CONTROLLED SUBSTANCES INVENTORY CONTROLS – RISK-BASED DESIGN AND ASSESSMENT

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PROJECT LEAD, AUDIT SERVICES
ALLINA HEALTH
Allina Health

- Twin Cities; not-for profit system serving MN and WI
- 11 hospitals, 1,716 beds; 90+ clinics; 3 ASC
- 14 retail pharmacies
- Specialty medical services, hospice, rehabilitation, EMS
- Nearly 24,000 employees
- 5,000 associated and employed physicians
- 107,700 IP visits; 1,154,800 OP visits
- 6,128,500 work RVUs
Learning Objectives

1. Plan and execute risk-based audit / consulting engagements
2. Apply control self-assessment techniques to audit fieldwork
3. Develop tools and quantify risk for an audit
4. Facilitate risk and controls communications to non-audit subject matter experts
5. Project management tips
What are Controlled Substances?

- narcotics, depressants, and stimulants
- manufactured for legitimate medical use
- subject to abuse
- classified depending on the potential for abuse
- Schedules I, II, III, IV or V
- under legal control according to the provision of the Controlled Substances Act of 1970
  - Title 21 – Food and Drugs
  - Chapter 13 - Drug Abuse Prevention and Control
  - Subchapter I - Control and Enforcement
- Drug Enforcement Agency (DEA)
What is Drug Diversion?

• Any criminal act or deviation that removes a prescription drug [controlled substance] from its intended path from the manufacturer to the patient

• In 2009, prescription drug overdose deaths exceeded
  • motor vehicle deaths
  • deaths from illegal street drugs, such as cocaine, heroin, and amphetamines

- U.S. Center for Disease Control and Prevention
Diversion in the Headlines

• 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 Headlines

- 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
Risks

- Patient and employee safety; Quality outcomes
- Regulatory and financial - significant fines and penalties
  - Walgreens - record settlement of $80m
  - unprecedented number of record-keeping and dispensing violations
  - “...knew or should have known...”
  - surrendered ability to distribute or dispense controlled substances listed in Schedules II – V for two years
    - US Department of Justice, Southern Florida
- Revocation of DEA license, entity and/or staff
Governance Strategy / Implementation

**Board Strategy**
- Strengthen risk management programs around controlled substances

**Implementation**
- Develop a process for communicating and managing identified impairment or diversion (HR)
- Educate leaders about identifying impairment and/or diversion (HR)
- Identify best practices for controls to minimize opportunities for diversion (Operations)
Objective and Guiding Principles

Objective

- Develop a methodology to identify, understand and quantify controlled substances inventory risks across Allina in a manner that supports a risk-based approach to adopting standard practices to mitigate risk exposures found during the process.

Guiding Principles

- diversion will happen
- investment in controls should be based on risk and opportunity to mitigate risk
- coordination and communication provide consistency and support the mitigation strategy
Consulting Engagements

- Natural extension of assurance and investigative services
- Systematic, disciplined approach
- Clarify expectations, roles, responsibilities and accountabilities
- Timeframe, timelines
- Understand deliverables
- Make a plan and share it regularly
- Establish communications methods for the Steering Committee and key stakeholders
- Escalation protocols
Control Self-assessment (CSA)

- Collaboration with management
- Identifying risks and exposures
- Assessing efficiency and effectiveness of controls
- Assemble subject matter experts
- Facilitation and project management skills
- Developing tools when none exist
- Discussion and decision making as a team
- Management trained, risk mitigation knowledge, ownership and responsibility
Steering Committee

• Provides guidance, oversight and approvals
• Upward reporting to executive leaders and Board
• Comprised of Key Stakeholders
  
  Human Resources  Security
  Pharmacies  Compliance
  - Inpatient  Patient Care
  - Retail
  - Clinic
  Emergency Medical Services
  Legal and Risk
  Audit Services

Allina Health
Governance Council / Work Team

- Charter - Sets responsibilities and authority
  - Strategic Direction, Compliance, System Coordination
- Promotes the process to stakeholders
- Provides direction on risk-mitigation efforts
- Reports to the Steering Committee
- Opines on “high impact/high cost” control designs that require approval by others prior to commitments
- Does not supersede existing site responsibilities for safeguarding controlled substances
Members

- medical and nursing leadership (2)
- hospital pharmacy leadership (4)
- clinic pharmacy leadership (1)
- retail pharmacy leadership (1)
- medical transportation leadership (1)
- Corporate pharmacy leadership (1)
- Corporate Compliance leadership (1)
- Drug Diversion Program Manager (new) (1)
- other executive leaders as deemed necessary
Project Management Notes

