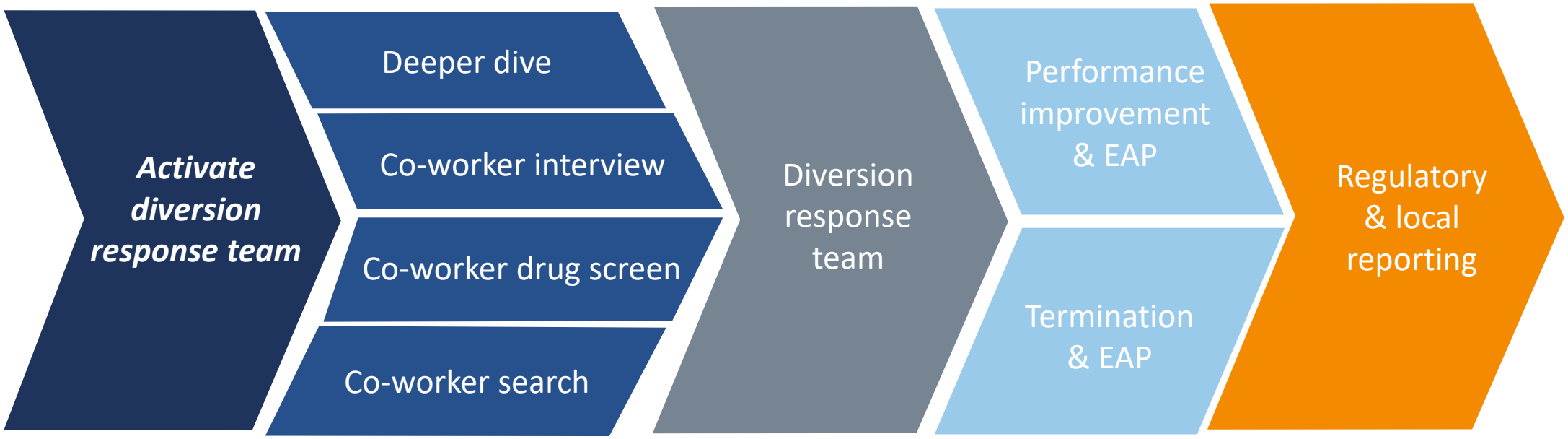
- Overrides
- Discrepancies
- Null or canceled transactions
- Waste reconciliation or audit
- Transactions by user or medication

Audit Reconciliation Process for Variances Identified in Diversion Monitoring



Investigations

Active Investigation Process

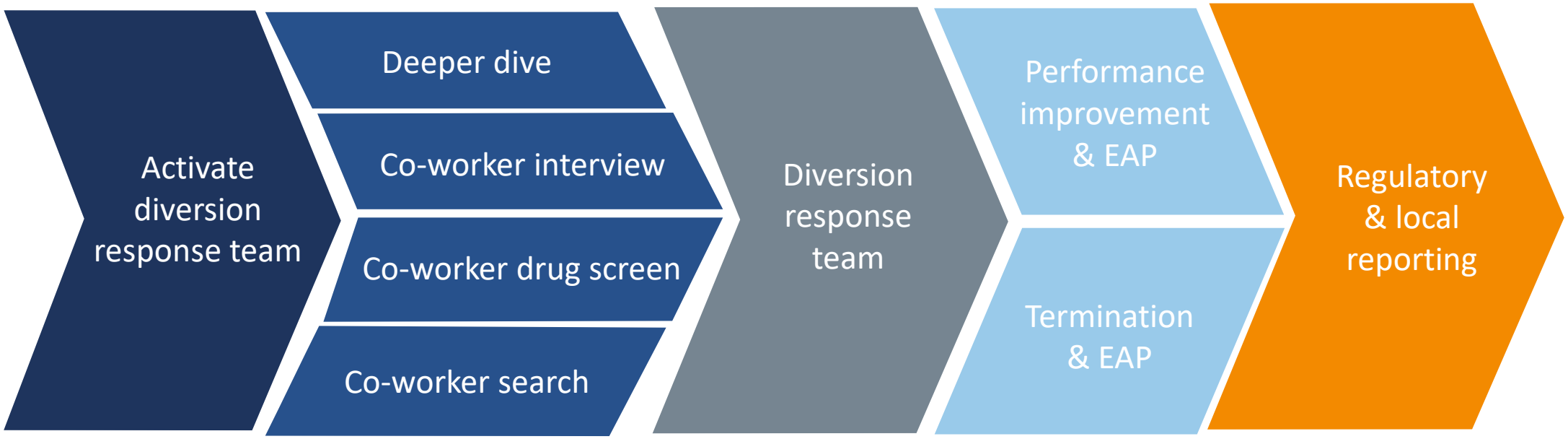


Diversion Response Team

Adhoc members:

- Safety/security
- Compliance
- Quality
- Risk management
- Infection prevention

Active Investigation Process



Mercy's Health System Drug Diversion Prevention Program

Implementation of Drug Diversion Prevention Program (Hospital or Health System)

Assessment Question 1

Which of the following indicates the need for implementation of opioid stewardship at an acute care hospital?

a. Promoting responsible opioid prescribing
b. Reducing unnecessary patient exposure to opioids
c. Encouraging use of safe alternatives to opioids
d. Reducing harm to patients with opioid use disorder
e. All of the above

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a. Promoting responsible opioid prescribing

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Assessment Question 2

Which of the following are key components of a successful opioid stewardship program?

a. Leadership

b. Accountability

c. Policies and guidelines

d. Education (patient, providers and co-worker)

e. Tracking, monitoring and reporting

f. All of the above

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Assessment Question 3

Which of the following are essential components of a comprehensive healthcare drug diversion prevention program?

a. Co-worker education
b. Policies and procedures
c. Internal controls
d. Monitoring for drug diversion
e. Management of diversion investigations
f. All of the above

Assessment Question 3

Which of the following are essential components of a comprehensive healthcare drug diversion prevention program?

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b. Policies and procedures
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e. Management of diversion investigations
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References

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Thank you…

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