Minnesota Controlled Substance Diversion Prevention Coalition

March 2012

Final Report

MINNESOTA MDH DEPARTMENT OF HEALTH

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 Vetor 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

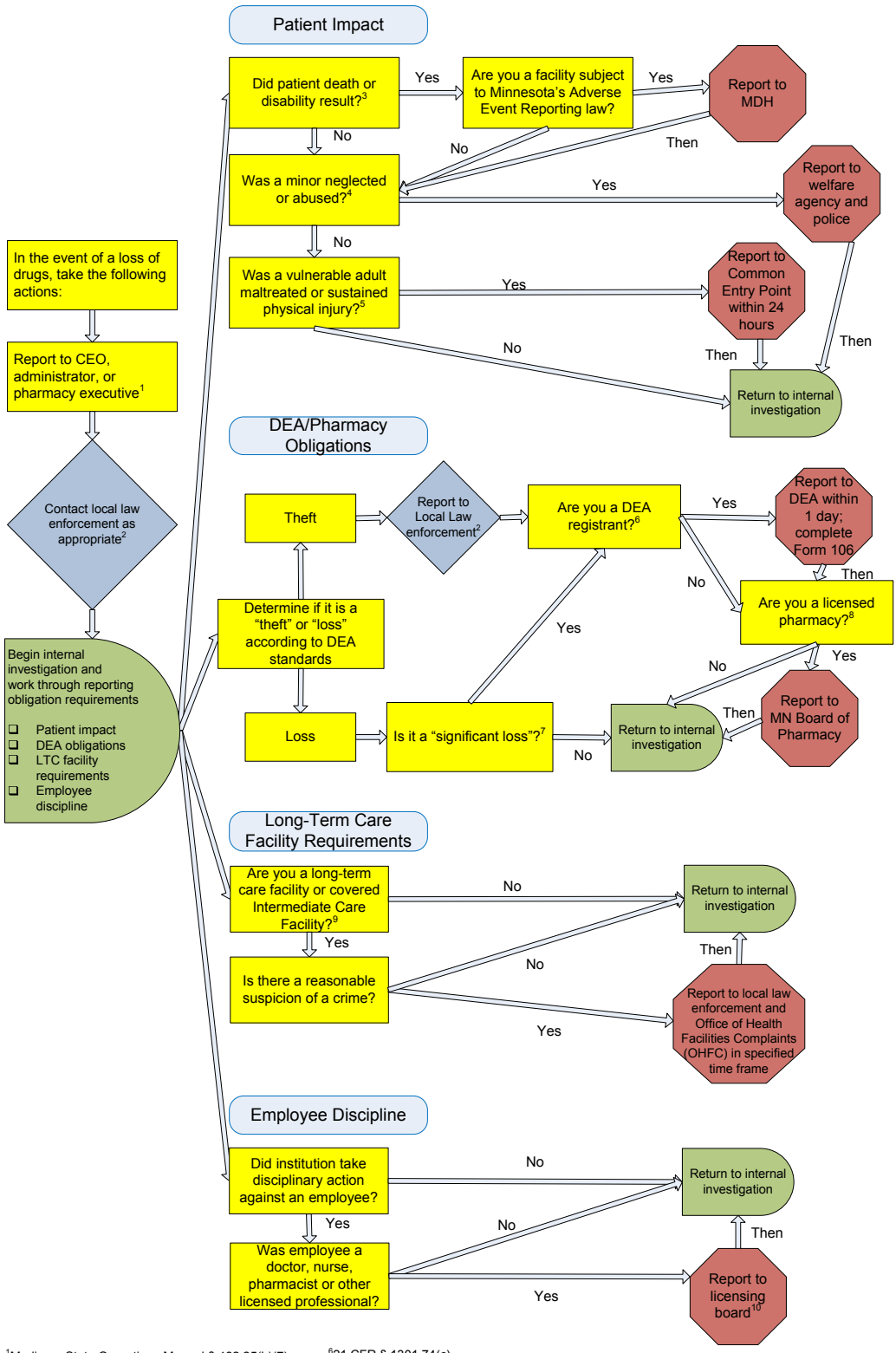
- Disseminate roadmap and resources to Minnesota health care facilities.
- Educate public through the MDH website.
- Disseminate/educate through professional societies and journals.

