Pathway to Prevent Diversion of Controlled Substances in Long-Term Care

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Prepared by Apiari LLC

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The team reached out to several experts in their fields to obtain information pertinent to the project. We would like to thank the *National Council for the State Boards of Nursing*, the *Minnesota Department of Human Rights*, and the *Minneapolis VA Health Care System* for their time and expertise.

We would also like to thank LeadingAge Minnesota for providing meeting space across the project.

Introduction

We are excited to present you with the Minnesota Pathway to Prevent Diversion of Controlled Substances in Long-term Care. Controlled substance diversion is a serious safety and quality issue that has an impact on residents' quality of care and life, while also increasing the risk of misuse of diverted medications in the community and contributing to an overarching opioid crisis in Minnesota. This project has sought to identify best practices and provide resources to assist nursing facilities with identifying and mitigating controlled substance diversion in a standardized and accelerated fashion. This will benefit residents by assuring that their medications are secure and free from tampering, that health care providers are not impaired, and that residents' pain is effectively managed.

This pathway is the product of a collaborative team of stakeholders with deep roots in long-term care and a desire to provide practical resources to long-term care facilities and their residents. The team completed an extensive review of literature and of all controlled substance investigations across Minnesota in the last three years. These reviews led to the structure of this pathway and include interventions for all phases of the controlled substance "life cycle." All conversations and decisions were based on a resident-centered framework and a belief that preventing diversion improves resident care across the state.

How to use this Pathway

Controlled substance diversion is widespread across healthcare, and national organizations recommend that all health care facilities develop a controlled substance diversion prevention program, but it is often difficult to know where to start or if there are gaps in the current program.

It is unlikely that any facility will implement all of the team's recommendations. This pathway is intended to help leaders increase their awareness of the issue, systematically assess their facilities and processes, and create an individualized plan to implement interventions that will mitigate vulnerabilities and improve care within their context and facility culture. Once a facility has identified their direction, they can implement interventions using their internal QAPI structure for roll-out, monitoring implementation, and measuring outcomes.

Technology and Change

Technology is changing clinical practice quickly, and adoption of technological solutions can improve care. New innovations or decreased cost may allow technology to revolutionize controlled substance monitoring in long-term care.

Whenever possible, the team attempted to create recommendations that are evergreen, acknowledging uncertainty about future resources that may be available – and the broad spectrum of technological solutions and adoption across Minnesota's long-term care facilities.

Investigation

When reviewing investigations, the team realized that guidance from experts and a standardized data set could be helpful for leaders when faced with potential diversion in their homes. This pathway includes internal investigation recommendations for nursing facilities

when they suspect diversion – and a standardized data set intended for surveyors to complete during investigations to ensure the state is able to identify trends and opportunities.

Employment Practices and Reporting

A troubling diversion trend exists across the industry. In the absence of definitive evidence, health care workers who divert controlled substances are often able to quit in lieu of being fired. They are able move from facility to facility, diverting medications from each location and from the residents and patients in their care, sometimes over a period of years.

The team has created recommendations around hiring to ensure prospective employees have the opportunity to explain themselves and that prospective employers have the information they need to make well-informed hiring decisions.

*The team also highly recommends that leaders report clinicians who are governed by a state board when there is a **suspicion** of diversion. The board may then complete an appropriate investigation and ensure their licensed and certified clinicians are practicing safely.*

