



Minnesota Controlled Substance Diversion Prevention Coalition

March 2012

Final Report



Minnesota Hospital Association

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Overall Purpose

Controlled substance diversion by health care professionals is a serious issue that can lead to potential patient harm and/or patient safety issues. 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.

Coalition Objectives

- To provide a menu of best practices and resources that health care facilities can utilize to prevent and increase awareness of controlled substance diversion.
- To provide guidance to investigatory agencies on how/when/with whom information can be shared, in order to ensure that agencies work together toward common goals, avoid stepping on toes, and have a better understanding of jurisdictional issues.
- Provide a menu of resources for provider organizations to meet state and federal reporting requirements of controlled substance diversion.
- Write final coalition report including recommendations for disseminating coalition work.
- Recommend measures to quantify cases of health care professional controlled substance diversion.
- Share this information with the public.

Key Coalition Outcomes

- Created broad-based stakeholder forum to identify and share strategies to increase awareness of and prevent controlled substance diversion.
- Identified communication strategies across investigative agencies and health care facilities.
- Developed ‘Controlled Substance Diversion Prevention’ Roadmap of Best Practices.
- Created flow chart of regulatory requirements.
- Collated coalition work and tools in final coalition report.
- Posted resources on website to increase public awareness.
- Identified the need to articulate how/where the data/outcomes will be documented in the future.

Timeline

- May 2011— MDH and MHA launch coalition.
- June 2011 — Initial coalition meeting held and workgroups commissioned.
- July-Jan 2012 — Workgroup meetings and monthly full coalition meetings to work toward meeting goals and objectives.
- Feb 2012 — Final roadmap and tool developed.
- March 2012 — Final report and resources disseminated and posted on the MDH and MHA websites.

Coalition Structure and Workgroups

The initial coalition meeting was held in June 2011. The coalition met over the course of nine months and commissioned five workgroups to accomplish the following goals:

- Gather best practices and resources for health care organizations, professionals and the public to prevent controlled substance diversion; and to increase awareness and detection/surveillance if drug diversion occurs.
- Identify strategies to increase communication across coalition organizations and investigative organizations if controlled substance diversion occurs.
- Identify state and federal legal obligations, statutory requirements, audit protocols and resources to assist health care organizations' response if controlled substance diversion occurs in their organization.
- Develop/disseminate resources to health care organizations, professionals and the public.
- Discuss measurement in order to measure scope of issue and coalition impact.

Coalition Participants

The coalition was a collaborative effort of a broad-based stakeholder group across a variety of care settings including hospitals, long-term care facilities, home care and hospice. Participants included: Aging Services of Minnesota; Association for Professionals in Infection Control and Epidemiology-Minnesota; HealthPartners; Health Professionals Services Program; Hennepin County Attorneys Office; Drug Enforcement Administration; U.S. Food and Drug Administration/Office of Criminal Investigations Minneapolis Domicile; Hennepin County Medical Center; Mayo Clinic Rochester; Metropolitan Health Plan; Minneapolis Police Department; Minnesota Board of Medical Practice; Minnesota Board of Nursing; Minnesota Board of Pharmacy; Minnesota Department of Health; Minnesota Department of Public Safety; Minnesota Directors of Nursing Administration; Minnesota Pharmacist Association; Minnesota Society of Health-System Pharmacists; Minnesota Hospital Association; Retail Pharmacy.

Background

- There have been several high-profile cases of health care workers diverting drugs from health care facilities in Minnesota. Because drug diversion is a serious issue that can lead to potential patient harm and/or patient safety issues, MHA, MDH and a coalition of partners, including law enforcement, have come together to address the issue.
- Prescription drug abuse is a national epidemic. And, as long as there is drug addiction, there will be thefts to obtain these drugs.
- Theft or diversion of a controlled substance — even one pill — is a felony crime.
- Controlled substances are more available. The number of opiate prescriptions dispensed by US retail pharmacies increased from 76 million in 1991 to 210 million in 2010 — triple the number. The number of prescriptions for stimulants increased from 5 million in 1991 to 45 million in 2010. (SDI's Vektor One[®]: National (VONA))
- Over the past year, this task force has identified best practices and resources for health care organizations to increase awareness of and prevention of drug diversion.
- Hospitals and other health care providers routinely and regularly review records of administered controlled substances to determine if there is a pattern that may be indicative of diversion. They take this work very seriously and have policies and procedures to detect diversion.
- From 2005 to 2011, there were 250 reports of theft or loss of controlled substances associated with health care workers. This does not include stand-alone or retail pharmacies. Reports increased from 16 in 2006 to 52 in 2010. That's a 325 percent increase. Controlled substances most associated with a theft or loss event were hydrocodone, oxycodone, hydromorphone, morphine sulfate, and fentanyl. (See appendix B for additional information)
- The new controlled substances diversion prevention roadmap will improve hospitals' storage and security; procurement; prescribing; preparation and dispensing; administration of controlled substances; handling of controlled substances waste, such as sharps; and follow-up when diversion is suspected.
- In addition, organizations will collaborate with local law enforcement; communicate expectations to staff that they speak up when they become aware of an issue related to drug diversion; and put in place training and education programs for staff.
- As health care facilities adopt the recommendations of this group, we anticipate the numbers of reports to increase due to increased awareness of diversion. As the roadmap practices to limit diversion are implemented, the number of reports will be expected to decrease in subsequent years.
- The vast majorities of health care professionals would never divert drugs from their workplace or their patients.
- Patients need to be active participants in their care and they should not be afraid to tell their caregiver if they are in excessive pain knowing that they are supposed to be taking pain medication. Patients should also speak up if they suspect that a caregiver is taking any of their medication or appears impaired.

