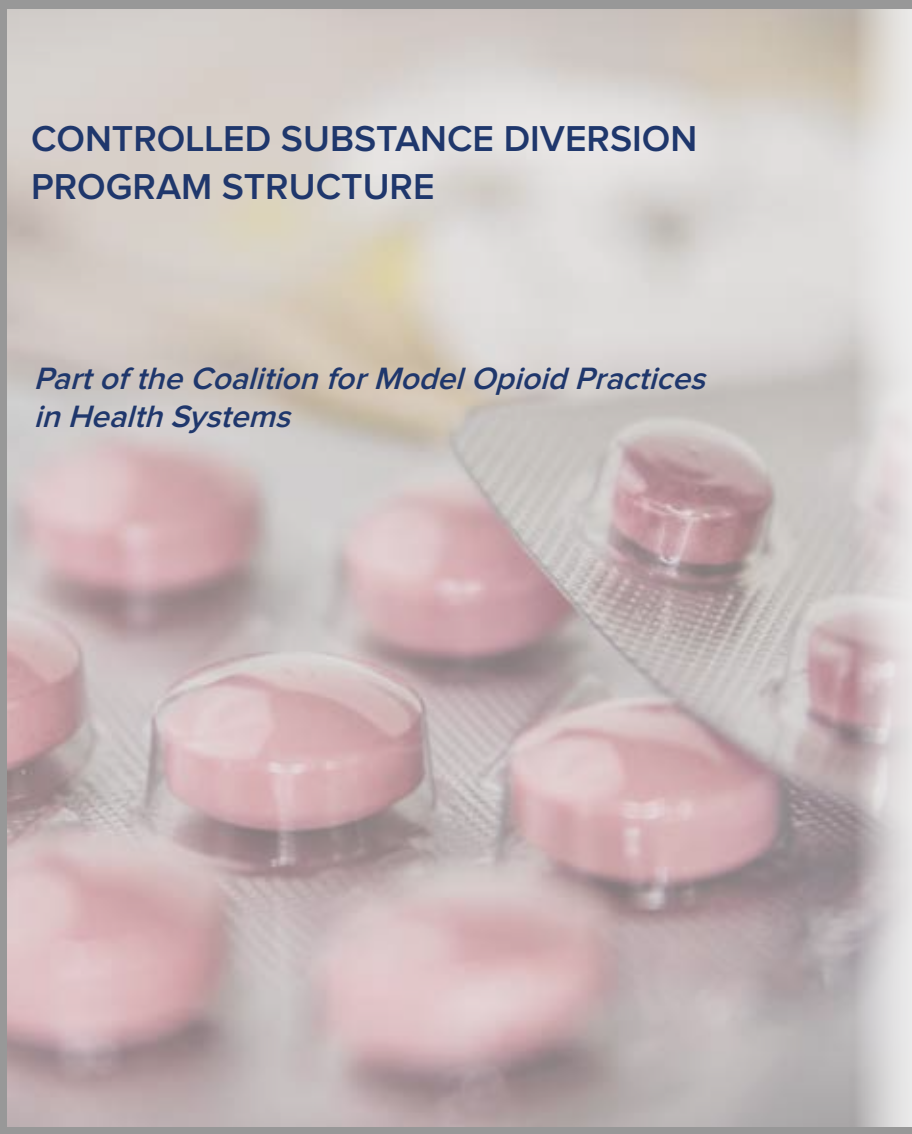
CONTROLLED SUBSTANCE DIVERSION PROGRAM STRUCTURE

Part of the Coalition for Model Opioid Practices in Health Systems



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How can diversion happen in the hospital or health-system?[1]