- SME’s were on “borrowed time”; use time wisely
- Be transparent; advise that you are “managing time”
- Brainstorm sessions - “managed creativity”
- Work sessions - advance work for team reaction
- Expert facilitations skills
  - Building consensus and seeking agreement
  - Reaching conclusions, making decisions
  - Replowing a plowed field
  - Parking Lot
Drug Diversion Program Overview

1. Conduct diversion risk assessment
2. Create organizational control “Standards”
3. Design control environment by area - Threshold
4. Quantify risk; establish risk tolerance/appetite
5. Current state or operational gap assessment
6. Evaluate gaps; determine remediation; recommend
7. Communicate, report; corrective action plans
8. Follow up; periodic reassessment
1. Diversion Risk Assessment

- What could prevent us from successfully safeguarding our controlled substance inventories?
- Understand our threats, vulnerabilities, weaknesses, and other exposures
- Understand our resiliency and response capabilities
- Risk assessment conducted with SME’s from IP pharmacy, retail, clinic, EMS; all RPH except EMS
- Risk-based
  - Targeted attention to business processes
  - Focused, relevant, responsive, and decisive
Assessment Tool

• Find an assessment tool that works for your needs
• Failure Modes and Effects Analysis (FMEA) Tool available from the Institute for Healthcare Improvement (IHI)
• Some modifications, simple spreadsheet, simple calculations
• Tool captured:
  • Threat details
  • Assessment criteria
  • Calculated a risk score
Threats Brainstorm

- Brainstorm on possible diversion threats or events

- **Think like a “criminal”**
  - What is an activity that could happen?
  - Who has the opportunity to do it?
  - How did it happen, method used?
  - How soon would you detect it?
  - What could go wrong because of it?

- Prepare an “idea list” of threats in advance

- Participants prioritize the list by greatest threat

- Begin assessing with the greatest threat
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.
## Threat Documentation Tool

<table>
<thead>
<tr>
<th>Failure Mode (Credible Threats in Hospitals)</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>diversion during manual transport from pharmacy to pt care area, or between pt care units</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Failure Causes (Vulnerability)</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>open carts (no locks), have significant time under control of one person, cart moves through a very public area.</td>
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<thead>
<tr>
<th>Who/what does it? (Actor - internal, external)</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>staff,</td>
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<thead>
<tr>
<th>How did they do it? (Method)</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
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<tbody>
<tr>
<td>remove or tamper with product from cart</td>
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<tr>
<th>Failure Effects (Outcome)</th>
<th>SME 1</th>
<th>SME 2</th>
<th>SME 3</th>
<th>SME 4</th>
<th>SME 5</th>
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<tr>
<td>poor pain control, risk of infection</td>
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<thead>
<tr>
<th></th>
<th>Severity</th>
<th>Likelihood of Occurrence</th>
<th>Detection &amp; Response</th>
<th>Control Maturity</th>
<th>Operational Risk Score</th>
<th>Risk Mitigation Score</th>
<th>Risk Profile Number (RPN)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.4</td>
<td>2.2</td>
<td>4</td>
<td>4</td>
<td>3.8</td>
<td>15.2</td>
<td>109.44</td>
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<td>16</td>
<td>20</td>
</tr>
</tbody>
</table>

| Allina Health |
Top 10 Diversion Risks

The 52 identified risks were grouped by similarity. This information will be used to drive the standards.

<table>
<thead>
<tr>
<th>Risk Exposures</th>
<th>RPN *</th>
<th>Hospital</th>
<th>Ambulatory</th>
<th>AMT</th>
<th>ACP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Administering partial dosages</td>
<td>12.7</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>2. Theft of a patient's drugs from</td>
<td>11.7</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>3. Wasting processes</td>
<td>11.1</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>4. Fraudulent Rx (pads, electronic,</td>
<td>10.8</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>5. Tampering with product</td>
<td>10.5</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>6. Manually controlled inventory</td>
<td>10.2</td>
<td>x</td>
<td>x</td>
<td>x</td>
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</tr>
<tr>
<td>7. Access to facilities and</td>
<td>9.38</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>8. Pyxis controlled inventory</td>
<td>8.79</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>9. Ordering, stocking and</td>
<td>8.09</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>10. Transport and delivery</td>
<td>7.72</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

Areas where risks are present
### Controlled Substances Flowchart

**Flow of Controlled Substances from Supplier to Pending Patient Administration or Rx Fill**

<table>
<thead>
<tr>
<th>Supply Source</th>
<th>DEA Registrant Authorized Purchaser and Receiver</th>
<th>IP Pharmacy Intermediate Processes</th>
<th>Destination awaiting dispensing or patient administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinics</strong> MD Registrant</td>
<td>ACP-Retail Allina Registrant</td>
<td>Hospitals Allina Registrant</td>
<td>some EMS MD Registrant</td>
</tr>
<tr>
<td>Aspen etc.</td>
<td>MOB</td>
<td>IV Prep</td>
<td>Satellite Locations Narc Boxes</td>
</tr>
<tr>
<td>Ritchie HH</td>
<td>ACP-Retail Allina Registrant</td>
<td>Pyxis Medstations Manual Deliveries</td>
<td></td>
</tr>
<tr>
<td>Community etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CII - CV Approved Vendors**

