Original Article

Preventing Large-Scale Controlled Substance Diversion From Within the Pharmacy

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Abstract

Large-scale diversion of controlled substances (CS) from within a hospital or health system pharmacy is a rare but growing problem. It is the responsibility of pharmacy leadership to scrutinize control processes to expose weaknesses. This article reviews examples of large-scale diversion incidents and diversion techniques and provides practical strategies to stimulate enhanced CS security within the pharmacy staff. Large-scale diversion from within a pharmacy department can be averted by a pharmacist-in-charge who is informed and proactive in taking effective countermeasures.

Key Words—controlled substances, diversion, narcotics, pharmacy management

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The pharmacist-in-charge (PIC) has multiple responsibilities related to preventing controlled substances (CS) diversion.¹ The PIC's responsibility to prevent and detect small-scale diversion by hospital employees has received a lot of attention, and many recommendations have been published in the literature.^{2–8} In our experience, most PICs are familiar with this area of concern and devote considerable time to this responsibility. Compared to small-scale diversions, large-scale theft of CS from a hospital pharmacy is rare, but it is nonetheless extremely important for the PIC to take steps to prevent and detect large-scale diversion.⁹

INSIDE JOB

Large-scale diversion of CS within the hospital is by its nature an inside job. In a typical scenario, one or more pharmacy technicians or pharmacists use their position of trust to divert large amounts of CS from within the pharmacy and then illegally sell it to another party who has connections for illicit distribution. Because PICs often find it hard to imagine that a pharmacy co-worker – a member of the “pharmacy team” inner circle – would commit such a crime and breach of trust, it is hard for them to devote valuable time to take steps to assess their risk. Diversion risks should be assessed and action taken *before* a large-

scale diversion occurs. Early action may prevent this theft from occurring.

TAKE ACTION NOW

The number of large-scale diversions from within pharmacies appears to be rising in recent years. A few of the most notable incidents are listed in **Table 1**. In addition to the significant fines, repercussions from such diversions include:

- Negative publicity for the institution,
- Unplanned personnel changes and staffing challenges in the pharmacy department (including possible leadership changes),
- Danger for the local community in which these CS have been made widely available (see the transcripts from a 2011 Congressional hearing highlighting these dangers and the 2011 White House Plan “Epidemic: Responding to America’s Prescription Drug Abuse Crisis.”^{10,11}), and
- Chaos in the lives of the perpetrators, typically due to law enforcement action but sometimes due to drug trafficking violence.¹²

When small-scale diversion occurs within the pharmacy, the “pill count” can be 1 or 2 orders of

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Table 1. Significant examples of high profile large-scale controlled substances (CS) diversion in hospital, community, and mail-order pharmacy settings

Maryland (2005): 7,900 oxycodone extended-release (ER) tablets were unaccounted for. No arrests were made. The university hospital agreed to a settlement with the US Attorney's office and paid a \$250,000 fine.¹⁹

Indiana (2007): A female pharmacy technician was responsible for diverting more than 623,000 tablets of hydrocodone-acetaminophen tablets from a hospital's clinic pharmacy. Her son (not an employee) was also implicated. The not-for-profit hospital paid \$2 million in fines.²⁰

Texas (2010): Five hospital pharmacy employees were fired after being arrested for diverting more than 370,000 CS dosage forms (primarily hydrocodone-acetaminophen tablets) from the hospital clinic pharmacies. Some of the technicians allegedly chose to train as technicians and hired on with the express intent of large-scale CS diversion with the support of outsiders. Two nonemployees were also arrested. The public hospital paid \$100,000 in fines.²¹

Pennsylvania (2012): Mail-order pharmacy chain paid \$2.75 million in settlement with US Attorney's office for allowing employee diversion of an undisclosed amount of prescription controlled substances into "illicit channels" and for other violations.²²

magnitude higher than what routinely occurs in a patient care area. For example, a nurse diverting CS for personal use might steal 4 doses a day over a 30-day period for a total of 120 doses lost per month. When a pharmacy employee is diverting CS with the intent to sell, quantities in excess of 1,200 doses or even 12,000 doses are possible.

Further examination of the what, why, who, how and where of inside job diversions exposes details that are peculiar to large-scale CS diversions from within pharmacy settings.

WHAT?