Procurement	• Purchase order and packing slip removed from records; • Unauthorized individual orders for controlled substance on stolen DEA Form 222; • Product container is compromised.
Preparing and Dispensing	• Controlled substances are replaced by products of similar appearance when prepacking; • Removing volume from premixed infusions; • Multidose vial overfill diverted • Prepared syringe contents are replaced with saline.
Prescribing	• Prescription pads are diverted and forged to obtain controlled substances; • Provider self-prescribes a controlled substance; • Verbal orders for controlled substance created by not verified by prescriber; • Written prescriptions altered by patients.
Administration	• Controlled substances are withdrawn from an automated dispensing cabinet (ADC) after patient is transferred or discharged; • Medication documented as given but not administered to the patient; • Waste is not adequately witnessed and subsequently diverted; • Substitute drug is removed and administered while the controlled substance is diverted.
Waste and Removal	• Controlled substance waste is removed from an unsecure waste container; • Controlled substance waste in syringe is replaced by saline; • Expired controlled substances are diverted from holding areas.

How to monitor for diversion in a hospital or health-system?

Diversion During Patient Care	• Inconsistent or incorrect charting • Displays inconsistent work quality with times of high and low efficiency • Offers to medicate other nurses' patients on a regular basis • Obtains larger dose of narcotics when the ordered dose is unavailable, then documents the remaining amount as wasted • Requests to care for specific patients • Illustrates specific narcotic use with patients under his/her care • Patients reveal consistent pain scale patters or complain that narcotics are not having the desired effect (especially when administered PRN) only on this particular nurse's shift

Behavioral indicators	• Isolates self from others, eats meals alone, avoids staff social events • Frequent, unexplained disappearances during shift; taking frequent and/or long trips to the bathroom • Work absenteeism – absences without notification and an excessive number of sick days • Often shows up on off days to finish work, retrieve forgotten items, or say 'hi' to coworkers • Frequently volunteers to work extra shifts • Frequently spills or wastes narcotics; excessive or unexplained breakage of narcotics vials • Chaotic/stressful home and/or personal life • Refuses to comply with narcotic diversional investigational procedures • Excessive amounts of time spent near a drug supply • Unreliability in keeping appointments and meeting deadlines • Work performance may alternate between periods of high and low productivity; suffers from mistakes due to inattention, poor judgment, and bad decisions • Interpersonal relations with colleagues, staff, and patients suffer. Rarely admits errors of accepts blame for errors or oversights. • Sloppy recordkeeping • Progressive deterioration in personal appearance and hygiene • Uncharacteristic deterioration of handwriting and charting • Wearing long sleeves when inappropriate • Personality change – mood swings, anxiety, depression, lack of impulse control, suicidal thoughts or gestures • Patient and staff complaints about healthcare provider's changing attitude/ behavior • Doctor prescribing controlled substances for a patient that is not his/hers or that has been discharged. • Always administering the maximum amount of pain meds • Always using the shortest length of time to administer pain meds • Asking colleagues to write prescriptions for self • Unusual interest in pain medications • Requests to work evenings, nights or weekends (when supervision is limited)
Signs and Symptoms of Drug Addiction	• Poor memory or concentration • Shakiness • Hand tremors • Unsteady gait • Disheveled • Slurred speech • Constricted pupils • Diaphoresis • Change in weight • Change in appearance

How Are Hospitals and Health Systems Doing???

COMPLIANCE WITH SELECTED PRACTICE RECOMMENDATIONS FOR DIVERSION DETECTION AND PREVENTION.[2]