- **Phase 1 2012 - 2013**
- **Phase 2 2014**

**IP Pharmacy Areas and Hospital Departments**

- **Select areas using a risk based approach based on RA Results**
- **Procedural Areas**
  - Cardio Cath
  - IVR
  - Endo
  - Med Surg
  - ICU
  - Mental Health etc.

**EMS**

- Eagle Creek Moundsview Cambridge etc.
- Hutchison etc.
2. Inventory Control Standards - Objectives

• One set of *Standards*, applicable entity-wide
• Consistent practices for employees and non-employees
• Support regulatory compliance
• Ensure staff and patients’ safety
• Reasonable assurances of appropriate safeguards
• Drug diversion risk eliminated or reduced to an acceptable level
• Place employees in defendable positions
• Vetted with stakeholders
• Approved by Steering Committee
• Framework and tool for capturing data (database)
• Review and assess existing bodies of work
• Codify a number of existing practices
• Risk-based, not all inclusive; best guard against diversion
• Provide education on control objectives vs. activities
• How to make the Standards “reasonable” for all types of business areas
• Most significant control objectives
• Range of control methods to achieve each Standard
Data Structure

- Unique Identifying Number for each Standard
- Category (9)
  - Sub-category (0 to 5)
    - Control Standard (61) – business objective
      - Methods (up to 5) – Activities or qualities of an activity that contribute to achieving the Standard
        - ranked from Less Desirable → More Desirable
- Question (78) – designed for CSA questionnaire
Standards Framework Categories

A. User Access to Physical Areas, Devices and Business Applications
B. Inventory Maintenance
C. Safeguards of Physical Surroundings
D. Safeguards of Inventory Storage Devices, Containers
E. Inventory Item Safeguards
F. Medication Orders and Filling
G. Patient Administration
H. Waste and Destruction
J. Monitoring and Oversight
Subcategories

A. User Access to Physical Areas, Devices and Business Applications
   a. Access Authorization – New Hires
   b. Access Management – Employee Changes
   c. User Roles and Responsibilities – Administration
   d. User Roles and Responsibilities – Segregation of Duties

B. Inventory Maintenance
   a. C2 Inventory Ordering Authorization
   b. C3-C5 Inventory Ordering Authorization
   c. Inventory Ordering – DEA Form 222 Safeguards
   d. Inventory Purchasing
   e. Inventory Item Levels
Subcategories – cont.

C. Safeguards of Physical Surroundings
   a. Areas Housing Controlled Substances

D. Safeguards of Inventory Storage Devices, Containers
   a. Locked Storage
   b. Custody

E. Inventory Item Safeguards
   a. Custody
   b. Item Security
   c. Inventory Counts
   d. Patient’s Own Medications
Subcategories – cont.

F. Medication Orders and Filling
   a. Transaction Authorization
   b. Filling / Dosage

G. Patient Administration

H. Waste and Destruction
   a. Waste
   b. Destruction

J. Monitoring and Oversight
   a. Transaction Reconciliation
   b. User Activity Monitoring
Example

Identifying Number = C.a.S17.q24
Category = C. Safeguards of Physical Surroundings
Subcategory = a. Rooms and Areas Housing Controlled Substances

Control Standard = S17.
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.
Methods

A. Video surveillance is not used at this facility.

B. Relying on established video surveillance that is used at this facility. Pharmacy / medication storage area is not a specific target.

C. Video surveillance is present for the pharmacy / medication storage area, but limited to department entrances only. No surveillance of user areas.

D. Video surveillance present in high risk pharmacy / medication storage areas.
## Standards Framework Layout

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SUB-CATEGORY</th>
<th>#</th>
<th>CONTROL STANDARDS</th>
<th>Question*</th>
<th>METHODS - Activities or qualities of activity that effect the control standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safeguards of Physical</td>
<td>Areas Housing</td>
<td>C,a517,q24</td>
<td>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.</td>
<td>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.</td>
<td>(Least Desirable -------------&gt; Most Desirable)</td>
</tr>
</tbody>
</table>
Key Stakeholder Review

• Engage key stakeholder
• Buy in on foundational document that will be integral to the program
• Manage vetting process and response gathering
• "The Control Standards and associated Methods are clearly written, easily read and understood; there are minimal ambiguities."
  • Strongly Agree
  • Agree
  • Disagree
  • Strongly Disagree
3. Desired Control Design - Threshold