Prevention Roadmap Outline

1. 'SAFE' Infrastructure

- **S:** Safety teams/Organizational Structure
 - ▶ Organization defines controlled substance (CS) diversion prevention program.
 - ▶ An organizational structure is in place which supports an effective (CS) diversion prevention program.
 - ▶ Organization proactively collaborates with local law enforcement.
- **A:** Access to information
 - ▶ Organization reviews and audits relevant data which could indicate potential CS diversion.
 - ▶ Organization tracks and reviews measures recommended by Coalition.
- **F:** Facility expectations
 - ▶ Organization communicates expectation that staff “speak up” when they become aware of an issue related to CS prevention diversion.
 - ▶ The facility’s HR practices support an effective organization-wide CS diversion prevention program.
- **E:** Educate staff and patients
 - ▶ Organization has in place an effective and comprehensive training and education program.

2. Best Practice Principles

- Storage and security
- Procurement
- Prescribing
- Preparation and dispensing
- Administration of CS
- Handling CS waste
- Follow-up when diversion suspected

For the full prevention roadmap, visit the MDH or MHA’s websites.

3. Tool Kit

In addition to the full Controlled Substance Diversion Prevention Roadmap, other resources are available in the Controlled Substance Diversion Prevention Tool Kit with tools such as:

- Flow chart of reporting guidelines and requirements
- Related statutes
- Sample policies and procedures
- Education

For the tool kit, visit the MDH or MHA’s websites.