Practice Recommendation (Department)	**Respondents FOLLOWING Recommendation (%)**	
	1-399 Beds	**≥400 Beds**
If CSOS not used, log of DEA Form 222 kept ensuring all forms are accounted for. (Pharmacy)	79	90
Individual responsible for ordering controlled substances in not responsible for receiving the order. (Pharmacy)	73	87
Cameras directed at controlled substance storage areas. (Pharmacy)	55	73
Personal belongings banned from drug storage areas. (Pharmacy)	24	37
Controlled substances dispensed for an OR case always reconciled by pharmacy against products documented as administered or returned to the pharmacy for wasting. (Surgical Services)	44	63
Controlled substances not used in an OR case returned to pharmacy for wasting. (Surgical Services)	20	57
ADC discrepancy resolution explanations “always” or “sometimes” investigated for validity (Nursing Units)	98	92
Use of “blind” count when accessing a controlled substance pocket in the ADC. (Nursing Units)	91	88
ADC discrepancies analyzed to identify individuals most frequently involved in discrepancies. (Nursing Units)	67	72
ADC stock outages investigated for potential diversion. (Nursing Units)	61	57
Biometric fingerprint scan used for ADC access. (Nursing Units)	58	66
Locking cases used to secure non-PCA controlled substance infusion containers while being administered. (Nursing Units)	34	36
Alert sent to pharmacy leaders when a specified ADC per-transaction threshold exceeded. (Nursing Units)	26	35

Key points for Pharmacy Directors[3]

1. Be proactive. Expect diversion. The US Substance Abuse and Mental Health Services Administration estimates that 1 in every 10 health professionals struggle with addiction or drug abuse. (http://www.ismp.org/newsletters/nursing/issues/NurseAdviseERR201604.pdf)[4]
2. Engage hospital leadership early. Make senior leadership aware of cases like:
    a. Mass General Hospital (https://www.justice.gov/usao-ma/pr/mgh-pay-23-million-resolve-drug-diversion-allegations)
    b. Emory University Hospital Midtown (http://www.georgiahealthnews.com/2016/03/years-large-scale-drug-thefts-reported-emory-hospital/)
    c. Intermountain Healthcare (https://www.beckershospitalreview.com/legal-regulatory-issues/intermountain-healthcare-settles-drug-diversion-case-for-1m.html)
3. Drug diversion is not just a pharmacy problem. All disciples must be involved in diversion prevention including but not limited to:
    a. C-suite leaders
    b. Human Resources
    c. Compliance
    d. Pharmacy
    e. Nursing
    f. Medical staff
    g. Special/Hospital Police and security
4. Train and educate staff, providers, and leaders about the scope of controlled substance diversion in healthcare. (See the Diversion Awareness Education for Staff document that is part of this toolkit.)
5. Conduct a gap analysis to identify strengths and weaknesses in your current diversion program.
6. Make controlled substance compliance a priority within the pharmacy, dedicating staff or staff time to diversion prevention and detection activities.

Below you will find two checklists for your use in evaluating your organization's compliance with regulatory standards and best practices for controlled substance diversion prevention. The first checklist is a simple "yes or no" questionnaire. These are items that are either fully implemented or not implemented. The corresponding regulation is listed in the first column for your reference.

In the second questionnaire you will respond with the level of implementation for each item, as these may be in process but not yet fully implemented. Using these two questionnaires will provide you with a greater understanding of the gaps that exist in your organization around optimal controlled substance diversion prevention.

CONTROLLED SUBSTANCES AUDIT CHECKLIST

DATE:_____ **AUDITOR:**_____

SITE NAME: _____

Review the following questions and respond with a YES or NO based on your current compliance with the regulatory standard for controlled substance management

APPLICABLE SECTIONS (21 CFR 1300)	OBSERVATION	YES	NO
Registration (Part 1301)	• Does the site possess a current DEA registration?	❑	❑
	• Is the current DEA registration displayed on site?	❑	❑
	• Is there a current State registration displayed on site?	❑	❑
Employee Screening (Part 1301.90 – 1301.93	• Does the drug screening process adequately test for all potentially diverted controlled substances?	❑	❑
	• Are any investigational controlled substances properly labelled?	❑	❑
Labelling & Packaging (Part 1302)			