- 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
    - *(BA in Phase 1)* Retail, Clinic, EMS, IP Pharm, Satellite Pharm, Surgery / OR Anesthesia environment
- 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
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SUB-CATEGORY</th>
<th>#</th>
<th>CONTROL STANDARDS</th>
<th>Question*</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Access to Physical Areas and Storage Devices, Containers, and Inventory Control Business Applications (systems)</td>
<td>User Roles &amp; Responsibilities - Segregation of Duties</td>
<td>A-d.S4.q5</td>
<td>Business processes are designed to minimize a user's ability to control sequential steps of a transaction. Granting user's access to perform sequential steps of a transaction is strongly discouraged and only considered on an as needed basis. More than two individuals are involved in the following business processes.</td>
<td>Are pharmacists / technicians / buyers / non-clinicians able to complete any two consecutive or sequential steps in a controlled substance transaction? - Order from Supplier - Receive - Shelve - Prepare/Fill - Deliver/Transport - Waste/Destroy - And update drug records related to the transaction</td>
</tr>
</tbody>
</table>

**METHODS** - Activities or qualities of activity that effect the control standard  
*(Least Desirable --------- > Most Desirable)*

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are users who have access to and perform all or multiple steps of this transaction.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>There are individual users who have access to and perform all or multiple steps of this transaction.</td>
<td></td>
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<tr>
<td>An individual user does not have the ability to or the ability to perform these sequential steps. Two or more people perform the steps in this transaction.</td>
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</tbody>
</table>
4. Quantify Risk and Risk Tolerance

- Choosing the desired control environment, or Threshold, will likely leave some undesirable risks on the table
- Inherent risks of the business area
- Uniform approach to quantifying risks
- Compare risk exposures across all business areas
- Facilitates more informed communications to stakeholders
- Steering Committee approval of all Thresholds
- Keep scoring methodology simple
  - Threshold Risk = Most Desirable Method $\triangleleft$ Designed Method $\triangleright$
Scoring Approach

• The methods for each *Standard* were given a score based on a percentage of the whole

• 9 Categories
  • 8 categories @11% of the whole (100%)
  • 1 category @12% of the whole (100%)

• Each *Standard* is a percentage of the category
  • If there were 5 *Standards* in a category; each would count as 1/5th of 11%

• Up to 5 possible methods for each *Standard*, (A-E)
  • If there were 4 possible methods (A, B, C, or D)
    • A = 0%; B = 33%; C = 67%; D = 100% “points

• Scoring calculation = Points x 1/part of 11%
Risk Tolerance / Risk Appetite

• How much risk is management willing to accept in pursuit of its mission to deliver safe, high-quality patient care?

• Physical limitations of the work environment

• Practical considerations for operational effectiveness and efficiencies,

• Reliance on less desirable controls that are operating effectively

• Quantify risk - example:
  • Applicable Standards, most desirable method 1,000
  • Business Area Threshold, designed method 750
  • Gap or Threshold Risk 250
## Where are the Residual Risks?

<table>
<thead>
<tr>
<th>Allina Standards Category</th>
<th># of Applicable Assessment Questions(a)</th>
<th>Threshold Control Level(b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. User Access to Physical Areas, Devices and Business Applications</strong></td>
<td>8</td>
<td>Green 6 6 8 6 6 6 6 6 6</td>
</tr>
<tr>
<td><strong>B. Inventory Maintenance</strong></td>
<td>9</td>
<td>Orange 8 8 9 9 2 na na na</td>
</tr>
<tr>
<td><strong>C. Safeguards of Physical Surroundings</strong></td>
<td>9</td>
<td>Green 5 6 9 8 5 5 5 8</td>
</tr>
<tr>
<td><strong>D. Safeguards of Inventory Storage Devices, Containers</strong></td>
<td>9</td>
<td>Green 6 6 9 9 6 6 6 9</td>
</tr>
<tr>
<td><strong>E. Inventory Item Safeguards</strong></td>
<td>17</td>
<td>Green 10 10 10 10 14 13 7 7 8</td>
</tr>
<tr>
<td><strong>F. Medication Orders and Filling</strong></td>
<td>3</td>
<td>Green 2 2 2 2 2 2 2 2 2</td>
</tr>
<tr>
<td><strong>G. Patient Administration</strong></td>
<td>6</td>
<td>na 4 3 na na 5 5 5</td>
</tr>
<tr>
<td><strong>H. Waste and Destruction</strong></td>
<td>5</td>
<td>Green 2 5 5 5 3 3 3 3</td>
</tr>
<tr>
<td><strong>J. Monitoring and Oversight</strong></td>
<td>12</td>
<td>Green 6 7 10 12 4 2 2 2 2</td>
</tr>
</tbody>
</table>

