DRUG DIVERSION
TIPS AND PRACTICES TO PREVENT, DETECT AND
RESPOND TO POTENTIAL DIVERSION IN YOUR
PHARMACY

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ALLINA HEALTH

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

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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

December 1, 2009 US Pharmacist Publication
Prescription Drug Abuse: Strategies to Reduce Diversion

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.	
Cause of Death	**Number of Deaths**
Total Drug Overdoses	38,329
Car Crashes	35,498
Firearms	31,672

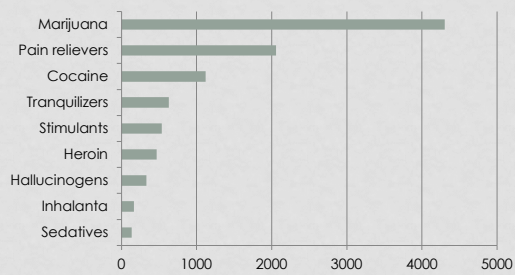| Total Drug Overdoses	
Pharmaceutical Drug Overdoses	22,134
Prescription Opioid/Pain Reliever Overdoses	16,651

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

Number of Americans aged 12 or older that reported the use of an illicit drug or medication in the past month

Year	Value
1993	5
2000	14
2004	19.1
2008	20.1
2012	23.9

Data in millions

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

Marijuana
Pain relievers
Cocaine
Tranquilizers
Stimulants
Heroin
Hallucinogens
Inhalanta
Sedatives

0   1000   2000   3000   4000   5000

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

National Survey on Drug Use and Health - 2012

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*

Taken from MN DOH website: according to data from the U.S. Drug Enforcement Administration (DEA).

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 Heath 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…
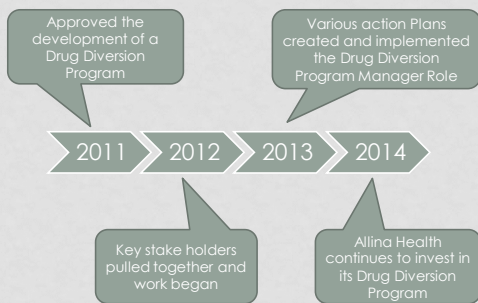
What Does a Drug Diversion Program Look Like?

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
- 15 retail pharmacy sites
  - 844,601 retail pharmacy prescriptions filled
- 3 ambulatory care centers

Allina Health

2013 Data

DRUG DIVERSION PROGRAM TIMELINE

Approved the development of a Drug Diversion Program

Various action Plans created and implemented the Drug Diversion Program Manager Role

2011 › 2012 › 2013 › 2014

Key stake holders pulled together and work began

Allina Health continues to invest in its Drug Diversion Program

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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

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

FINAL STANDARD LAYOUT

CATEGORY	SUB-CATEGORY	#	CONTROL STANDARDS	Question*	METHODS - Activities or qualities of activity that effect the control standard (Least Desirable ----------> Most Desirable)			
					A	B	C	D
Safeguards of Physical Surroundings	Areas Housing Controlled Substances	C.a.S17.q24	Video surveillance is implemented in Pharmacy's areas of higher risk. Risk factors can include traffic patterns in the area, individuals with sole custody, consideration of other physical safeguards, etc.	What is the best description of video surveillance methods in use in the pharmacy / medication storage areas?	Video surveillance is not used at this facility	Relying on established video surveillance that is used at this facility. Pharmacy / medication storage area is not a specific target.	Video surveillance is present for the pharmacy / medication storage area, but limited to department entrances only. No surveillance of user areas.	Video surveillance present in high risk pharmacy / medication storage areas.

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.
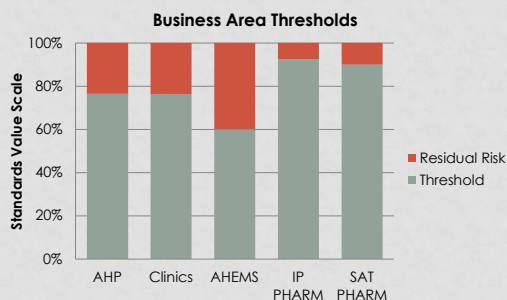
RISK

- 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

SAMPLE DATA

Business Area Thresholds

Chart — Standards Value Scale (y-axis 0%–100%) by business area: AHP, Clinics, AHEMS, IP PHARM, SAT PHARM. Legend: Residual Risk, Threshold.