APPLICABLE SECTIONS (21 CFR 1300)	OBSERVATIONS	YES	NO
Records & Reports (Part 1304)	• Does the audit site have records for the last two years on site or readily retrievable?	❑	❑
	• Does the inventory reflect all controlled substances "on hand" and delineated by controlled substance? Please document if the inventory reflects being taken on the opening of the business day or the closing of the business day.	❑	❑
	• With regard to changes in the re-scheduling of a controlled substance, are there any compounds handled at the audit site that were re-scheduled and are either not included in an initial inventory at the time of being re-scheduled or are not part of the biennial inventory? If so, specify compounds and nature of schedule change and date.	❑	❑
Order Forms (Part 1305)	• Are unexecuted DEA 222 forms secured in a locked or restricted access area? .	❑	❑
	• Are there any log book entries (for receipt or distribution) for C_{II} compound that do not have an accompanying DEA 222 form?	❑	❑
	• Are any of the DEA 222 forms signed by someone other than an authorized POA? Ensure the POA signing the DEA 222 forms is authorized by the current DEA Registrant. Also check if any revoked POA signed a DEA 222 form past the date of revocation.	❑	❑
	• Are the DEA 222 forms executed appropriately?	❑	❑
Destruction and/ or Disposal (Part 1307)	• Review destruction records (DEA 41 forms) for the last two years	❑	❑
	• If on-site destruction is performed, confirm that DEA authorization is in place (e.g., letter in the files).	❑	❑
	• If off-site destruction (e.g., transport to incinerator) is performed, have the DEA stipulations been met? For example, if DEA requires one (1) month prior notice, is the letter notifying DEA of the proposed destruction date in accordance with those conditions? If conditions are not met, specify in comments section.	❑	❑

APPLICABLE SECTIONS (21 CFR 1300)	OBSERVATIONS	YES	NO
Training	• Are current training records for the employees handling CS materials readily available?	❑	❑
	• Does training occur for: (1) all new employees at the beginning of employment, (2) only for new employees who are likely to handle CS materials, (3) annually for all employees, (4) annually only for employees likely to handle CS materials, or (5) on a supervisor-specified basis. Indicate any and all situations by numbers in the comments section.	❑	❑
Loss/ Diversion Reports	• Are there any documented situations of unaccounted losses or potential diversion of product that were not reported to the DEA?	❑	❑

SCORING KEY

A	There has been **no activity** to implement this item.
B	This item has been **formally discussed and considered, but it has not been implemented**.
C	This item has been **partially implemented in some or all areas** of the organization.
D	This item is **fully implemented in some areas** of the organization.
E	This item is **fully implemented throughout** the organization.
N/A	Not Applicable

For each of the following items use the scoring key above to assess compliance with each of the recommendations. This audit tool will help your organization identify any gaps in your current controlled substance management processes. We encourage you to use the information gained from this exercise to evaluate improvements to strengthen your current processes.

		A	B	C	D	E	N/A
Ensure that hiring procedures include adequate background checks.	A criminal background check is completed for all new hires.						
	Licenses are verified with appropriate licensing boards for all new licensed staff members.						
	CMS LEIE database is checked for all new hires.						
Evaluate employee access to CS and eliminate access as necessary.	Regular assessment of all practitioners with access to controlled substances to ensure databases only include individuals permitted to have access.						
	A defined process is in place for the ongoing, timely management of employee access to CS when employee is terminated or transferred.						
	Access for terminated/transferred employees should be discontinued within a week of the employees' departure.						