**Summary:** # of Applicable Assessment Questions | Threshold Control Level
--- | ---
78 | Green 45 54 65 65 43 36 36 43

Color Key: Green = 0 to 10%; Yellow = 11% to 24%; Orange = 25% to 49%; Red = 50% or higher; Grey = na
5. Conduct 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”
**Business Area CSA Questionnaire**

*INSTRUCTIONS: Place an "x" to the left of the response (e.g. A, B, etc.) that BEST reflects your area's most PREVALENT practices. We are interested in what is currently happening even if it differs from policies & procedures.*

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SUB-CATEGORY</th>
<th>#</th>
<th>CONTROL STANDARDS</th>
<th>Question*</th>
<th>METHODS - Activities or qualities of activity that effect the control standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safeguards of Physical Surroundings</td>
<td>Areas Housing Controlled Substances Ca.S17.q24</td>
<td>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.</td>
<td>What is the best description of video surveillance methods in use in the pharmacy / medication storage areas?</td>
<td>Video surveillance is not used at this facility</td>
<td>Relying on established video surveillance that is used at this facility. Pharmacy / medication storage area is not a specific target.</td>
</tr>
</tbody>
</table>

**Operational Gap = BA Threshold**  D  -  Current State  C
6. Evaluate results

- Council ensures consistent, risk-based approaches across the organization
- Each *Standard* was classified; key or non-key
  - **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
Council’s Evaluation Tool

- Risk-based results presentation
- Focuses Council’s discussion during meetings
- Scores within 90% of Threshold – no action*
  - *Except if deficient on any **Required Standard**
- Results presented in the following order
  - **Required** – Global (*nearly all locations deficient*)
  - **Required** – Location Specific (*a few sites deficient*)
  - **Addressable** – Global
  - **Addressable** – Location Specific
Analyze the Operational Gaps

<table>
<thead>
<tr>
<th>Business Area’s Thresholds</th>
<th>Current States</th>
<th>Drug Diversion Council’s Evaluation and Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
<td>Letter</td>
<td>Threshold Response</td>
</tr>
<tr>
<td>C.s.17.024</td>
<td>D</td>
<td>Video surveillance present in high risk pharmacy / medication storage areas.</td>
</tr>
</tbody>
</table>

- **Target Score —** Numeric score projected after recommended target remediation activities are implemented
Council’s Recommendations

Inpatient Pharmacy

<table>
<thead>
<tr>
<th>Locations to date</th>
<th>ANW</th>
<th>MCY</th>
<th>UTY</th>
<th>UHI</th>
<th>BUF</th>
<th>CAM</th>
<th>NU</th>
<th>OWA</th>
<th>PEI</th>
<th>RF</th>
<th>STF</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/2012 Current State</td>
<td>691</td>
<td>710</td>
<td>727</td>
<td>785</td>
<td>804</td>
<td>813</td>
<td>873</td>
<td>860</td>
<td>837</td>
<td>896</td>
<td>877</td>
</tr>
<tr>
<td>9/2013 Target State</td>
<td>860</td>
<td>865</td>
<td>865</td>
<td>885</td>
<td>860</td>
<td>863</td>
<td>863</td>
<td>885</td>
<td>873</td>
<td>867</td>
<td>896</td>
</tr>
</tbody>
</table>

IP Pharmacy Threshold, 930
90%, 837

Allina Drug Diversion Control Standards Value Scale:
- Current State 12/2012
- Target State 9/2013
- IP Pharmacy Threshold
- 90%
7. Communications / Reporting

- 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
## Scorecard Examples

### Operations Scorecard (example)

<table>
<thead>
<tr>
<th>Diversion Control Risk Levels</th>
<th>Allina Standards Risk Appetite</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less mitigated</td>
</tr>
<tr>
<td></td>
<td>100</td>
</tr>
<tr>
<td><strong>Business Area - Inpatient Pharmacy</strong></td>
<td></td>
</tr>
<tr>
<td>Council's Threshold Score</td>
<td>563</td>
</tr>
<tr>
<td>Assessments</td>
<td></td>
</tr>
<tr>
<td>Location 1 Actual Score</td>
<td>Targeted Score</td>
</tr>
<tr>
<td>Location 2 Actual Score</td>
<td>Targeted Score</td>
</tr>
</tbody>
</table>

