DISCLOSURE

I have nothing to disclose

AGENDA

- Define diversion and discuss various methods of diversion
- Discuss various legal implications/requirements
- Drug diversion statistics
- Outline components of a successful oversight program
- Describe an active Drug Diversion Program
DEFINITION

• Merriam-Webster
  • The act of changing the direction or use of something

• Drug Enforcement Agency
  • Diversion is the use of prescription drugs for recreational purposes

• Allina Health
  • Any deviation that removes a prescription drug from its intended path from the manufacturer to the intended patient

METHODS OF DIVERSION

• Doctor Shopping
  • “Traditional” drug dealing
  • Theft from pharmacies, homes, hospitals
  • Acquiring prescription drugs via the internet without a physician visit
  • Receiving drugs from friends/family
  • Buying drugs from patient’s after they leave clinics/pharmacies
  • Faking legitimate illness (e.g. sports injury, anxiety) to obtain a prescription

DIVERSION IN THE NEWS

• A pharmacist in charge at a retail pharmacy had diverted Schedule II and III substances for a period of approximately three years. –Minnesota

• A non-hospital employee posing as a nurse was stealing patients’ painkillers while they were in their hospital rooms, watching, and also tampered with a machine that administers drugs, and cutting the line from the machine to the patient. –Washington: Minnesota
DIVERSION IN THE NEWS

• A care provider had multiple narcotics “wastes” at unexplained times; signed out different medications at the same time, assigned drugs to patients other than his own, or charted them incorrectly. – Pennsylvania

• Twice a week over a four-month period a care provider siphoned some of the controlled substance out of patients’ IV drip bags. 25 patients contract a rare bacterial infection. -Minnesota

LEGAL IMPLICATIONS

• Safety
  • Patient
  • Employee
• Quality outcomes
• Regulatory and financial - significant fines and penalties
  • Walgreens - record settlement of $80m in June 2013
• Revocation of DEA license
  • entity and/or staff

LEGAL REQUIREMENTS

• Controlled Substance Act of 1970
• Food and Drug Administration
  • Office of Criminal Investigation
• DEA
• State/Local Law Enforcement
• MN Board of Pharmacy
  • Prescription Drug Monitoring Program
• MN Department of Health
• Other various professional organizations
  • MN Board of Nursing
### FEBRUARY 20, 2013 PRESS RELEASE
CENTER FOR DISEASE CONTROL & PREVENTION

#### 2010: Statistics on Causes of Death in the U.S.

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Number of Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Drug Overdoses</td>
<td>38,329</td>
</tr>
<tr>
<td>Car Crashes</td>
<td>35,498</td>
</tr>
<tr>
<td>Firearms</td>
<td>31,672</td>
</tr>
</tbody>
</table>

#### Total Drug Overdoses

| Pharmaceutical Drug Overdoses  | 22,134 |
| Prescription Opioid/Pain Reliever Overdoses | 16,651 |

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#### DATA FROM THE ANNUAL NATIONAL SURVEY ON DRUG USE AND HEALTH CONDUCTED BY THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

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#### SPECIFIC ILLICIT DRUG DEPENDENCE OR ABUSE IN THE PAST YEAR AMONG PERSONS AGED 12 OR OLDER

- Marijuana
- Pain relievers
- Cocaine
- Tranquilizers
- Stimulants
- Heroin
- Hallucinogens
- Inhalants
- Sedatives

- 2012 Data from the annual National Survey on Drug Use and Health (NSDUH) conducted by the Substance Abuse and Mental Health Services Administration
CONTROLLED SUBSTANCES MOST ASSOCIATED WITH A THEFT OR LOSS EVENT

- hydrocodone
- Oxycodone
- hydromorphone
- morphine sulphate
- fentanyl

MN STATISTICS

- From 2005 to 2011, there were 250 reports of theft or loss of controlled substances in hospitals and nursing homes
- There was a 352% increase in reports between 2006 (16*) and 2010 (52*)
  * Retail pharmacy thefts are not included in these numbers

MINNESOTA COALITION

- In May 2011, the Minnesota Department of Health (MDH) and the Minnesota Hospital Association (MHA) invited a coalition of hospital, provider, law enforcement, licensing and other health care stakeholders to collaboratively address this important issue.
- The coalition completed its work in April 2012 – for more information go to the MN Dept. of Health website:

  www.health.state.mn.us/patientsafety/drugdiversion
COMPONENTS OF A SUCCESSFUL 
DRUG DIVERSION PROGRAM

S
• Safety teams/organizational structure

A
• Access to information/accurate reporting:
  monitoring; surveillance detection system

F
• Facility expectations

E
• Educate staff

COMPONENTS OF A SUCCESSFUL 
DRUG DIVERSION PROGRAM

• STORAGE & SECURITY
• PROCUREMENT
• PRESCRIBING
• PREPARATION & DISPENSING
• ADMINISTRATION
• HANDLING WASTE
• MONITORING OF AND PROCESS IF DIVERSION IS 
  SUSPECTED

Excerpt from the Road Map
http://www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/controlled-
  substance-diversion-prevention-roadmap.pdf

SO...