Determine whether vulnerabilities exist for Internal diversion.	Designate a storage area for personal belongings in the pharmacy.						
	Require boxes be broken down inside the pharmacy.						
	Dispose of all regular pharmacy trash in clear bags and store all waste securely.						
	Promptly return drug inventory to the shelf or store in a secure area while awaiting return to stock at the time of claim reversal from the pharmacy billing system.						
	Account for outdated drugs removed from the pharmacy shelf by inventory of outdates at the time the drug is pulled from the shelf.						
	Store outdated controlled substances in a secure location within the pharmacy.						
	Use a tamper-evident or resistant receptacle for drugs awaiting transport.						
	Access to CS storage areas is minimized and limited to authorized staff.						
	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.						
	Only authorized pharmacy staff can purchase CS.						
	Separation of duties exist between the ordering and receipt of CS.						
	Two individuals count and check-in CS received and confirm that order, invoice, and product-received documentation match.						
	Electronic CS Ordering System (CSOS) is utilized (eliminates paper DEA 222 forms).						
	Diversion controls are in place when controlled substances are re-packaged by pharmacy personnel.						
	A process to track and reconcile controlled substance inventory when multidose/bulk containers of controlled substances are used to prepare IV products.						

Minimize opportunities for diversion involving automated dispensing machines (ADM).	ADM technology is utilized in patient care areas for the distribution and accountability of CS.						
	ADM managed CS are stored in a location with single pocket access.						
	Bar code scanning is utilized when replenishing ADM Medstations.						
	A “blind count” process is used for all ADM managed CS.						
	The number of CS on ADM override status is minimized.						
	CS delivery to non-ADM areas requires co-signature for delivery and return.						
	CS are only administered by licensed independent practitioners or other licensed or registered health care providers within their scope of practice.						
	CS are retrieved from storage areas as close to the time of administration as possible.						
	Are controlled medications secured in all storage locations?						

	The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.						
	CS for one patient at a time are obtained from the ADM / locked storage area.						
	The individual retrieving the CS from ADM / locked storage area is also the person that administers the medication.						
	The wasting of all CS requires an independent witness and documentation, except in situations where waste is being returned to Pharmacy for assay and wasting.						
	An individual witnessing CS wasting verifies that the volume / amount being wasted matches the documentation and physically watches the medication being wasted per policy.						
	All instances of waste are rendered non-retrievable.						
	Patient-specific CS infusions are contained in a locked box utilizing no-port tubing unless under constant surveillance.						
	Unused ADM managed CS are returned to a return bin and not to the original ADM pocket.						
	All CS returns to the pharmacy require co-signature in the patient care area and in the pharmacy.						
	All CS administered are documented in the medical record.						
	ADM managed CS counts are verified each time a CS drawer is accessed.						
	ADM managed CS are manually inventoried by two authorized healthcare providers if a blind count has not been performed within ten days.						
	Non-ADM managed CS are manually inventoried by two authorized healthcare providers every shift.						
	ADM CS discrepancies created by a blind count are resolved by two authorized healthcare providers within the shift / business day in which these are discovered.						
	A process is in place for investigating discrepancies that are not satisfactorily resolved.						
	Lock-out times for ADMs and duration for temporary access are assessed for which each practitioner is granted access.						

Maintain accurate controlled substance inventory.	Maintain perpetual inventory for all Controlled Substances Act (CSA) Schedule II controlled substances.						
	Perform random inventory counts on CSA Schedule III through V controlled substances.						
	Document and witness all controlled substance inventory counts.						
Examine documentation of a physical inventory that has taken place within the last 2 years. Verify the following inventory components:	Date of the inventory						
	Indication of whether the inventory was taken at the beginning or close of business.						
	Name of each controlled substance inventoried						
	Finished form of each of the substances inventoried (for example: 10 milligram tablet)						
	Number of dose units of each finished form in the commercial container (for example: three 100 tablet bottles)						
	Exact count for CSA Schedule II drugs						
	Estimated count for CSA Schedule III, IV, and V drugs unless the container holds more than 1,000 dosage units						
	Exact count for Schedule III, IV, and V drugs if the container holds more than 1,000 dosage units						
	Count on effective date of rule for previously non-controlled drugs that are reclassified as controlled substances						
	Count on effective date of rule for controlled substances that have a change in scheduling						
	Separate CSA Schedule II inventories and records.						
	Separate CSA Schedule III, IV, and V inventories and records (if not, controlled substance information must be readily retrievable from non-controlled substance pharmacy records).						