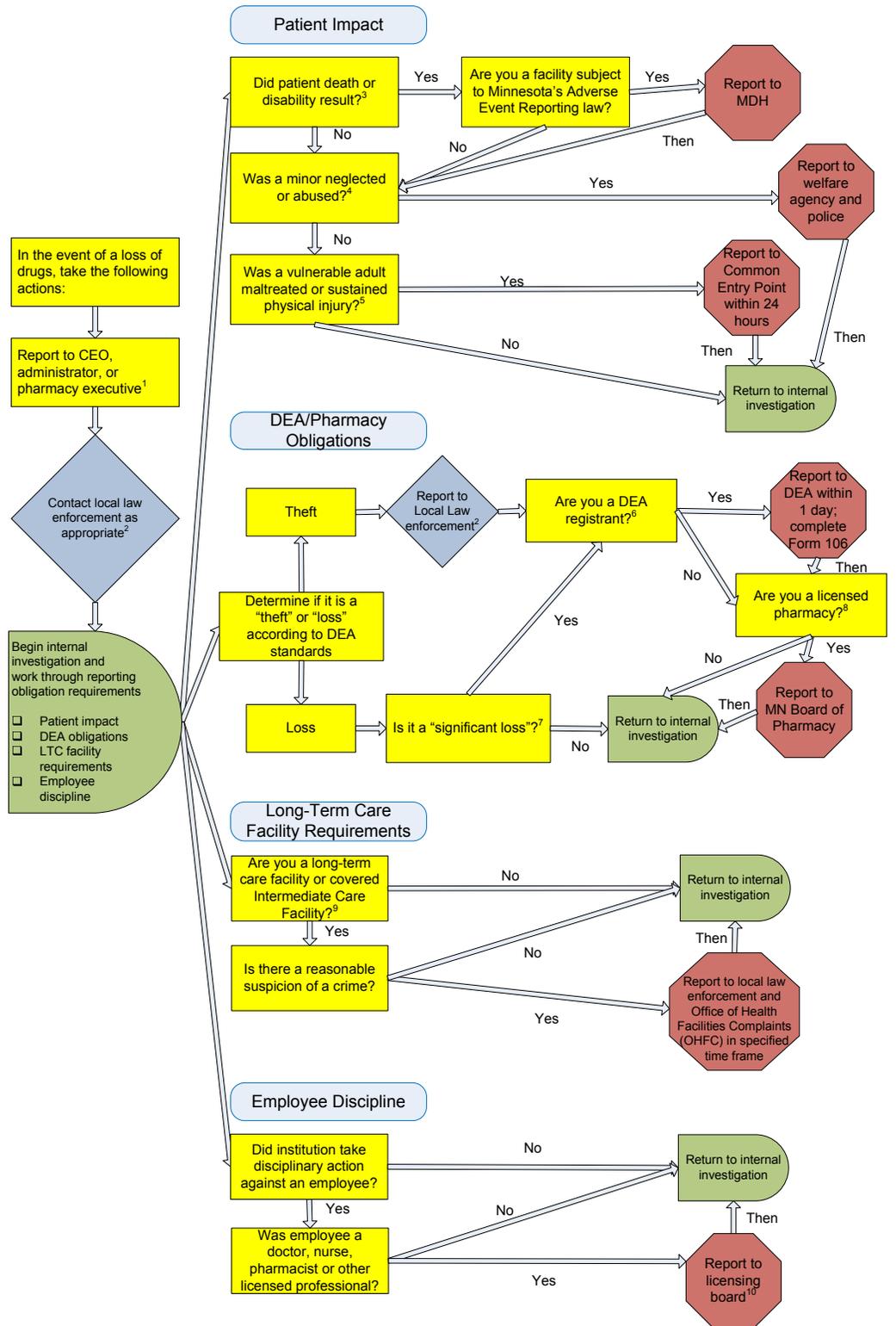
Next Steps

- Disseminate roadmap and resources to Minnesota health care facilities.
- Educate public through the MDH website.
- Disseminate/educate through professional societies and journals.

Appendix A

Minnesota
Department of
Health/Minnesota
Hospital Association
Controlled
Substance Diversion
Prevention
Reporting Guidelines
and Requirements

Controlled Substance Diversion Prevention Summary of Minnesota Reporting Requirements and Guidelines



¹Medicare State Operations Manual § 482.25(b)(7) (hospitals); § 483.60 (Certified Nursing Homes)
²Drug Diversion Prevention Roadmap (March 2012)
³Minnesota Statutes Annotated § 144.7065
⁴MSA § 626.556
⁵MSA § 626.557
⁶21 CFR § 1301.74(c)
⁷21 CFR § 1301.76(b); 68 FR 40577-8 (July 8, 2003)
⁸Minnesota Administrative Code § 6800.4800
⁹42 USCA § 1320B-25
¹⁰MSA § 148.263 (for nurses); MSA § 147.111 (for physicians)

Appendix B

Minnesota Department of Health/Minnesota Hospital Association
Controlled Substance Diversion Prevention Data Report

Reports of Theft or Loss of Controlled Substances to the U.S. Drug Enforcement Administration (DEA) via Form DEA-106

Goal: Provide consistently collected data associated with health care worker controlled substance diversion.

Purpose: Assess the scope of health care worker controlled substance diversion, identify possible trends over time, target areas for future programs, and assess impact of coalition resources.

Process: Multiple data sources were evaluated for possible use. Consistent definitions and long-term collection made data submitted in Form DEA-106, Report of Theft or Loss of Controlled Substances the most useful for our stated purpose.

Definitions

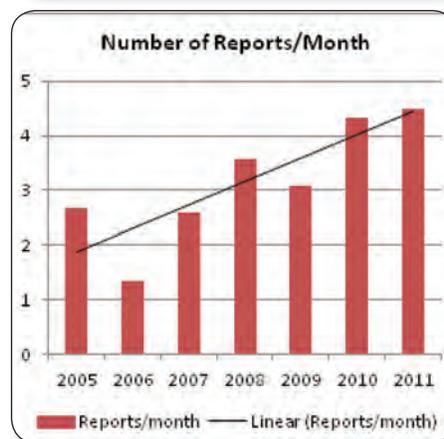
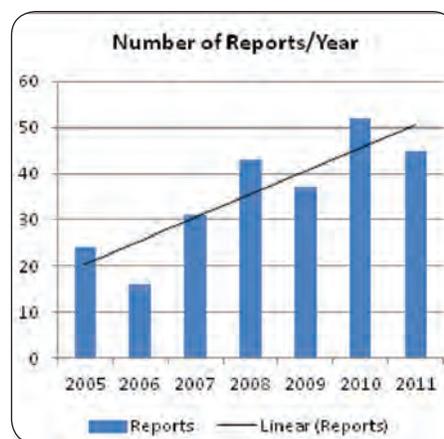
Report: A single filing of Form DEA-106 indicating a theft or loss due to “employee pilferage” or “other” that occurred at a Minnesota hospital pharmacy, clinic pharmacy, retail pharmacy physically co-located in a clinic or hospital, or practitioners who were licensed to store controlled substances for use by patients (i.e., outpatient surgery center).