The target CS of large-scale diversion are not typically the same CS that are diverted for personal use. CS diverted on a large-scale are intended for outside sale. The target CS today are primarily oral dosage forms of opioids (hydrocodone and oxycodone products), sedatives (especially alprazolam), and stimulants (amphetamine derivatives, phentermine).¹⁰

WHY?

Prescription drug abuse is "the fastest growing drug problem in America."¹⁰ There is an increased illicit market demand for "safer" pharmaceutical grade drugs of abuse in pill form over home-manufactured drugs of abuse (especially injectables). Almost one-third of new drug abusers report that their first experience involved a prescription drug.¹³ These drugs, especially alprazolam, are sometimes used by young people in a very dangerous combination with alcohol.¹⁴ Pharmacies are a natural source for these high-demand drugs. Health care is sometimes viewed as a big business, and some pharmacy employees with modest salaries may feel little guilt in stealing from a corporation as opposed to stealing from a person.¹⁵

WHO?

Individuals involved in large-scale diversion are typically the most trusted pharmacy employees. The employees must hold a position of trust to have the access necessary to divert. They are often long-time employees; it takes time to understand the controls in place and to identify gaps in security.¹⁵ They may be pharmacy technicians; they may be pharmacists. Gender is not a determining factor; perpetrators of large-scale diversions have been men acting alone as well as women acting as agents for men. No employee – no matter their longevity, experience, or value – can be considered beyond suspicion.

HOW?

How does an employee successfully divert a large amount of CS? The observations of a pharmacy director from almost 30 years ago still hold true: "Each (drug) distribution system has certain weak points where it is especially susceptible to abuse and diversion."¹⁶ Table 2 lists the most common methods for large-scale CS diversion and prevention strategies to address each risk.

WHERE?

Pharmacy diversions may occur from within the inpatient pharmacy, but hospital outpatient pharmacies or other pharmacy satellites that handle controlled substances are also at risk.

SUMMARY OF RECOMMENDATIONS

Screen and re-screen pharmacy employees. In addition to the routine urine drug screen and criminal background check that are performed at the time of initial hire for hospital employees, it is important to annually repeat these security checks for pharmacy staff. The urine drug test should be

Table 2. Steps to minimize the risks for large-scale controlled substances diversions

Method of diversion	How is it done?	How is it discovered and prevented?
Disappearing invoice	The culprit orders a separate illicit invoice for CS. He or she diverts the drugs upon receipt and destroys the invoice.	Wholesalers provide a written “manifest” that delineates the total number of invoices containing CS that are being delivered. Don’t discard the manifest as a useless cover sheet. The PIC or delegate must verify the actual number of invoices signed in versus the manifest. Warning: A manifest may not accompany CS shipped direct from the manufacturer or a compounding pharmacy. “Separation of duties” is an important control. Do not allow the person ordering CS to be the same person to receive CS. ⁹ If this is not possible, supervision is key. Carefully supervise the CS receiving process. Review CS invoices for anomalies, such as large bulk bottles of CS being ordered into the “unit-dose” hospital pharmacy.
Disappearing last page of the invoice	The last page of a CS invoice is destroyed and the drugs on that page are diverted.	All drug invoices should indicate the total number of pages in the invoice. The PIC or delegate must verify that drugs detailed in all the pages of an invoice are being received.
Received, but not into the secure inventory	Even if there is a well-supervised receipt of all CS from all pages of all the invoices, the culprit diverts drug prior to storage in the narcotic vault.	The movement of drugs from time of receipt into the perpetual inventoried narcotic vault must be supervised in real time. Video camera surveillance is helpful. Periodically conducting an audit where the dates and quantities ordered on CS invoices from the wholesaler are compared to dates and quantities of CS logged into CS secure inventory is key for identifying this method diversion, as well as the others noted above. ⁹ See Figure 1.
Stolen from uncontrolled inventory	The culprit simply takes the uncontrolled CS off the shelf and smuggles it out of the department in a personal bag or in the trash can from which is later salvaged.	Periodically conducting an audit where the quantities ordered on CS invoices from the wholesaler are compared to quantities of CS dispensed (less expired quantity returned) is key for identifying this method diversion. See Figure 1. Finding a bulk bottle of a CS out of place without apparent reason is a flag for diversion. This type of diversion is best prevented by moving class 3 CS inventory into a secure perpetual inventory vault.
Fraudulent transfer of drug between facilities or floors	The culprit completes paperwork for a fictitious transfer of class 3 CS to another facility and diverts the supply. The culprit may request a transfer of class 3 CS from an outside facility and divert the stock.	The same risk for diversion is present if the CS are transferred between patient care areas. Limit the number of persons authorized to transfer CS and secure and audit DEA 222 forms. ^{9,16} Perform an audit of transferred CS to ensure the receiving facility/floor actually received the drugs. Before paying invoices for drugs transferred between facilities, confirm that inventory was received into stock. When transferring CS between ADC units, return the CS to the secure narcotic vault prior to reissue to another ADC.
Almost “returned to sender”	The culprit creates a CS return record for class 3 CS that never actually occurred and diverts the supply.	Limit the number of persons authorized to return CS. Audit returns to see that wholesaler credits for the return are posted.