Learning Culture

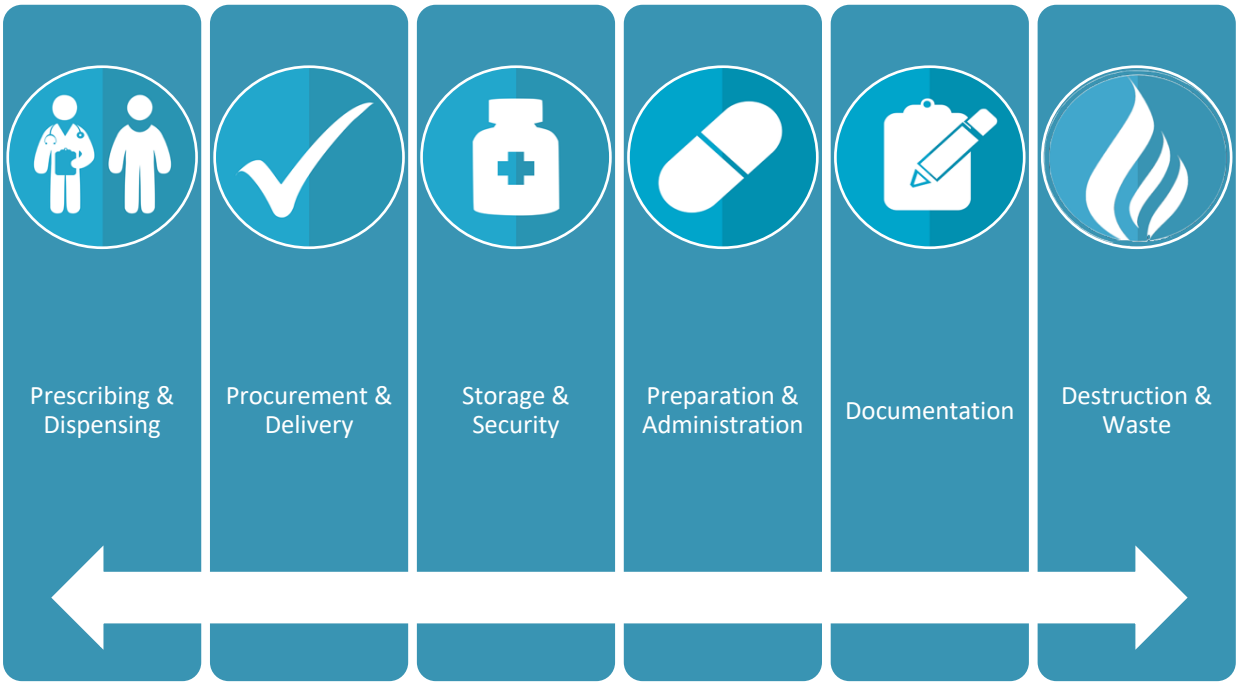
At times, healthcare systems create no-win situations for clinicians or set them up to make errors. While clinicians are responsible for their practice, leaders are responsible for the environment in which they practice. Creating an environment where it is easier to do the "right thing" than the "wrong thing" assists in providing the best care for residents.

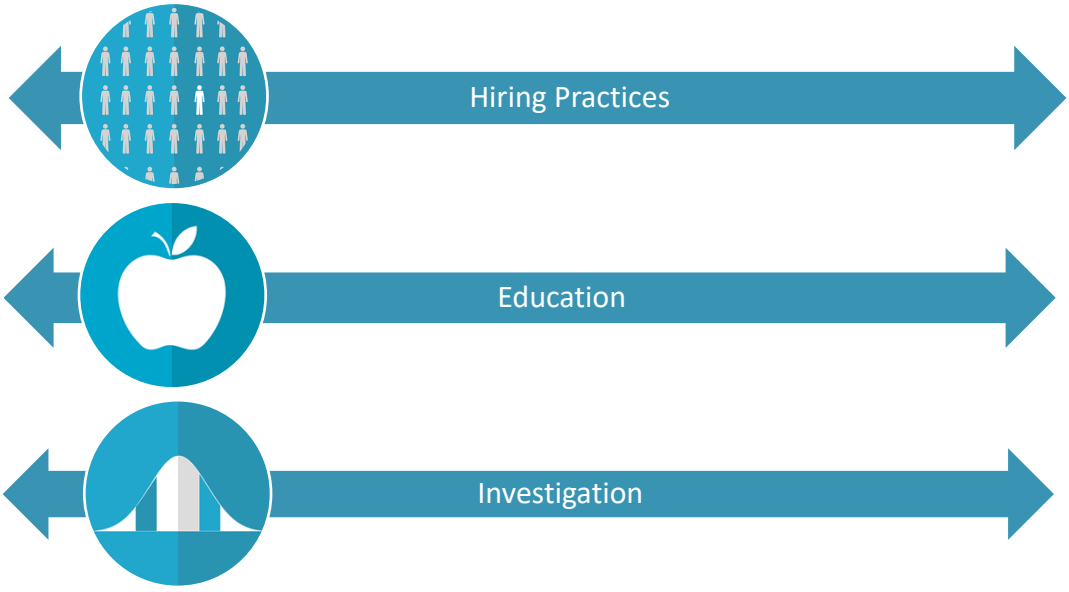
The team encourages leaders in homes across the state to adopt a learning culture and use opportunities to improve policy and process over time. This includes pro-actively interviewing employees to understand areas where employees have identified opportunities for improvement.