What Does a Drug Diversion 
Program Look Like?
ALLINA HEALTH BACKGROUND

- Large not-for-profit systems serving MN and WI
- 26,405 employees; 5,000 associated and employed physicians; and more than 4,100 volunteers
- 12 hospitals
  - 112,973 inpatient hospital admissions
  - 1.2 million hospital outpatient admissions
- 23 hospital-based clinics
- 57 Allina Health clinics
  - 3.3 million clinic visits
- 1.2 million health system pharmacy sites
  - 844,601 retail pharmacy prescriptions filled
- 3 ambulatory care centers

ALLINA HEALTH DRUG DIVERSION PROGRAM OVERVIEW

- Governance
  - Oversight
  - Strategy/Direction
- Drug Diversion Control Standards
- Risk Based Approach Assessments
- Proactive Monitoring
- Incident Response and Reporting
  - Incident workflows
  - Reporting
- Education
  - All Employees
  - Manager Tool kit

DRUG DIVERSION PROGRAM TIMELINE

- Approved the development of a Drug Diversion Program
- Various action plans created and implemented
- Key stakeholders pulled together and work began
- Allina Health continues to invest in its Drug Diversion Program
GOVERNANCE - OVERSIGHT

- Ethics Compliance and Oversight Committee (ECOC)
- Drug Diversion Steering Committee
- Drug Diversion Council

GOVERNANCE STRATEGY/DIRECTION

- Conduct diversion risk assessment
- Create organizational control “Standards”
- Design control environment by area - Threshold
- Quantify risk; establish risk tolerance/appetite
- Current state or operational gap assessment
- Evaluate gaps; determine remediation; recommend
- Communicate, report; corrective action plans
- Follow up; periodic reassessment

ALLINA BUSINESS AREAS

- Retail Pharmacies
- Clinics
- Emergency Medical Services
- IP Hospital Pharmacies
- Hospital Satellite Pharmacies
- OR with ADC (automated dispensing cabinets)
- OR with out ADC
- OR with combo
CONTROL STANDARDS

• Business Area (BA) Threshold
  • Design the desired state through the risk-based application of applicable Standards and methods to a specific business area or clinical practice method

• Optimally position control environments
  • Relative to business needs and diversion risk response
  • Design might include less desirable Methods

• Necessary for measuring a gap by business area
  • Threshold Gap (risk) = Most Desirable Method - Designed Method

CONTROL STANDARDS

• User Access to Physical Areas, Devices and Business Applications
• Inventory Maintenance
• Safeguards of Physical Surroundings
• Safeguards of Inventory Storage Devices, Containers
• Inventory Item Safeguards
• Medication Orders and Filling
• Patient Administration
• Waste and Destruction
• Monitoring and Oversight

STANDARD SUBCATEGORIES

• User Access to Physical Areas, Devices and Business Applications
  • Access Authorization – New Hires
  • Access Management – Employee Changes
  • User Roles and Responsibilities – Administration
  • User Roles and Responsibilities – Segregation of Duties

• Inventory Maintenance
  • C2 Inventory Ordering Authorization
  • C3-C5 Inventory Ordering Authorization
  • Inventory Ordering – DEA Form 222 Safeguards
  • Inventory Purchasing
  • Inventory Item Levels
RISK BASED APPROACH ASSESSMENTS

Operational Gap Assessment
- CSA Questionnaire to capture Current State
- One question written for each Standard
- Business area questionnaire extracted based on Threshold selections
- User-friendly format; clear instructions
- Individual, group or facilitated sessions
- Content was lengthy, high-level reading
- Objective was to gather the “how”, rather than “if”

ASSESSMENT CRITERIA
- Severity - How much harm will occur to a patient because of this?
- Likelihood of Occurrence - How likely is it that diversion by this method will occur?
- Detection & Response - How likely is it that the failure will be detected and we’ll be able to identify the cause?
- Control Maturity - The current state of controls designed to minimize the likelihood that the failure will jeopardize our ability to achieve business objectives.
**RISK**