BUSINESS AREA CSA QUESTIONNAIRE SAMPLE

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
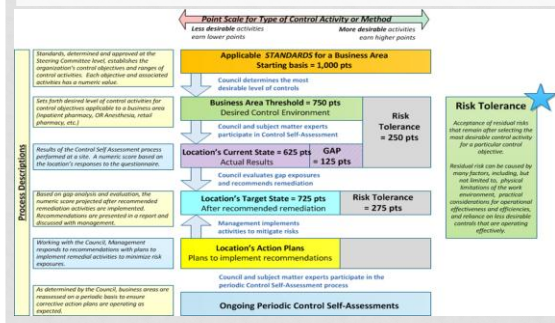
RECOMMENDATIONS

SAMPLE DATA

ALLINA HEALTH DRUG DIVERSION PROGRAM OVERVIEW

SAMPLE DATA

PROACTIVE MONITORING

PROACTIVE WORKFLOW

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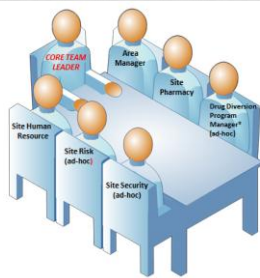
Core Team includes
- Site Pharmacy Leader
- Human Resources
- Manager

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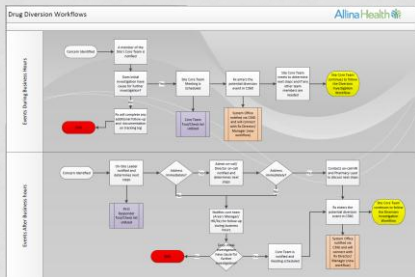- Communications

Core Team Leader decided by site team

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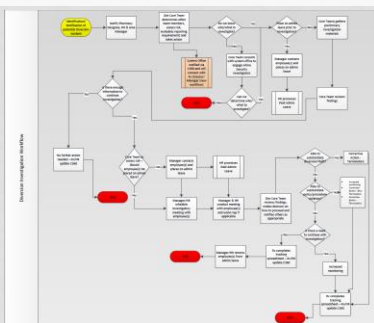
INCIDENT RESPONSE

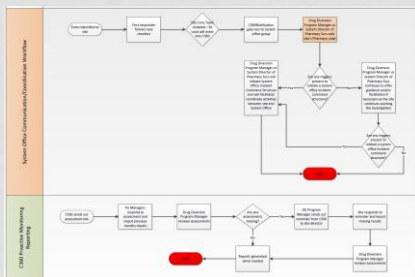- Tool Purpose is to help guide and ensure those critical first steps are addressed

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INCIDENT WORKFLOWS

INCIDENT WORKFLOWS

ADDITIONAL WORKFLOWS

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

Operations Scorecard (example)					
Diversion Control Risk Levels	Allina *Standards* Risk Appetite				
	Less mitigated				Better mitigated
	100	400	600	800	1000
Business Area -Inpatient Pharmacy					
Council's Threshold Score				825	
Assessments					
Location 1 Actual Score		563			
Targeted Score				825	
Reassess in 24 mos.				806	
Location 2 Actual Score			795		
Targeted Score			795		
Reassess in 24 mos.			775		
Business Area - OR Anesthesia					
Council's Threshold Score		600			
Assessments					
Location 1 Actual Score	192				
Targeted Score		536			
Reassess in 12 mos.		510			
Location 2 Actual Score	235				
Targeted Score	395				
Reassess in 12 mos.	395				

Executive Scorecard (example)		
Stakeholder Reporting	**Risks Current**	**Risks Post Mitigation**
IP Pharmacies	Yellow	Green
Threshold	Green	Green
Loc 1	Yellow	Green
Loc 2	Yellow	Yellow
OR Anesthesia	Red	Orange
Threshold	Yellow	Yellow
Loc 1	Red	Yellow
Loc 2	Red	Red

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 stake holders 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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