*When errors occur, if they are not a result of maliciousness or negligence, the team recommends looking at the **process** and not the **person**. Did the clinician have all of the information and equipment they needed? Are there gaps in education? Were there extenuating circumstances? Is everyone at the facility working in this way? Is there a process change that can be made to improve care across the home? A non-punitive response to error – that results in better process – improves resident safety.*

Pathway Structure

The pathway identifies interventions to improve facility process in each stage of the controlled substance life cycle. In addition, there is guidance into hiring practices, recommended employee education, equipment assistance, and a template for investigation into potential diversion events.





Toolkit

The team has developed resources that correspond that many of the recommendations in the pathway:

1. Education: This module includes curriculum outlines, slide decks, orientation checklist components, competency content, and check-off templates.
2. Templates: This module includes draft letters to care partners to communicate or request changes in process.
3. Guidance: This module includes guidance documents to help implement or complete specific interventions in the toolkit.
4. Equipment: While the team did not recommend specific brands or features, this module should help facilities as they start searching for equipment that helps to prevent diversion.

As with the pathway, the tools are intended to be a starting point for long-term care centers to tailor to their specific situation and context.

Prescribing & Dispensing

Core Recommendations

- ❑ The facility has implemented "quality limits" on prescriptions, including prescription length, quantity, and dosing ranges for controlled substances.
  Rationale: When a prescription continues without review, it is more likely for a CS prescription to be inappropriate for the resident's condition.
- ❑ The facility has a process in place to review and discontinue PRN controlled substances that have not been administered in >30 days (unless there is resident-centered rationale for continuation.)
  Rationale: Decreasing storage of unused CS decreases opportunities for diversion and improves safety.
- ❑ The facility contracts with a pharmacy that is able to provide a description of the controlled substance being dispensed as part of the labeling process (e.g. Oxycontin 10 mg is a small white tablet with letters "OP" on one side and the numeral "10" on other side.)
  Rationale: Clear descriptions of medication increases a nurses' ability to ensure correct medication and decreases opportunity for CS tampering.
- ❑ The facility contracts with a pharmacy that will communicate appearance changes when there is a brand/manufacturing change for controlled substances.
  Rationale: Clinicians are more likely to notice an unexpected change in medication appearance if there is a practice of notification in place.
- ❑ The facility has a policy whereby only the provider who has ordered a medication can sign the physical prescription.
  Rationale: When a facility culture exists where providers "cover" for one another by signing orders, there is more opportunity for error or diversion.

Advanced Recommendations

- ❑ The facility institutes a "2-nurse sign-off" process for all urgent/emergent medication orders.
  Rationale: When nursing resources are available for this intervention, the process improves controlled substance security for emergency medications.
- ❑ The facility institutes a review process for all emergency medication orders.
  Rationale: Emergency medications are a high-risk area for diversion. Reviewing all emergency medications decreases opportunity to abuse emergency medication availability.
- ❑ The facility contracts and sets up process with a pharmacy that is able to complete "partial fills" according to Board of Pharmacy and DEA rules when appropriate.
  Rationale: Decreasing storage amounts of CS decreases opportunities for diversion and improves safety.