Event: An instance of theft or loss for each separate drug. A single report may have contained multiple events of theft or loss. If multiple events are contained in a single report, it is unknown if each event occurred over a period of time or at a single point in time. Greater detail on the associated drug was available on reports that were filed electronically but was not available on those reports completed as a paper filing.

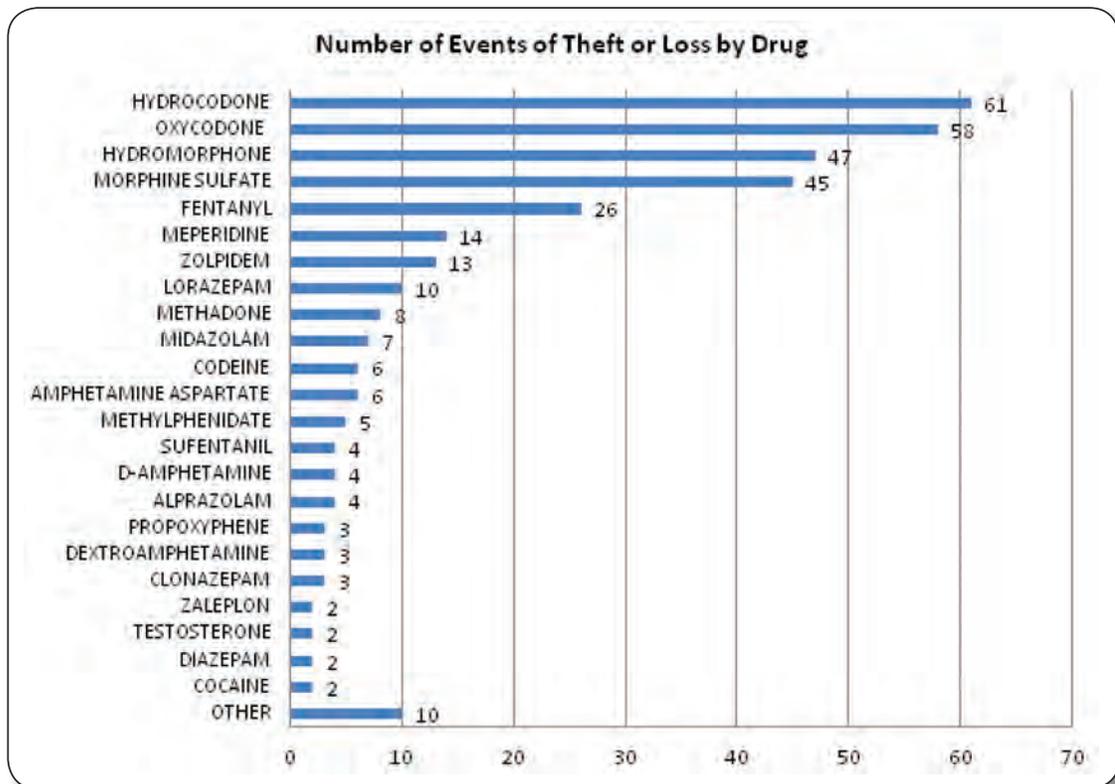
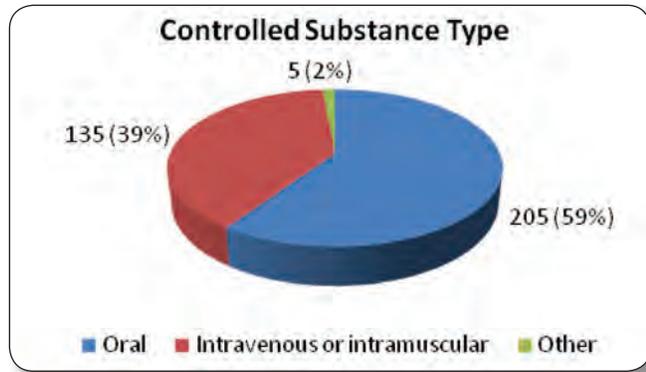
Data available: Form DEA-106 data were consistently available from April 2005 – November 2011.