Ensure that Pharmacy Managers know what to do when a controlled substance loss takes place.	Access an electronic version of the DEA Form 106, Report of Theft or Loss of Controlled Substances on the DEA's Office of Diversion Control website.						
	Complete and submit the DEA Form 106 within 1 business day after discovery of the theft or loss.						
	Keep a copy of the submitted report for 2 years.						
	Ensure that all staff members know who to report to when a controlled substance loss has taken place.						
Ensure that all persons in leadership positions know what to do when diversion is suspected.	Ensure that there is a policy, procedure, or protocol in place for reporting of diversion to necessary personnel.						
	A 24-hour x 7 days-per-week medication diversion pager or phone number is available to report (anonymously if desired) suspected medication diversion.						
A multi-disciplinary committee for controlled substance oversight is in place.	A multidisciplinary "Medication Diversion Prevention Committee," or equivalent, exists to provide leadership and direction for all medication diversion activities.						
	This committee meets regularly to evaluate institutional policies, procedures, and issues of non-adherence, and diversion surveillance						
Ensure that a person on several persons regularly survey employee activity involving CS.	CS diversion incidents are collated, reviewed, and analyzed to identify further opportunities for improvement in existing systems						
	Currently uses electronic or manual diversion surveillance tool on a routine basis.						
	All paper CS "Disposition and Inventory" sheets are reviewed and audited.						
	ADM CS surveillance reports are regularly created and assessed.						

	Ordering vs Dispensing vs Administration documentation is audited (electronic preferred).						
	Patient assessment and medication administration documentation is audited on a regular basis.						
	Camera coverage of all automated dispensing machines is present.						
	Camera surveillance is present in primary CS pharmacy storage area (e.g CS vault).						
	CS waste is randomly tested for content. Random spectrophotometry of controlled substance waste is performed.						
The Pharmacy Manager's duties include:	Ensure a complete controlled substance inventory is completed biennially.						
	Complete a controlled substance inventory within 10 days of change in pharmacy manager.						
Address vulnerabilities for external diversion by patients.	Submit all State Prescription Drug Monitoring Program (PDMP) required reporting elements.						
	Report to the State PDMP by the end of the next business day after a controlled substance is dispensed						
	Perform periodic quality assurance to ensure data submission is accurate and complete.						
	Do not ignore insurance rejects and process Medicaid reimbursable prescriptions for cash or bypass insurance altogether.						
	Do not process early refill overrides for prescription drugs for any patient.						

Determine whether vulnerabilities exist regarding physical security of the pharmacy.	Restrict pharmacy access to authorized pharmacy personnel by key or key code.						
	If feasible, assign a unique security alarm code for each pharmacist authorized to have access to the pharmacy.						
	Periodically examine security logs to ensure personnel access the pharmacy only at appropriate times.						
	Create only pharmacy keys that clearly state, “Do not duplicate”.						
	Place any spare pharmacy key inside a container in a locked safe outside of the pharmacy and affix a tamper-evident seal to the key container.						
	Use a key log to document each time the spare key is accessed. Include the name and signature of the pharmacist, the date, and the name and signature of a witness.						
	Re-key the pharmacy in the event of a security breach.						
Consider current procedures to communicate with other professionals—prescribers, other pharmacies, law enforcement, and State licensing boards.	Document and disseminate information received from prescribers, between pharmacies in and around your local area, by State and local law enforcement, and by State licensing boards.						
	Store external communications received in a manner that pharmacy personnel can readily review the communications.						
Organizational policies exist that address all aspects of CS medication use processes.	Policies are regularly reviewed and are compliant with federal and state regulations.						
	Policies and procedures are established to address controlled substances brought into the hospital by a patient.						
	A policy and standard operating procedures governing controlled substance handling, including waste and diversion reporting, is current and up to date.						
	Procedures are in place to ensure security of controlled substances and safety of personnel transporting to off-site locations.						
	Guidelines are in place for the handling of suspected impaired employees and drug testing.						
	Organizational policies are adhered to by all staff.						