(continued)

Table 2. Steps to minimize the risks for large-scale controlled substances diversions (CONT.)

Method of diversion	How is it done?	How is it discovered and prevented?
Intercepted return	The culprit intercepts overstock CS being returned from an ADC.	Establish procedures that require CS returned from ADC to be immediately received in secure main vault inventory. Audit the process. CS vault to ADC transaction “compare” reports are a useful tool and are much easier to reconcile when vend-load/refill-return transactions are completed in real time.
Diverting compounded CS waste	The culprit feigns the IV room wasting process for CS compounded products that cannot be returned to a reverse distributor.	Implement a real-time verification step by a pharmacist. Rotate the waste and verification responsibilities between multiple staff.
Expiring the unexpired	The culprit “expires” drug from the ADC or secure narcotic vault and diverts it.	Audit the “expiring” of CS stock from the ADC and main vault to ensure that it is eventually converted to outgoing expired goods. At the time of transfer to the reverse wholesaler, audit actual counts on hand versus expected counts. ^{9,23} Monitor for trends in ADC or CS vault return bin discrepancies. Beware of lost “universal” return bin keys.
Raiding the expired bin	The culprit steals drugs out of the expired bin before they are picked up by the reverse distributor.	

Note: ADC = automated dispensing cabinet; CS = controlled substances; DEA = Drug Enforcement Administration; PIC = pharmacist-in-charge.

focused on the health care professionals and include prescription drugs of abuse. Of course, a diverter who is not abusing CS will not be identified by a urine drug screen. The US Drug Enforcement Administration (DEA) recommends careful screening of employees of CS distributors and CS manufacturers, which includes criminal background checks and credit checks.¹⁷

Divide duties. Separate the CS ordering and the CS receiving functions. Do not allow one person to control both of these functions. Cross-train staff and then rotate them through these separate roles. This prevents a single staff member from having sole control over a specific function and allows for different perspectives of the procedures and their possible vulnerabilities.

Limit CS access. Control the number of pharmacy personnel who order and handle bulk CS. Even if your state does not require class 3, 4, and 5 dosage forms to be locked up in a secure CS storage vault, bring them into locked storage anyway.

Optimize the use of CS automation. CS automation and inventory tracking software records hand-offs and simplifies reporting and auditing. Take advantage of all the security features your systems offer.

Improve surveillance. Improve video camera surveillance.² Multichannel digital video recorders have come down in price. Every pharmacy department can

afford one. Consider installing “bird’s eye” view cameras directly above areas where CS are received and dispensed within the pharmacy. These allow for a clear

Figure 1. Method for auditing counts of a controlled substance while it moves through inventory. The estimated time for each step is indicated in boxes. The first go-round may take longer while you familiarize yourself with the needed reports. CS = controlled substances; min = minutes.

detailed view. Require staff to handle CS under the camera's view.

Guard the door. Install door controls (such as electronic badge readers) that track each employee's entry. Establish policies that restrict off-duty pharmacy employee access.¹⁸ Monitor nonpharmacy employees who routinely work within the department (housekeepers, vendor reps, etc), and always escort pharmacy department "guests." Limit access to CS storage areas to pharmacy staff who are assigned to CS-related tasks. Question any unusual activity, particularly in CS storage areas. Set clear expectations with staff about moving bags and boxes from the pharmacy. "Discourage employees from carrying bags and purses to work."¹⁵ Review the location of personal lockers. Are they hidden from view? Are they accessible to nonpharmacy personnel?