Findings:

- 250 unique reports of theft or loss occurred between April 2005 and November 2011.
- 134 (54%) were from the 7-county Minneapolis-St. Paul metropolitan area (Anoka, Carver, Dakota, Hennepin, Ramsey, Scott and Washington counties) with the remainder reported from areas outside these 7 counties.
- Reports increased from 16 (1.3 per month) in 2006 to 52 (4.3 per month) in 2010.
- During the first 10 months of 2011, there were 45 reports (4.5 per month).



- Of the 250 reports, 143 (57%) were filed electronically with drug-specific event data.
- 66 (46%) reports included more than one event per report with 345 unique events.
- Of the 345 events, 205 (59%) involved oral medications, 135 (39%) intravenous or intramuscular medications, and 5 (2%) medications administered via other routes.
- Controlled substances most associated with a theft or loss event were hydrocodone (18%), oxycodone (17%), hydromorphone (14%), morphine sulphate (13%), and fentanyl (8%).



Interpretation:

- Reports of theft or loss have increased by 325% from years 2006 – 2010.
- The number of monthly reports for 2011 was higher than 2010.
- Approximately an equal number of reports were from the 7-county metropolitan area compared to other counties. This reflects the population distribution in Minnesota.
- It is unclear if changes in reporting behavior occurred during this time frame as the DEA implemented an electronic reporting system.
- It is unclear to what degree recent investigations and media coverage have impacted the number of events reported via Form DEA-106.

Recommendations:

- Data from Form DEA-106 reports should be used to assess ongoing progress to prevent health care worker controlled substance diversion.
- Assuming health care facilities adopt guidance for best practices of identifying health care worker controlled substance diversion, we anticipate the numbers of Form DEA-106 reports to increase. This will likely result in an increase in the number of reports in the near term after implementation.
- As standard practices to limit diversion are implemented in health care facilities, it is expected that the number of Form DEA-106 reports will decrease in subsequent years.
- Identification and reporting of additional information sources such as aggregated health care worker controlled substance diversion events from organizations such as the Minnesota Board of Medical Practice, Board of Nursing, Board of Pharmacy, and/or Health Professionals Service Program may provide additional and complementary data. This could offer a more nuanced assessment of the best practices developed by this group.

Appendix C

Minnesota Department of Health/Minnesota Hospital Association
Controlled Substance Diversion Prevention Tool Kit Table of Contents

S

- Medication Diversion Prevention Coordinator Job Description
- Sample Policy, March 8, 2012
- 2010 Minnesota Statutes 152.025 – Controlled Substance Crime in the Fifth Degree
- Medicare Drug Integrity Contractors’ Identification of Potential Part D Fraud and Abuse
- Code N – A Multidisciplinary Approach to Proactive Drug Diversion Prevention
- Code N – Checklist for Investigation of Controlled Substance Diversion
- Prescription Drug Abuse & Addiction – Past, Present and Future: The Paradigm for an Epidemic
- 2011 Minnesota Statutes
- Minnesota Administrative Rule 6800.4800 – Reporting Controlled Substance Losses
- Minnesota Administrative Rule 6800.2600 – Automated Counting and Distribution
- 2011 Minnesota Statute 152.11 – Written or Oral Prescriptions, Requisites
- Minnesota Administrative Rule 6800.0100 – Definitions

A

- Record Comparison Worksheet

F

- Drug Diversion Investigative Agencies
- Statutes Grid
- Drug Diversion Reporting Obligation flow sheet
- Communicating Outcomes to Patients

E

- Substance Abuse and Mental Health Services Administration
- New York Department of Health website
- Drug Enforcement Administration
- National Association Drug Diversion Investigators
- Compliance with Recommendations for Prevention and Detection of Controlled-Substance Diversion in Hospitals
- Presentation – Security of Controlled Substances Hennepin County Medical Center
- White Paper: Updating Language to Enhance Nurse Narcotic Safety
- Substance Use Disorder in Nursing
- Identifying Potentially Impaired Practitioners
- Drug Store News Continuing Education: Drug Diversion
- Drug Diversion – Retail Pharmacy
- Chemical Dependency and the Physician
- Sample Pharmacy Policy
- Sample Drug and Alcohol Testing Checklist
- Sample Drug and Alcohol Testing – Manager Toolkit

- The Addicted Physician – A Rational Response to an Irrational Disease
- Prescription Drug Alert – Protect Your Kids!
- Pain Management Patient Brochure

Clinical Bundle

- Suggested Approach to Potential Drug Diversion Investigations Resource, provided by Mayo Clinic