- How much risk is management willing to accept in pursuit of its mission to deliver safe, high-quality patient care?
- Practical considerations for operational effectiveness and efficiencies
  - Physical limitations of the work environment
- Developed a Standards Value Scale

**TOLERANCE / APPETITE**

- **Business Area Threshold**
  - The numeric value (sum of the applicable Standards' control activities) attributed to the optimally positioned controlled substance control environment for the business area relative to business needs and diversion risk response.
- **Residual Risk**
  - Risk remaining after management determines the optimally positioned control environment for a business area
- **Risk Appetite**
  - The amount of residual risk Allina is willing to accept in pursuit of its mission to deliver safe, high-quality patient care

**RISK/THRESHOLDS**

![Chart showing Business Area Thresholds]
EVALUATE RESULTS

- Council ensures consistent, risk-based approach across the organization
- Each Standard was classified
  - Required – Must evaluate and remediate risk
  - Addressable – Must evaluate risk and encourage remediation; or explain reason for not remediating
- Gaps present globally or location specific
- Gaps where remediation is not recommended
  - Best balance of efficiency and cost
  - Considers size and complexity of location

RECOMMENDATIONS

- Drug Diversion Control Standard Value Scale
- Initial State 12/2012
- Current State 7/2014
- Target 2013
INCIDENT RESPONSE

- Step 1: Potential Drug Diversion event is identified and reported
- Step 2: Assess event and determine if there is a need to continue with full investigation
- Step 3: Pull team together, assess risk, Conduct Investigation
- Step 4: Evaluate findings, and Determine the Appropriate Level of Corrective Action if applicable
- Step 5: Review findings, implement and Report if applicable
- Step 6: close event and debrief

CORE TEAM

Core Team includes:
- Site Pharmacy Leader
- Human Resources
- Manager

Additional Ad Hoc Members include both local and system resources:
- Program Manager
- Compliance
- Risk
- Security
- Security Investigator
- Legal
- Labor Relations
- Communications

Core Team Leader decided by site team

*NOTE: The Core Team DOES NOT include the suspect, any witness or other front line staff member.

INCIDENT RESPONSE

- Tool Purpose is to help guide and ensure those critical first steps are addressed
REPORTING - INCIDENT

- Regulatory
  - Ensure required reporting occurs when applicable
  - DEA
  - BOP
  - BON
  - DOH – If risk of Blood Born Pathogen exposure

- System
  - Leadership where incident occurred
  - Drug Diversion Program Manager
  - Other System Office staff as needed
  - Risk
  - Compliance
  - Legal
  - HR
  - System Senior leadership if applicable

REPORTING - ASSESSMENT

- Significant gaps are clearly communicated to site-based owners
- Draft report discussed with management
- Report template
  - Executive summary
    - Thresholds and residual risk for the business area
    - High level summary of exposure areas
    - Current state score and target score
    - Details of gap assessment and evaluation
  - Appendixes describe the Program

REPORTING - PROGRAM

SAMPLE DATA
EDUCATION

• Routine
  • Developed an annual Drug Diversion Education module that each Allina Health employee is required to take
  • Content is updated each year as needed

  • All new Allina Health employees receive additional Drug Diversion education as part of their new employee orientation
  • Content is updated as the Program expands

• Internal Drug Diversion Web page
  • Various resources for employees
    • Tip sheet on Drug Diversion Risks and Behaviors
    • How to report suspected diversion

EDUCATION

• Ad-Hoc
  • Education Programs for key stakeholders in each business area (Managers, HR, Risk, Quality, Pharmacy, Compliance)
    • Created when:
      • New tools are created
      • Changes to reporting tools
      • Changes to event response

  • Internal Drug Diversion Web page
    • Various resources for managers
      • HR policies
      • Program Information
      • Manager Tool – Kit
      • Responsibilities
      • Incident Response Procedure

TOOLS FOR ALLINA HEALTH EMPLOYEES

Allina intranet webpages:

  AKN Drug Diversion Page

  MyAllina Manager Toolkit
  MyAllina: Manager Resources – Performance – Drug Discrepancy/Diversion
WRAP UP

- Diversion will happen and it's all of our jobs to report suspected diversion to keep our patients, yourself and your coworkers safe.
- All sites that facilitate the use of controlled substances should have some level of diversion monitoring/detection activities occurring.
- Response to a potential diversion event needs to be swift:
  - Investigation work needs to be timely.
- Take advantage of the resources available:
  - MHA Roadmap.

QUESTIONS

Thank You
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