Toolkit

Draft letter to Medical Directors
Draft letter to Pharmacy

Procurement & Delivery

Core Recommendations

- ❑ The facility has a process where controlled substances are delivered directly to nursing staff. Ensure that medications are never left unattended (i.e. "dropped off") when delivered.
  Rationale: Nurses can secure the shipment immediately, ensuring security of controlled substances.
- ❑ The facility has a process where two staff check-in all medications (one individual must be a nurse or pharmacist and the other individual must receive training on the check-in process.)
  Rationale: Two staff verification protects the individuals who are checking in the medication, decreases error, and decreases opportunities for diversion
- ❑ The facility uses an electronic process or bound log books for tracking of controlled substances in each cart.
  Rationale: Pages can disappear from binders or be subject to tampering. Bound log books or a tracked electronic process improves the security and integrity of controlled substance counts.
- ❑ The facility contracts with a pharmacy that will communicate appearance changes when there is a brand/manufacturing change for controlled substances.
  Rationale: Clinicians are more likely to notice an unexpected change in medication appearance if there is a practice of notification in place.
- ❑ The facility contracts with a pharmacy who is able to provide labeling that facilitates clinicians checking in medication. This may be in the form of a pre-printed adhesive label to place in the log book or providing electronic support such as barcodes to facilitate the home's electronic process.
  Rationale: Decreasing manual entry of medications increases efficiency for "checking in" medications and decreases transcription errors.

Advanced Recommendations

- ❑ The facility works with its affiliate hospitals and local providers to create a process where there are no hard copies of prescriptions sent from hospital to the nursing facility.
  Rationale: Hard copies of prescriptions provide opportunity for diversion in transit.

Toolkit

- Draft letter to delivery service
- Draft letter to pharmacy
- After-hours or Small Facility Controlled Substance Check-in Competency
- Bound Controlled Substance Tracking (Log) Book information sheet

Storage & Security

Core Recommendations

- ❑ Controlled substances are double-locked (including refrigerators.)
  Rationale: Additional layers of security keep controlled substances safe.
- ❑ Counts are completed consistently at every hand-off of care.
  Rationale: Effective counts follow a "chain-of-custody" philosophy, which creates accountability for CS security.
- ❑ Counts include a process to monitor for tampering.
  Rationale: It is difficult to identify when tampering has occurred unless there is a process in place for tampering surveillance.
- ❑ The facility has a process for hand-off security (key, biometrics, or access device).
  Rationale: Secure medication storage is dependent on medications being securely stored, with tight control of access.
- ❑ A process is in place to address discrepancies 24-hours per day.
  Rationale: The longer the amount of time between a CS discrepancy and investigation, the less likely it is for an investigation to result in valuable information.

Advanced Recommendations

- ❑ Controlled substance doses are supplied in unit-dose when available and in the smallest dose possible when unit dose is not available.
  Rationale: Decreasing waste decreases diversion risk for a facility.
- ❑ The facility invests in video surveillance equipment around places where controlled substances are stored and dispensed, following all law and regulation for video monitoring.
  Rationale: Video surveillance can catch controlled substance diversion incidents, protecting innocent staff and serving as a deterrent for diversion.
- ❑ The facility invests in automated dispensing machines with biometrics and "blind counts" for all controlled substance administration.
  Rationale: Automated dispensing machines create "blind counts," which are safer, more efficient, and reliable than manual counting of controlled substances.
- ❑ The facility invests in medication carts with biometrics to unlock access to controlled substances.
  Rationale: Biometric access decreases keeps track of all people accessing the medication cart.
- ❑ When a facility operates on 12-hour shifts, the facility takes additional care when the same two nurses are scheduled back-to-back for several days.
  Rationale: Nurses can have decreased attention to counts when passing off care to a consistent colleague. If there is an unnoticed problem, this increases the time between discrepancy and discovery.

Toolkit

- Controlled Substance Count Demonstration competency – Content and Check-off
- Medication Cart Security information sheet
- Automated dispensing machine information sheet

Preparation & Administration

Core Recommendations

- ❑ Nurses are educated on the proper way to prepare, administer, and document controlled substances and the rationale behind the process that ensures safety.
  Rationale: Nursing culture is one of the most important elements in CS safety. Nurses need to understand the "why" of their process to be able to deploy it successful.
- ❑ Leadership interviews nurses/clinicians to identify facility-specific areas of vulnerability.
  Rationale: Clinicians have the best perspective to identify risks within the facility. Pro-active interviews can identify vulnerability prior to an occurrence.
- ❑ The facility completes core quality reviews of controlled substance administration on a schedule, looking for outliers.
  Rationale: When nurses administer more CS medications than their peers it is worth closer, pro-active scrutiny for diversion. Nurses who are the only clinician dispensing CS medication to a single resident also warrant additional oversight.