Additional Links/Resources

- Narcotic Enforcement – Changes to Controlled Substance Schedules in New York State
- Unbecoming a Nurse – Bypassing the Hidden Chemical Dependency Trap
- Kimberly S. New – Compliance Specialist, Controlled Substance Surveillance



Road Map to Controlled Substance Diversion Prevention



Minnesota Hospital Association

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

SAFE Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
 <p>Safety Teams/ Organizational Structure</p>	<ol style="list-style-type: none"> 1. Organization defines Controlled Substance (CS) diversion prevention program. 2. An organizational structure is in place which supports an effective CS diversion prevention program. 3. Organization proactively collaborates with local law enforcement. 4. Organization fulfills any requirements to report diversion or loss of controlled substances to the appropriate agencies. 	<ol style="list-style-type: none"> 1a. The organization has an interdisciplinary team involved in developing and overseeing the CS Diversion Prevention Program. 1b. The CS Diversion Prevention Program includes prevention, detection, and investigation. 1c. The CS Prevention Program is reviewed by the team and updated at least annually. 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas: <ul style="list-style-type: none"> – Medical staff – Pharmacy – Nursing – Security – Human Resources – Patient safety/Risk Management/Compliance – Administration – Legal Ad hoc – Communications Ad hoc 2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. 2b. The coordinator(s) has dedicated time to serve in this coordination function. 2c. The organization has a team prepared to respond to suspected CS diversion situations. 2d. The organization has policies and procedures that address all aspects of the CS use processes and are regularly reviewed. 2e. Policies and procedures are regularly reviewed to assure compliance with state and federal laws. 3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss CS diversion prevention program and establish a communication strategy (including public) prior to CS diversion situations. 4a. The organization is aware of the reporting requirements found in the statutes and rules administered by Minnesota’s Health-Related Licensing Boards, including the provisions of Minnesota Statutes Section 214.33. 4b. DEA registrant or their designee reports all controlled substance thefts or significant loss to the DEA and as required by federal and state rules.
 <p>Access to information/ Accurate Reporting/ Monitoring/ Surveillance/ Detection System</p>	<ol style="list-style-type: none"> 1. Organization reviews and audits relevant data which could indicate potential CS diversion. 2. Organization tracks and reviews measures recommended by Coalition. 	<ol style="list-style-type: none"> 1a. The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets, CS “Disposition and Inventory” sheets. 2a. The organization has a process in place to review and analyze CS data on a regular basis. 2b. The organization shares findings from the data analysis on a regular basis. 2c. If diversion is suspected there is a process in place to activate response team to include patient care manager, pharmacy, HR, security. 2d. If diversion is suspected, the organization has a process in place to contact local, state, federal law enforcement.

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

SAFE Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
<p>F Facility Expectations</p>	<ol style="list-style-type: none"> 1. Organization communicates expectation that staff “speak up” when they become aware of an issue related to CS diversion. 2. Organization establishes full disclosure policy. 3. The organization’s HR practices support an effective organization-wide CS diversion prevention program. 4. Organization does not allow sharing of pass codes. 	<ol style="list-style-type: none"> 1a. Senior leadership has clearly communicated that all staff are expected to speak up and will be supported in speaking up when they become aware of possible diversion. 1b. The organization has a clearly defined process for speaking up and “stopping the line” if a potential safety issue has been identified by staff. The process clearly outlines: <ul style="list-style-type: none"> – when to stop the line; – how to stop the line (e.g. “I need clarity”); – the chain of command to follow if not supported in stopping the line; – clear communication to staff from managers and leadership that staff will be supported if they speak up. 2a. The organization has a clearly defined full disclosure policy and process to communicate to patients/families that are impacted by CS prevention diversion. 3a. Organization has established and communicated ways for staff to anonymously speak up (e.g. hot line, paper or electronic submission). 3b. Organization has a process in place to remove impaired caregiver from patient care. 3c. The organization conducts pre-employment background check and drug testing for Licensed Independent Practitioner (LIP) and employees. 3d. A log of staff photographs and signatures are maintained as appropriate. 3e. The organization has a process to manage employee access to CS when terminated or transferred in a timely fashion. 3f. Organization has developed a “for cause policy” for drug testing. 4a. Organization establishes and enforces a policy of not sharing pass codes [e.g. EMR, Automated Distribution Machine (ADM), pharmacy door code].
<p>E Educate Staff [and Patients]</p>	<ol style="list-style-type: none"> 1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention. 	<ol style="list-style-type: none"> 1a. The CS Diversion and Prevention team attend training on CS diversion prevention and statutory requirements. [e.g. National Association of Drug Diversion Investigators (NADDI), professional associations, licensing boards, state, local, and federal law enforcement] 1b. Expectations and supporting education have been incorporated into training for all new staff and Licensed Independent Practitioner (LIP). Expectations and training includes, at a minimum: 1c. Providing awareness training to know the signs of diversion. 1d. Resources are available to support employees and LIP, e.g. Employee Assistance Programs (EAP) and Health Professional Services Programs (HPSP). 1e. The facility requires training on CS policies and procedures prior to authorizing staff to have CS access. 1f. The facility provides ongoing staff education at least annually to promote the safe handling of CS and awareness of CS diversion. 1g. The organization provides patient education on safe medication handling, including potential for diversion.