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



[1]Medicare State Operations Manual § 482.25(b)(7) (hospitals); § 483.60 (Certified Nursing Homes)
[2]Drug Diversion Prevention Roadmap (March 2012)
[3]Minnesota Statutes Annotated § 144.7065
[4]MSA § 626.556
[5]MSA § 626.557
[6]21 CFR § 1301.74(c)
[7]21 CFR § 1301.76(b); 68 FR 40577-8 (July 8, 2003)
[8]Minnesota Administrative Code § 6800.4800
[9]42 USCA § 1320B-25
[10]MSA § 148.263 (for nurses); MSA § 147.111 (for physicians)

3/28/12

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).

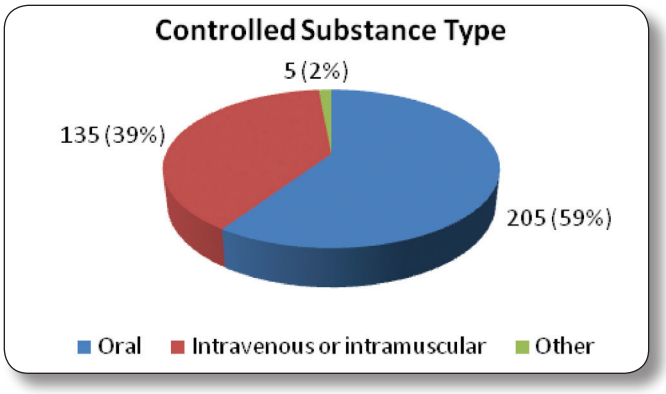
Event: An instance of theft or loss for each separate drug. A single report may have contained multiple events of theft or loss. If multiple events are contained in a single report, it is unknown if each event occurred over a period of time or at a single point in time. Greater detail on the associated 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.

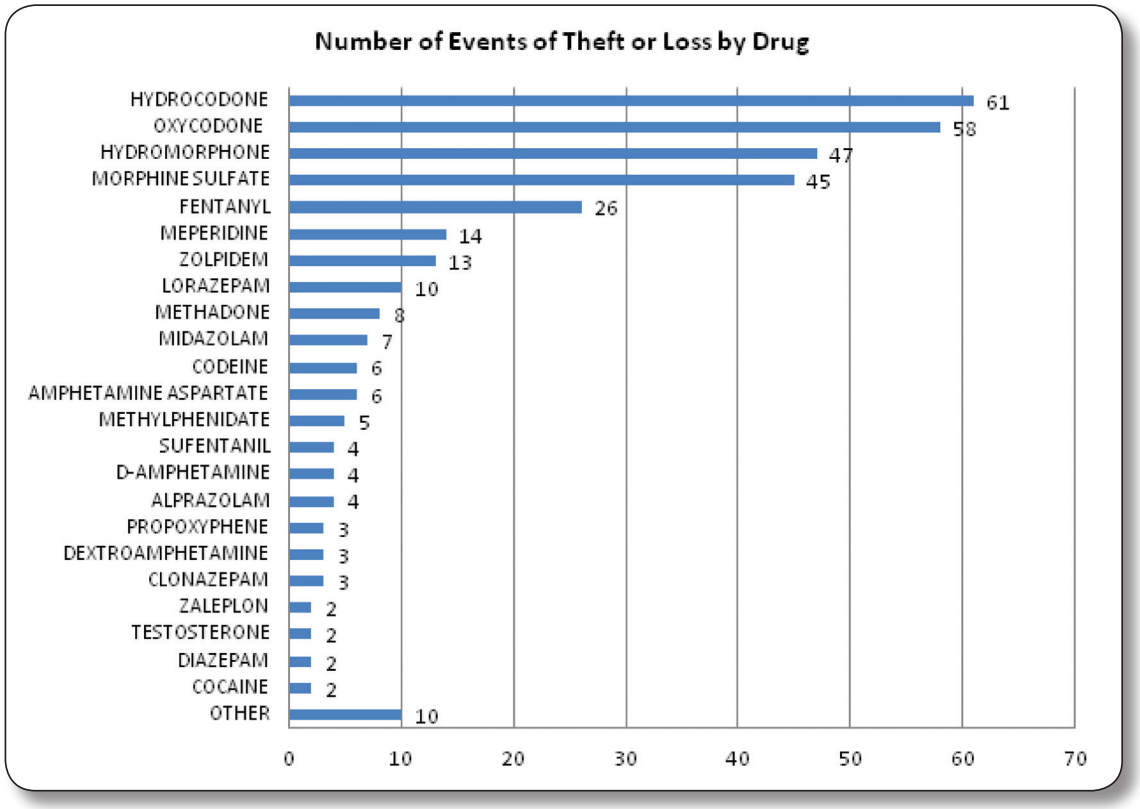
Findings:

- 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