Understand your processes. Map out your processes. Closely examine each CS hand-off and identify risk points for diversion (see **Figure 2**). Each risk point should have an audit or process control designed to minimize diversion risk. Evaluate existing controls; make improvements and add additional controls when needed. CS transactions that are documented electronically (eg, CS vault to automated dispensing cabinet [ADC] refill) are more easily monitored and audited.

CS transactions in which one or both sides of the transaction are documented manually (eg, CS compounding or non-ADC floor stock transfers) are particularly problematic and should be closely scrutinized.

Audit in versus out. Pharmacy leaders should familiarize themselves with the following questions; these are the first questions asked by a DEA agent during an on-site investigation following a significant loss:

1. How much of this CS is ordered?
2. How much is received?
3. How does this compare with previous months?
4. How much is going out and being billed through normal channels?

Pharmacy leaders must regularly audit the movement of CS through the department.

Create a calendar for success. Delineate daily CS security tasks and calendar monthly and annual tasks (see **Table 3**).

Get smart. Educate yourself about CS ordering, distribution, dispensing, administration, and destruction. Attend seminars that discuss CS security. Learn from your peers who may have had difficult experiences and are willing to share the wisdom they have gained.

Figure 2. Example of controlled substances (CS) process flow with diversion risk points and audits. Numbered items represent a CS process hand-off or diversion risk point. Corresponding audits and process controls are listed for each numbered hand-off or diversion risk point. ADC = automated dispensing cabinet; Admin = drug administration; BCMA = barcode medication administration; Disp = dispense; FS = floor stock; Non BCMA = not barcode medication administration; Pt = patient; RTS = return to stock; Rx = prescription.

Table 3. Sample schedule for controlled substances (CS) security tasks for preventing or detecting large-scale diversion

Frequency	Task
Each occurrence	“CS return to vendor” audit: confirm vendor receipt and account credited “CS expired, wasted” audit: confirm quantities accepted by reverse distributor equal amounts removed from CS vault
Daily	“CS ordered vs received vs stored” audit: compare CS manifest vs quantities received and added to inventory Review CS vault distribution vs ADC restock: “Compare” report Review CS vault: “discrepancies” report Perform inventory count once per shift for non-ADC CS inventory
Monthly or quarterly	Review staff with high volume (3+ SD) CS transactions “ADC removal vs admin/waste” audit Review account statements vs manifests/invoices “CS transfer” audit: review CS transfers to other facilities/pharmacies CS vault inventory count: perform complete inventory count of CS vault Review CS vault transaction corrections “CS issued to satellite pharmacy” audit: review satellite pharmacy CS inventory log vs CS vault distributions “CS compounding and waste” audit: review IV compounding and waste logs vs CS vault distributions “CS to hospital/clinic FS” audit: review distributions to non-ADC inventory locations with outstanding CS tracking forms. Ask whether they have remaining inventory for this medication? Are returned CS tracking forms, CSARs, and PCA flow sheets complete/accurate?
Annually	CS “high level” audit: begin with last year’s annual inventory counts for selected high-risk CS. Add to them each month’s purchases, subtract out each month’s dispensing, and compare the balance to this year’s inventory count. Physical security audit: review physical access barriers; test door locks and alarm systems. CS access by pharmacist: review CS vault access and dispensing cabinet records by pharmacist; look for outliers Pharmacy staff in-service: review your expectations and positions of trust; review procedures in place for preventing diversion.

Note: ADC = automated dispensing cabinet; CSAR = controlled substance administration record; FS = floor stock; PCA = patient-controlled analgesia; SD = standard deviation.

Foster a culture of control. Encourage pharmacy staff to ask questions, make suggestions, and discreetly report concerns about CS security within the pharmacy department. Share the actions you are taking within pharmacy with other departments. When a pharmacy director asks other stakeholders (nursing, anesthesiology, etc) to do their part in enhancing CS security, the message is better accepted when the diversion detection and prevention efforts within the pharmacy itself are rigorous.

CONCLUSION

The pharmacy is a target for large-scale diversion of controlled substances. A lack of foresight in taking

simple preventative actions is ultimately a failure of leadership. Verify your processes and controls through review and audit. If a large-scale CS diversion occurs, employee morale is impacted and the aftermath can disrupt a pharmacy department’s ability to provide optimal services. Patients deserve a circumspect culture demonstrated by appropriate checks and balances practiced by a disciplined and diligent pharmacy staff.

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