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
<p>STORAGE AND SECURITY</p>	<p>1. The organization stores CS and other high risk items securely, in all settings and circumstances.</p> <p>2. Organization uses camera surveillance in high risk areas as appropriate.</p>	<p>The organization has a process in place for securing CS which includes:</p> <p>1a. CS are not to be left unattended at any time.</p> <p>1b. CS are stored in a locked location [Automated Distribution Machine (ADM), CII vault, locked cabinet/drawer/box] at all times. (ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed healthcare facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.)</p> <p>1c. ADM managed CS are stored in a location with single pocket access.</p> <p>1d. Access to CS storage areas is limited to authorized staff.</p> <p>1e. Non-ADM CS cabinets are secured with an electronic lock, cipher lock or key.</p> <p>1f. Removing ADM and non-ADM access for terminated employees.</p> <p>1g. Patient specific CS infusions (PCAs, epidurals, and continuous infusions) are enclosed in a locked box utilizing no-port tubing.</p> <p>1h. Controlling and accounting for keys.</p> <p>1i. Prescription pads/paper are stored in ADM, locked location, or under control of LIP.</p> <p>1j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area.</p> <p>1k. Electronic and non-electronic prescriptions comply with state and federal requirements</p> <p>1l. CS brought in by a patient that cannot be returned home are inventoried by two authorized healthcare staff and stored in a locked, limited access area.</p> <p>2a. Camera surveillance is used in primary CS Pharmacy storage area (e.g narc vault).</p> <p>2b. Camera surveillance is use in areas deemed high risk as determined by the organization (e.g. procedural areas) CS medication preparation areas in pharmacy OR, ER or medication areas with high use of CS.</p>

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
PROCUREMENT	1. The organization effectively and safely handles procurement in the hospital pharmacy.	<p>The organization has a process in place for procuring CS which includes:</p> <ul style="list-style-type: none"> 1a. All CS are obtained from the hospital pharmacy 1b. DEA’s Controlled Substance Ordering System (CSOS) is the preferred method for CII CS procurement. <i>(DEA’s CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee’s authorized user.)</i> 1c. Individuals authorized to order CII-V is limited to the DEA registrant and authorized individuals. 1d. DEA 222 forms are kept under perpetual inventory, secured, and only accessible by authorized individuals. <i>(Perpetual inventory is a Minnesota Board of Pharmacy requirement to monthly maintain and reconcile Schedule II controlled drugs.)</i> 1e. The person(s) authorized to order CS is not the same person who receives the CS. 1f. All invoices received will have the date when the medications are received and two signatures on the invoice.
PRESCRIBING	1. The organization’s ordering/ prescribing practices minimize the risk of CS diversion.	<p>The organization has a process in place for ordering/ prescribing CS which includes:</p> <ul style="list-style-type: none"> 1a. CS are prescribed only by licensed authorized prescribers with DEA registration or institutionally assigned DEA suffix. 1b. A valid order from an authorized prescriber exists for all CS administered. 1c. Patient specific CS orders are generated by electronic systems with controlled access except in emergency situations in accordance with applicable federal and state laws and rules. 1d. CS are not prescribed by an authorized prescriber for him/herself or an immediate family member. 1e. Range orders for CS are minimized.