### Executive Scorecard (example)

<table>
<thead>
<tr>
<th>Stakeholder Reporting</th>
<th>Risks Current</th>
<th>Risks Post Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP Pharmacies</td>
<td>Yellow</td>
<td>Green</td>
</tr>
<tr>
<td>Threshold</td>
<td>Green</td>
<td>Green</td>
</tr>
<tr>
<td>Location 1</td>
<td>Yellow</td>
<td>Green</td>
</tr>
<tr>
<td>Location 2</td>
<td>Yellow</td>
<td>Green</td>
</tr>
<tr>
<td>OR Anesthesia</td>
<td>Red</td>
<td>Orange</td>
</tr>
<tr>
<td>Threshold</td>
<td>Yellow</td>
<td>Yellow</td>
</tr>
<tr>
<td>Location 1</td>
<td>Red</td>
<td>Yellow</td>
</tr>
<tr>
<td>Location 2</td>
<td>Red</td>
<td>Red</td>
</tr>
</tbody>
</table>
Management Action Plans

• Designed to minimize risk
• Council representative works with site-leaders
• Discuss improvement opportunities
• Risk-mitigating action plans
• Targeted completion dates
• Accountable parties
• Site-based ownership for implementation
• Recorded and presented in a final report
8. Follow Up

• Currently a manual process through the Council
• Planned - Recommendations and corrective action plans logged into an automated tracking tool
• Ensure completion, follow-up, and ease of management oversight
• Involvement and escalation to executive leadership as necessary to resolve issues
• Program is designed so that periodic assessments can be implemented
Final Process

Process Descriptions

- Standards, determined and approved at the Steering Committee level, establishes the organization’s control objectives and ranges of control activities. Each objective and associated activities has a numeric value.

- Sets forth desired level of control activities for control objectives applicable to a business area (Inpatient pharmacy, OR Anesthesia, retail pharmacy, etc.)

- Results of the Control Self Assessment process performed at a site. A numeric score based on the location’s responses to the questionnaire.

- Based on gap analysis and evaluation, the numeric score projected after recommended remediation activities are implemented. Recommendations are presented in a report and discussed with management.

- Working with the Council, Management responds to recommendations with plans to implement remedial activities to minimize risk exposures.

- As determined by the Council, business areas are reassessed on a periodic basis to ensure corrective action plans are operating as expected.

Risk Tolerance

- Acceptance of residual risks that remain after selecting the most desirable control activity for a particular control objective.

- Residual risk can be caused by many factors, including, but not limited to, physical limitations of the work environment, practical considerations for operational effectiveness and efficiencies, and reliance on less desirable controls that are operating effectively.

- Risk Tolerance = 250 pts

- Location’s Target State = 725 pts
  - After recommended remediation
  - Risk Tolerance = 275 pts

- Council evaluates gap exposures and recommends remediation

- Management implements activities to mitigate risks

- Location’s Action Plans
  - Plans to implement recommendations

- Council and subject matter experts participate in the periodic Control Self-Assessment process

- Ongoing Periodic Control Self-Assessments

Point Scale for Type of Control Activity or Method

- Less desirable activities earn lower points
- More desirable activities earn higher points
Revelations

- Quantified “yardstick” for discussing risk appetite
- Driving uniformity across the organization
- Transparency
- Leadership buy-in
- Time commitment by SMEs, band-width
- Adhere to risk-based approaches
- Transition consulting to management ownership
- Sustainability
Technology

- Building an application
- Limited development resources
- No existing product to meet our needs
- Just begin - “blank sheet of paper”
- Designed in Excel spreadsheet
- Reporting in a combination of Word and Excel
- Development is in Access database
- Support scoring and reporting
- Much more to be done
Questions?

Vicki.phipps@allina.com
612-262-4847
Appendices

A. Resources
B. Spreadsheets, Charts and Visuals
   i. Initial Vision – used early in the engagement to discuss the planned work with the Steering Committee
   ii. Risk Assessment Scoring Criteria and Definitions – This tool helped SME be consistent when scoring a threat
   iii. Executive Summary: Summary by Category – This chart is in the report and summarized where gaps were identified, and those gaps where mitigation is not recommended
   iv. Program Overview – This is the report’s appendix that provides an overview of the program
   v. Control Standards – (file) Full set of Standards and questions
Appendix A
Resources

- Minnesota Hospital Association Drug Diversion Prevention Road Map. The road map is a collection of about 100 best practices for preventing and responding to controlled substance diversions.

- Drug Enforcement Administration, Office of Diversion Control
  http://www.deadiversion.usdoj.gov/

- Controlled Substances Act
  http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm
Appendix A
Resources – cont.