Some fundamental components of a Controlled Substance Diversion Program

1. Staff Training[1,5] (See the Diversion Awareness Education for Staff document that is part of this toolkit)
    a. Annual and ongoing.
    b. Case studies, computer-based learning modules, forums, newsletters.
    c. Suggested educational links:
        i. American College of Healthcare Executives (http://www.ache.org/)
        ii. American Medical Association (https://www.ama-assn.org/education/continuing-medical-education)
        iii. American Nurses Association (https://learn.ana-nursingknowledge.org/)
        iv. American Society of Anesthesiologists (https://www.asahq.org/)
        v. American Society of Health System Pharmacy (https://www.ashp.org/Professional-Development/Continuing-Education)
2. Surveillance and Monitoring[1,5]
    a. Medication Safety Rounds
        i. Multidisciplinary, educational, and non-punitive;
        ii. Monthly, quarterly;
        iii. Purpose:
            1. To understand unit practice and barriers,
            2. To build relationships between leaders and staff;
        iv. Encourage staff to share observed areas of weakness in medication control process.
    b. Patient Rounding
        i. Multidisciplinary
        ii. Daily
        iii. Purpose:
            1. To establish rapport with patients within the facility;
            2. To inquire about pain, anxiety, or sleeping complaints.
    c. Controlled Substance safety rounds/tracers
        i. Similar to accreditation tracers
        ii. Select a high risk area or a high risk drug and follow it through the system for ordering, receiving, storage, dispensing, administration, and wasting.
    d. User transaction reviews
        i. User selection based on utilization or random
        ii. Activity should be reviewed for all areas and not just areas the user is assigned
        iii. Review activity for the following:
            1. Timely wasting based on organizational policy
            2. Pulling more medication than ordered/administered
            3. Wasting buddies – always wasting with the same one or two other users
            4. Appropriate overrides in the ADCs
                a. Check for appropriateness and linking to subsequent orders
            5. Documentation in the medical record – are there differences between users and/or shifts in regards to pain scores and/or amount of drug administered
                a. MAR/eMAR and ADM/Paper reconciliation
                b. Audit dispenses of controlled substances with documentation in the medical record
                c. Ensure dispense amount equals administration + Waste + Returns

6. Only pulling meds for assigned patients
7. Only wasting for medications the user removed
8. Appropriate time between doses

e. ADC/Floor Restock reconciliation
   i. If automated – complete every shift
   ii. If manual – rotate users for each area
      1. Other options include using duplicate forms
      2. Obtain duplicate signatures for what left the pharmacy and what was restocked on the floor

f. Ensure use of an appropriate urine drug screen
   i. Not all urine drug screens check for fentanyl or other high risk controlled substances
   ii. Gold standard is Gas chromatography–mass spectrometry (GCMS)
   iii. Observed urine drug screens recommended for diversion cases
   iv. Consider random versus for cause drug screening

Pros and Cons of random urine drug screening

Pros	Cons
Identification of employees needing help	Cost
Improved policy compliance	Breach of privacy concerns
Potential decrease in safety events	Employee perceptions/reputations
Deterrent for diversion	False positives

3. Auditing - Develop an Audit Plan[1,5]
   a. Supply chain
      i. Reconcile purchase vs receipt into pharmacy's inventory;
      ii. Regularly review controlled substance storage and pharmacy access lists;
      iii. Audit DEA Form 222 and manifests from reverse distributors against record of products removed from pharmacy's expired inventory;
      iv. Review purchasing data by drug for significant variations from historical buying patterns;
      v. Audit DEA Form 222 and CSOS e222 forms for completeness and accuracy;
      vi. Review wholesaler and compounding pharmacy website access for ordering controlled substances.
   b. Internal pharmacy operations[1,5]
      i. Audit all transactions from the controlled storage vault to any non-automated storage destination (clinics, IV room, pre-packing, satellites);
      ii. Investigate any pharmacy inventory adjustments and associated discrepancy resolutions;
      iii. Reconcile dispensing transactions between vault and ADCs/
      iv. Reconcile compounded controlled substances removed from inventory against patient-specific orders and waste;
      v. Audit expired bin contents against expired removals from ADCs or transfers from vault inventory.