Advanced Recommendations

- ❑ The facility creates a system to track, compare, and analyze CS administration patterns of nurses on a quarterly schedule.
  Rationale: Statistical reports/data can give facilities high-quality information about administration patterns and potential diversion.
- ❑ The facility invests in medication carts with proximity card readers that lock when a nurse walks away from them.
  Rationale: Proximity card locking mechanisms keep carts secure during medication pass when a nurse must hurry to care for residents.

Toolkit

- Controlled Substances orientation checklist
- Controlled Substance Administration, Documentation, and Waste competency – content and check-off
- Pro-active Staff Safety Interview guidance document
- Controlled Substance Administration Review guidance document
- Medication Cart Security information sheet

Documentation

Core Recommendations

- ❑ The facility has clear and efficient (non-duplicative) standards for documentation of controlled substances.
  Rationale: When process is unclear or multiple standards exists, it creates both risk for nurses and opportunity for an individual seeking to divert.
- ❑ The facility has clearly-communicated professional standards for nursing & documentation.
  Rationale: State rules create standards that must be followed as a part of nursing practice.
- ❑ The facility has a process whereby documentation discrepancies are reported and addressed when they are discovered.
  Rationale: Documentation discrepancies sometimes do not trigger an investigation when medication is not overtly missing/counts are not off. Investigation of documentation errors helps identify diversion and helps improve facility process.

Advanced Recommendations

- ❑ The facility uses reports generated from their Electronic Health Record to assist in finding patterns and aberration in controlled substance administration.
  Rationale: Full utilization of EHR functions decreases manual work and provides data to make better decisions.

Toolkit

- Controlled Substance Administration, Documentation, and Waste competency – content and check-off
- Controlled Substance Discrepancy/Diversion Investigation guidance document

Waste & Destruction

Core Recommendations

- ❑ The facility has clear elements defined for when a dose of medication must be destroyed (wasted) and a clearly defined process and timeline for destruction.
  Rationale: Clear process eliminates opportunity for CS intended for destruction to disappear or be forgotten. This includes doses/medication not administered, discontinued prescriptions, and expired medications.
- ❑ The facility has secure storage for CS that cannot be destroyed immediately
  Rationale: Secure storage eliminates opportunity for CS intended for destruction to disappear.
- ❑ The facility has made an effort to change "waste" vocabulary to clearly delineate why a medication is being destroyed ("Destruction of a partially used dose" or "Destruction of dispensed dose that was unable to be administered)
  Rationale: When there is an effort to eliminate "waste" in the rest of healthcare, clinicians rationalize unsafe process that creates risk (e.g. Keeping the other half of a C.S. dose in a pocket to be administered later in a shift instead of wasting it at the time.) Clinicians can rationalize that they are not causing harm by diverting C.S. that would be "wasted" anyway.
- ❑ The facility has a clear process indicating the elements required to sign for "waste"
  Rationale: Clinicians can feel pressure to sign for waste they have not witnessed when there is not a clear standard. When clinicians understand the professional standard, there is less willingness to trespass.
- ❑ The facility has a clear process for clinicians to follow when elements required to sign for "waste" have not been met.
  Rationale: A facility increases C.S. safety when there is acknowledgement that something may happen that is outside of the standard process, and clinicians understand the expectations for managing this situation.

Advanced Recommendations

- ❑ The facility invests in a medication disposal system that immediately destroys unused doses and meets EPA requirements
  Rationale: When medications needing to be destroyed are not stockpiled, it improves security and decreases opportunity for diversion.
- ❑ The facility creates a process where unique individuals are involved in the CS destruction process (e.g. Two individuals in a facility are not the only individuals involved in CS destruction.)
  Rationale: Additional individuals remove opportunity for collusion in the waste process.