- Your state’s Board of Pharmacy website
- Institute of Internal Auditors (IIA) website
  www.theiia.org

*International Professional Practices Framework (IPPF)*
- Practice Advisory 1000.C1-1 *Principles Guiding the Performance of Consulting Activities of Internal Auditors*
- Practice Advisory 2120.A1-2 *Using Control Self-assessment for Assessing the Adequacy of Control Processes*
Appendix B.i. Initial Vision
### Scoring Threats - Scale & Definitions

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td><strong>Extreme</strong> Event causes a major safety or permanent injury</td>
</tr>
<tr>
<td>4</td>
<td><strong>High</strong> Event causes a major safety or non-permanent injury</td>
</tr>
<tr>
<td>3</td>
<td><strong>Moderate</strong> Event causes a minor to moderate injury</td>
</tr>
<tr>
<td>2</td>
<td><strong>Low</strong> Slight annoyance. Event causes very minor safety or no injury</td>
</tr>
<tr>
<td>1</td>
<td><strong>Negligible</strong> Event causes no injury, but has some other negative non-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>Very likely to occur</td>
</tr>
<tr>
<td>High</td>
<td>Strong possibility that it will occur</td>
</tr>
<tr>
<td>Moderate</td>
<td>Maybe occasionally</td>
</tr>
<tr>
<td>Low</td>
<td>Rarely</td>
</tr>
<tr>
<td>Remote</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Detection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Highly unlikely that we’ll detect this.</td>
</tr>
<tr>
<td>Slight</td>
<td>Low likelihood of detection and more difficult to identify the cause.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate likelihood of detection and identification of cause.</td>
</tr>
<tr>
<td>High</td>
<td>Highly likely that we’ll detect this and be able to trace back to the cause.</td>
</tr>
<tr>
<td>Certain</td>
<td>Extremely likely that we’ll detect this and can track the cause.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control Maturity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immature</td>
<td>Control design is weak or not apparent. Heavy reliance on individual integrity to mitigate risks. Management does not place high reliance on this design.</td>
</tr>
<tr>
<td>Less Mature</td>
<td>Control design is not always apparent or operating as designed; only somewhat reliable. Management relies on additional controls to mitigate risk.</td>
</tr>
<tr>
<td>Moderately Mature</td>
<td>Control design relies on high integrity of manual process to assure effectiveness. Generally reliable and most times consistent.</td>
</tr>
<tr>
<td>Highly Mature</td>
<td>Control design is very reliable and consistent. Functions with only occasional intervention.</td>
</tr>
<tr>
<td>Extremely Mature</td>
<td>Control design is extremely reliable and consistently effective. Functions well with little intervention.</td>
</tr>
</tbody>
</table>
Appendix B.iii.
Executive Summary: Summary by Category

<table>
<thead>
<tr>
<th>Council’s Recommendations Summary</th>
<th>Summary of Questions by Standards Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mitigation Opportunities Required (R) or Addressable (A)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No Mitigation, Risk Accepted on Standard #</td>
</tr>
<tr>
<td>Applicable Allina Standards Category</td>
<td></td>
</tr>
<tr>
<td>A. User Access to Physical Areas, Devices and Business Applications</td>
<td>6</td>
</tr>
<tr>
<td>B. Inventory Maintenance</td>
<td>8</td>
</tr>
<tr>
<td>C2 Inventory Ordering Authorization; C3-C5 Inventory Ordering Authorization; Inventory Ordering – DEA Form 222 Safeguards; Inventory Purchasing; Inventory Item Levels</td>
<td>9</td>
</tr>
<tr>
<td>C. Safeguards of Physical Surroundings</td>
<td>14</td>
</tr>
<tr>
<td>Rooms and Areas Housing Controlled Substances</td>
<td></td>
</tr>
<tr>
<td>D. Safeguards of Inventory Storage Devices, Containers</td>
<td></td>
</tr>
<tr>
<td>Locked Storage; Custody</td>
<td></td>
</tr>
<tr>
<td>E. Inventory Item Safeguards</td>
<td></td>
</tr>
<tr>
<td>Custody; Item Security; Inventory Logs; Inventory Counts; Patient’s Own Medications</td>
<td></td>
</tr>
<tr>
<td>F. Medication Orders and Filling</td>
<td></td>
</tr>
<tr>
<td>Transaction Authorization; Filling / Dosage</td>
<td></td>
</tr>
<tr>
<td>G. Patient Administration</td>
<td></td>
</tr>
<tr>
<td>H. Waste and Destruction</td>
<td></td>
</tr>
<tr>
<td>Waste; Destruction</td>
<td></td>
</tr>
<tr>
<td>J. Monitoring and Oversight</td>
<td></td>
</tr>
<tr>
<td>Transaction Reconciliation; Activity Monitoring</td>
<td></td>
</tr>
</tbody>
</table>

Summary: # of Applicable Assessment Questions | 65 | 10 | 8 | 3 | 26 | 18 | 4 |
**Appendix B.iv. Report Appendix: Program Overview**

### Diversion Control Assessment Program Overview

#### Program Scope
The Program is designed for implementation in all areas across Allina where controlled substances are present.

#### Program Objectives
Evaluate control environment designs and practices against the applicable Standards to determine a Threshold for the business area.