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
<p>PREPARATION & DISPENSING</p>	<p>1. The organization's preparation and dispensing practices minimize the risk of CS diversion.</p>	<p>The organization has a process in place for dispensing CS which includes:</p> <ul style="list-style-type: none"> 1a. CS are dispensed in single-unit-dose packaging. <i>(Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.)</i> 1b. Tamper-evident packaging is utilized for CS prepared by pharmacy. <i>(Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.)</i> 1c. Secure, locked, non-transparent medication delivery carts/containers are used to deliver CS and accessible only by authorized individuals. 1d. CS transported via pneumatic tube are sent via secured transaction. 1e. ADMs are utilized in patient care areas for the distribution of controlled substances and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. 1f. Bar code scanning is utilized when replenishing ADMs. 1g. A blind count process is used for narcotic vault and ADM distributed CS. <i>(Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.)</i> 1h. The number of CS on override status in profile ADMs is minimized (e.g. one time injectables for emergency situations only). 1i. Biometric-ID technology is used instead of passwords. If password is used, there must be a process to force password resetting on a regular interval. 1j. There must be a co-signature for delivery of CS to non-ADM areas 1k. ADM down time procedures must be defined to maintain the control, documentation and accountability of CS.
<p>ADMINISTRATION OF CS</p>	<p>1. The organization's CS administration practices minimize the risk of CS diversion.</p>	<p>The organization has a process in place for administering CS which includes:</p> <ul style="list-style-type: none"> 1a. Only health care providers operating within the scope of their practice may administer CS. 1b. Defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 min of the end of the procedure). 1c. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered. 1d. CS are removed for one patient at a time from ADMs and/or locked storage areas. 1e. The individual retrieving the CS from ADM / locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g. emergencies) and has policy/process in place to assure chain of custody. 1f. All CS drawn up into syringes, if not immediately administered, are labeled per institutional policy.

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
<p>HANDLING CS WASTE</p>	<p>1. The organization's "waste" handling practices maintain chain of custody to minimize the risk for CS diversion.</p> <p>2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.</p>	<p>Pharmacy:</p> <p>1a. CS waste from Compounded Sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed.</p> <p>Areas outside Pharmacy:</p> <p>1b. All Potentially Reusable Product (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. <i>(PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow for the medication to be re-issued to another patient.)</i></p> <p>1c. Unusable product (UP) CS are to be immediately wasted and witnessed by healthcare professionals per specific hospital procedures. <i>(UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/ beyond use date.)</i></p> <p>1d. The organization has identified the high risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs.</p> <p>1e. Organization has identified specific high risk CS medications (e.g., fentanyl) that are randomly assayed.</p> <p>1f. The organization has a process to randomly obtain and assay UP CS. For random assays the UP CS would not be subject to immediate witnessed waste.</p> <p>Wasting of UP CS:</p> <p>2a. Approved methods for wasting a CS are defined per federal, state and county laws and regulations.</p> <p>2b. The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except in situations where UP CS are being returned to pharmacy for assay.</p> <p>2c. An individual witnessing CS wasting verifies the volume / amount being wasted matches the documentation and physically watches the medication being wasted per policy.</p> <p>2d. Empty containers of CS (e.g., vials) are discarded in limited access waste containers.</p> <p>2e. The hospital takes measures to secure waste containers with trace UP CS to prevent tampering.</p> <p>PRP Returns:</p> <p>2f. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket.</p> <p>2g. All PRP CS returns to pharmacy require co-signature in the patient care area and in pharmacy</p> <p>Waste or Reverse Distribution:</p> <p>2h. DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company.</p>

Continued

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, others.

Component	Specific Action(s)	CONTROLLED SUBSTANCE Assessment Questions
<p>Monitoring of Controlled Substances and Process if Diversion is Suspected</p>	<ol style="list-style-type: none"> 1. The organization removes access to CS if diversion is suspected. 2. The organization monitors CS through inventory, reports, and audits. 3. Process is in place to resolve CS discrepancies. 4. Organization creates standard process to investigate potential diversion cases. 	<ol style="list-style-type: none"> 1a. All personnel actions (e.g. suspension, terminations and resignations) are communicated to pharmacy immediately so access to CS can be removed in a timeframe as defined by the organization. <p>The organization has a defined process in place to monitor CS on a regular basis which includes:</p> <ol style="list-style-type: none"> 2a. Auditing CS purchase invoices against CS order with receipt into the pharmacy's perpetual inventory. Tracking any CS purchases outside of the pharmacy department. 2b. Tracking movement of CS throughout the hospital, e.g. reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of receipt. 2c. Inventorying, at least monthly, all medications within an ADM or narcotic vault. 2d. Inventorying non automated CS storage areas at each shift change. 2e. Review of ADM reports, at least monthly, by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. 2f. Comparison of ADM CS activity to peers with similar staffing responsibilities and FTE appointments. 2g. Comparison of transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) to peers. 2h. Comparison of patient MAR—amount & quantity administered to what other caregivers administer on subsequent shifts (without patient change in condition). 2i. Comparison of non-ADM CS storage area record of use with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste. 3a. CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies which cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hrs (e.g. metric: unresolved nursing unit CS discrepancies > 24 hrs/total nursing unit CS discrepancies should be ≤8%). 4a. There is a standard process in place to investigate potential diversion cases. (Refer to models in Tool Kit)