Minnesota Hospital Association

Road Map to Controlled Substance Diversion Prevention 2.0

Patient Safety | Controlled Substance Diversion Prevention

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

SAFE Component	Assessment Questions	Yes	No
Safety Teams/ Organizational Structure	1a. The organization has an interdisciplinary team involved in developing and overseeing the CS DiversionPrevention 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: • 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.	☐	☐
Access to information/ Accurate Reporting/ Monitoring/ Surveillance/ Detection System	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.	☐	☐
Facility Expectations	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: • 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.	☐	☐

SAFE Component	Assessment Questions	Yes	No
	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].	☐	☐
Educate Staff (and Patients)	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 andawareness of CS diversion.	☐	☐
	1g. The organization provides patient education on safe medication handling, including potential for diversion.	☐	☐

STORAGE AND SECURITY

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
The organization has a process in place for securing CS which includes:			
1a. CS are not to be left unattended at any time.	☐	☐	
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.)	☐	☐	
1c. ADM managed CS are stored in a location with single pocket access. n/a: ☐	☐	☐	
1d. Access to CS storage areas is limited to authorized staff.	☐	☐	
1e. Non-ADM CS cabinets are secured with an electronic lock, cipher lock or key.	☐	☐	
1f. Removing ADM and non-ADM access for terminated employees.	☐	☐	
1g. Patient specific CS infusions (PCAs, epidurals, and continuous infusions) are enclosed in a locked box utilizing no-port tubing.	☐	☐	
1h. Controlling and accounting for keys.	☐	☐	
1i. Prescription pads/paper are stored in ADM, locked location, or under control of LIP.	☐	☐	
1j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area.	☐	☐	
1k. Electronic and non-electronic prescriptions comply with state and federal requirements	☐	☐	
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.	☐	☐	
2a. Camera surveillance is used in primary CS Pharmacy storage area (e.g narc vault).	☐	☐	
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.	☐	☐	

PROCUREMENT

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
The organization has a process in place for procuring CS which includes: 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. *(DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user.)*	☐	☐	
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. *(Perpetual inventory is a Minnesota Board of Pharmacy requirement to monthly maintain and reconcile Schedule II controlled drugs.)*	☐	☐	
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

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
The organization has a process in place for ordering/ prescribing CS which includes: 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.	☐	☐	

PREPARATION & DISPENSING

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
The organization has a process in place for dispensing CS which includes: 1a. CS are dispensed in single-unit-dose packaging. *(Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.)*	☐	☐	
1b. Tamper-evident packaging is utilized for CS prepared by pharmacy. *(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.)*	☐	☐	
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.　n/a: ☐	☐	☐	
1e. AD Ms are utilized in patient care areas for the distribution of　n/a: ☐ 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.　n/a: ☐	☐	☐	
1g. A blind count process is used for narcotic vault and ADM distributed CS. *(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.)*	☐	☐	

		n/a:	Yes	No	
1h.	The number of CS on override status in profile ADMs is minimized (e.g. one time injectables for emergency situations only).	n/a: ☐	☐	☐	
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.	n/a: ☐	☐	☐	
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.	n/a: ☐			

ADMINISTRATION OF CS

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
The organization has a process in place for administering CS which includes:			
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.	☐	☐	

HANDLING CS WASTE

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
Pharmacy:			
1a. CS waste from Compounded Sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed.	☐	☐	
Areas outside Pharmacy:			
1b. All Potentially Reusable Product (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. *(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.)*	☐	☐	
1c. Unusable product (UP) CS are to be immediately wasted and witnessed by healthcare professionals per specific hospital procedures. *(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.)*	☐	☐	
1d. The organization has identified the high risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs.	☐	☐	
1e. Organization has identified specific high risk CS medications (e.g., fentanyl) that are randomly assayed.	☐	☐	
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.	☐	☐	
Wasting of UP CS:			
2a. Approved methods for wasting a CS are defined per federal, state and county laws and regulations.	☐	☐	
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.	☐	☐	
2c. An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.	☐	☐	
2d. Empty containers of CS (e.g., vials) are discarded in limited access waste containers.	☐	☐	
2e. The hospital takes measures to secure waste containers with trace UP CS to prevent tampering.	☐	☐	

		Yes	No	
PRP Returns:				
2f.	PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket.　　n/a: ☐	☐	☐	
2g.	All PRP CS returns to pharmacy require co-signature in the patient care area and in pharmacy	☐	☐	
Waste or Reverse Distribution:				
2h.	DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company.	☐	☐	

Monitoring of CS and process if diversion is suspected

Audit Questions	Yes	No	If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
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.	☐	☐	
The organization has a defined process in place to monitor CS on a regular basis which includes: 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　　n/a: ☐ 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　　n/a: ☐ 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)	☐	☐	