Toolkit

- Controlled Substance Administration, Documentation, and Waste competency – content and check-off

Hiring Practices

Core Recommendations

- ❑ Accurate medication management, including controlled substances and according to professional standards, is listed as an essential function of the job in job descriptions.
  Rationale: Strong clinician job descriptions set expectations for prospective and current employees -- and gives a facility the ability to manage poor practice and medication mismanagement if there is an issue.
- ❑ The facility pro-actively sets expectations for professional behavior around medication management during the hiring process. (e.g. application, interview, and contingent offer.)
  Rationale: Setting expectations from the beginning of employment can deter clinicians seeking an opportunity to divert from accepting a job in a facility with higher accountability and monitoring.
- ❑ Employee job offers are contingent on successful reference checks from previous employers, following all Minnesota laws.
  Rationale: Reference checks allow potential employers to understand the employment history of potential employees – and know ahead of time if there are red flags around medication management.

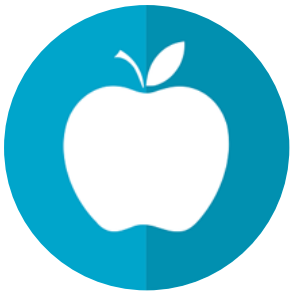
Advanced Recommendations

- ❑ The facility creates a policy and is able to complete "for cause" drug testing according to Minnesota's standards when there is an incident that would warrant concern for resident safety.
  Rationale: For-cause drug testing can serve as a deterrent for diversion and can provide evidence/insight if an employee is diverting for personal use.
- ❑ Employee job offers are contingent on a third-party background check with W-2 verification.
  Rationale: Third party W-2 verification can keep an employee from hiding jobs on their resume where they were fired for medication mismanagement or allowed to resign in lieu of being fired.

Toolkit

- Hiring Practices – Controlled Substance Guidance Document

Education



Core Recommendations

- ❑ All employees participate in education regarding drug diversion, including the definition of diversion, how diversion harms residents, facility-specific vulnerabilities (identified during the facility assessment), universal responsibility, how to report suspected diversion, the investigation process, and what to do if a person needs help with controlled substance addiction.
  Rationale: Employee awareness decreases the opportunities for unnoticed/unobserved diversion.
- ❑ Clinicians who administer controlled substances demonstrate competency in all aspects of the drug life cycle.
  Rationale: Ensuring clinicians understand all requirements for medication administration, documentation, and waste decreases errors of inattention.
- ❑ Clinicians who administer controlled substances demonstrate competency in counting procedures and documentation (including observation for tampering).
  Rationale: Ensuring clinicians understand all requirements for counting, including observation for tampering, ensures integrity of the controlled substance chain-of-custody over time.

Toolkit

- All-Staff Education Content
- Controlled Substance Administration, Documentation, and Waste competency – content and check-off
- Controlled Substance Count Demonstration competency – Content and Check-off
- Hiring Practices – Controlled Substance Guidance Document

Investigation

Core Recommendations

- ❑ The facility trains leaders so that a trained investigator is available 24-hours per day.
  Rationale: Employees need to know who to contact if they encounter a discrepancy 24-hours per day.
- ❑ If there is a suspected diversion event or if there are controlled substances that are unaccounted for, an investigation is launched immediately.
  Rationale: Delays in investigation – even a few hours – can allow an employee who is diverting to "cover their tracks."
- ❑ The facility completes a Root Cause Analysis of all medication investigations even if they were able to find the medication/resolve the discrepancy.
  Rationale: RCA helps to understand vulnerabilities and mitigate this risk effectively.

Toolkit

- Controlled Substance Discrepancy/Diversion Investigation guidance document
- Controlled Substance Discrepancy/Diversion Investigation template
- Minnesota Department of Health online Root Cause Analysis toolkit

Toolkit Index

Draft Letters

1. Draft letter to Delivery Services
2. Draft letter to Long-term Care Medical Directors
3. Draft letter to Long-term Care Pharmacists

Leadership Guidance/Education

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2. Hiring Practices Guidance Document
3. Internal Investigation Process
4. Investigation Template
5. Pro-Active Staff Safety Interview

Education Documents

1. All-staff education document
2. Clinician Education
    a. Orientation Checklist
    b. Controlled substance count competency documents
    c. Controlled substance administration and waste competency documents
3. After-hours or Small Facility Controlled Substance Check-in competency document

Equipment Guidance

1. Automated Dispensing Machines information sheet
2. Bound log books
3. Medication Cart information sheet
4. Medication Disposal sheet