c. Inpatient nursing units[1,5]
    i. Investigate transaction volume outliers;
    ii. Identify dispenses that are not associated with a corresponding administration documentation;
    iii. Random audit of medication transactions involving drugs with high likelihood of waste documentation;
    iv. Assess ADC discrepancy resolutions for validity;
    v. Review transactions for manually admitted patients and on patients with rapid discharge or transfer;
    vi. Review ADC settings with goal of promoting optimal security with efficient use;
    vii. Audit transaction quantities exceeding typically-expected values;
    viii. Look for "waste buddies" or frequent pairing of employees for wasting controlled substances.
d. Procedural areas[1,5]
    i. Audit procedural dispensing record against case administration record or anesthesia flow sheet;
    ii. Reconcile administrations and records of waste;
    iii. Validate the identity of controlled substances to be wasted;
    iv. Benchmark controlled substance utilization across providers by type of case.
e. Retail pharmacy locations[1,5]
    i. Reconcile purchase and inventory receipt;
    ii. Audit any inventory adjustments and associated discrepancy resolutions;
    iii. Reconcile CII log entries against prescriptions dispensed;
    iv. Audit samples of patients in the pharmacy information system or dispensing log against prescription data in the electronic medical record;
    v. Verity controlled substances awaiting pick up for seven days or more were properly returned to inventory;
    vi. Audit cash transactions for controlled substance prescriptions.
f. Emergency Medical Services (EMS)[6]
    i. Audit and inspect frequently including both the controlled substances count and medication packaging for evidence of tampering,
    ii. Proper recordkeeping for controlled substances as specified by state and federal guidelines. Maintain complete documentation of usage and wastage.
    iii. Resupply based only upon documented usage.
    iv. Tightly manage everyone's access to controlled substances. Require a witness during the restocking procedure. No single person should have unrestricted access to restock controlled substances.
    v. Utilize automated dispensing cabinets whenever possible.
g. Long Term Care/Skilled Nursing Facilities[7]
    i. Utilize high-security secure automated systems to safeguard and limit access.
    ii. Relocate medication storage systems to secure areas with surveillance cameras.
    iii. Audit dispensing and wasting records.
    iv. Upon patient death or changes in therapy, hold remaining medications in a secure location until the products can be returned to the pharmacy for destruction or until on-site destruction can occur. Include these "pending destruction" medications in the regularly scheduled controlled substance inventory.

   h. Home Health Care and Hospice[8,9]
      i. Evaluate and track controlled substance refill requests. Limit the supply of controlled substances to amounts less than the standard 14-day supply.
      ii. Assess and document the patient's response to administration of controlled substances.
      iii. Count controlled substances present at each visit for each patient.
      iv. Do not deliver, destroy, or dispose of controlled substances.
4. Automation & Technology[1,5]
   a. Utilize ADCs' proactive diversion reports.
      i. Controlled substance movement within and outside the vault;
      ii. Identification of abnormally high withdrawals of controlled substances (≥2 standard deviations from the mean depending on facility size);
      iii. Report identifying undocumented wastes exceeding specified time;
   b. Investigate usefulness of automation and technology for high priority areas.
      i. Use of automated anesthesia carts in procedural areas;
      ii. Surveillance cameras in high-risk areas like pharmacy, patient care unit medication preparation areas, cashiers' stations in retail settings.
5. Reporting
   See the NC Diversion Reporting Requirements document that is part of this toolkit.

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