Employ an assessment (gap analysis) and evaluation methodology to understand the overall control environment; and determine any changes to control environment designs in response to identified potential risk exposures.

Communicate assessment results and recommended risk-mitigating strategies. Work with business areas to develop corrective action plans to ensure that significant gaps addressed during the evaluation process are understood, remediation opportunities are discussed, and corrective action plans are designed to minimize risk.

Monitor status of corrective action plans and ongoing compliance with the Standards.

The assessment process utilizes the Control Assessment Tool (Tool) for conducting recurring, periodic assessments of control environment designs and effectiveness across Allina business areas where controlled substances are present. Using the Drug Diversion Control Standards as its foundation, each question and response choice presented in the Tool links to its related Standard. Business area subject matter experts respond to each question in the Tool; the scored responses provide a numeric value, or Current State value. The Current State is compared to the Threshold for the business area, identifying “gaps”. The Council reviews any variances and identifies risk exposures requiring additional risk-mitigating efforts or accepts the Current State and potential risk exposure. When warranted, significant issues will be escalated to the Committee, or other leadership groups, for additional consideration and input.

#### Diversion Control Council
On behalf of the Committee, the Diversion Control Council (Council) administers the Program and provides functional leadership across Allina for controlled substances control environment design and risk-based mitigation efforts to prevent and detect diversion of narcotics. This authority includes addressing and resolving differences in control environment designs and practices to the benefit of the Allina Health system at-large.
Drug Diversion Control Standards

The Standards is a list of reasonable and appropriate safeguards, or objectives, for the handling of controlled substances that optimally positions controlled substance control environments across the organization relative to business needs and diversion risk response; provides consistency in practices for Allina employees and non-employees; supports regulatory compliance and ensures staff and patients’ safety. Each Standard has a range of control activities (less desirable to most desirable) to achieve the Standard objective. See Attachment 1 for the complete Drug Diversion Control Standards document.

Assessment and Evaluation Methodology

The assessment process utilizes the Control Assessment Tool (Tool) for conducting recurring, periodic assessments of control environment designs and effectiveness across Allina business areas where controlled substances are present. Using the Drug Diversion Control Standards as its foundation, each question and response choice presented in the Tool links to its related Standard. Business area subject matter experts respond to each question in the Tool; the scored responses provide a numeric value, or Current State value. The Current State is compared to the Threshold for the business area, identifying “gaps”. The Council reviews any variances and identifies risk exposures requiring additional risk-mitigating efforts or accepts the Current State and potential risk exposure. When warranted, significant issues will be escalated to the Committee, or other leadership groups, for additional consideration and input.

Calculating Thresholds and Residual Risk

Standards Value Scale. In order to discuss controlled substances risks across Allina, the Council developed a risk quantification methodology, achieved by attributing a numerical value to each Standard and its range of control activities. Higher values are placed on the more desirable control activities. Each Standard is a percentage of the entire body of Standards. The Standard Value Scale ranges from 0 to 1000, with 1000 as the highest achievable score representing the most optimally positioned controlled substance control environment.

Business Area Threshold. After consulting the Standards, the Council determines which Standards are applicable to the business area, using the best risk-based application to the specific business area or clinical practice method, and professional judgments. Next, the level of desired control activity for the applicable Standard is determined. The Threshold is 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.** The range created between a business area’s Threshold and the *Standards* represents the risk remaining after management determines the optimally positioned controlled substance control environment for the business area to reduce the impact and likelihood of a drug diversion.

**Risk Appetite.** The amount of residual risk Allina is willing to accept in pursuit of its mission to deliver safe, high-quality patient care.

**Recommendation Ratings**

As determined by the Council, mitigating efforts will be recommended using a risk-based approach. The risk-based categories are as follows:

- **Required – Global**
  
  Risk mitigation activities are required; activities need to be approached at an entity level.

- **Required – Location Specific**
  
  Risk mitigation activities are required; activities need to be approached at specific locations.

- **Addressable – Global**
  
  Risk mitigation activities are strongly recommended; activities need to be approached at an entity level.

- **Addressable – Location Specific**
  
  Risk mitigation activities are strongly recommended; activities need to be approached at specific locations.

**Communicating Recommendations and Action Plans**

The Drug Diversion Council’s Draft Report (Draft) communicates results and recommendations to responsible parties at the business area. Working together, the Council and the business area’s operational management develop action plans and targeted completion dates for recommended risk-mitigating strategies. Final approved action plans and targeted completion dates are included in the Drug Diversion Council’s Final Report (Final). The Final is distributed to all stakeholders and the Committee. Recommendations and status on action plans are monitored.
Save the Date
September 21-24, 2014

33rd Annual Conference
Austin, Texas