

A PRACTICAL Controlled Substance Diversion Monitoring PLAYBOOK

BRANDON CLUBB
Pharmacy Operations Manager,
Indiana University Health

JOHN BURKE
President, IHFDA

HEIDI MCNEELY
Chief Nurse Specialist, Children's Colorado

MARIO ROSADO
System Director of Pharmacy, Steward Health Care

KIM NEW
Executive Director, IHFDA

JESSICA LARSEN GALLUP
Director of Pharmacy Business & Analytics,
Avera McKennan Hospital

CHARLIE CICHON
Executive Director, NADDI

LISA MCELHANEY
National President, NADDI

ROBERT LORD
Co-founder and President, Protenus



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Introduction

This Controlled Substance Diversion Monitoring Playbook creates a centralized and practical resource for healthcare organizations that are either starting, in the midst of creating, or optimizing their current drug diversion monitoring programs. A tremendous amount of work has been done in this area with the ASHP Guidelines,¹ the Minnesota Guidelines,² and many other resources from different organizations. Our goal with this piece is to provide one simple resource for getting a diversion program up-and-running, rather than piecing a plan together from disparate best practices.

There is also a need for updated guidance in the industry regarding advances in the field of Healthcare Compliance Analytics. Historical guidance on auditing protocols and reporting methodologies have proven to be less effective relative to recent advances, and we provide this handbook in the spirit of proposing new, improved methods to assure that all controlled substance transactions at your institution are appropriate.

Throughout the handbook, proper steps and protocols essential to a drug diversion program are explored. By systematically approaching each of these topics in alignment with the organization, health systems are able to establish the proper environment for Controlled Substance [CS] diversion monitoring and prevention.

Throughout this piece, one thing the reader must focus on is *workflow*.

Consider:



By changing your current workflow to one that leverages a next-generation approach, tremendous gains can be achieved, and your CS transaction assurance posture can be significantly improved.

¹ https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashxhttps://mn.gov/boards/assets/MN%20Controlled%20Substance%20Diversion%20Prevention%20Coalition%20Final%20Report_tcm21-29216.pdf

² https://mn.gov/boards/assets/MN%20Controlled%20Substance%20Diversion%20Prevention%20Coalition%20Final%20Report_tcm21-29216.pdf

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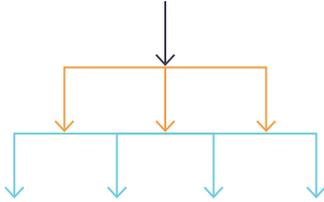
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Aligning the Organization

Bring together all stakeholders to agree on shared goals.

Step 1: Achieve executive buy-in



When establishing a diversion monitoring program, it is critical to educate your organization's senior leadership on the risks posed by drug diversion and the need to build a strong cross-departmental team of executives to tackle this problem. Without providing them with a solid understanding of why this is necessary, the proposal will go nowhere. Valuable resources that can support your argument include high-level editorials, ROI analyses, or guidance from such organizations as ASHP on the criticality of such programs.³

However, the key element to establish executive buy-in is to figure out what “wins” your organization currently prioritizes. While different organizations may have different incentives for enhancing diversion monitoring, some frequently cited key organizational initiatives that align with this work may include:

Workforce Efficiency/Time Savings

Many institutions spend an excessive amount of time and resources on monitoring diversion activity. Many health systems defer to individual supervisors to handle incidents within their respected units. Without the efficacy of a dedicated diversion program with organized leadership to monitor, identify, and evaluate diversion-related incidents throughout the facility, the recidivism rates of diversion will continue at great costs.

With tight margins closing in on nearly all health systems, offering opportunities to use FTEs that are currently monitoring diversion on other critical, strategic tasks can resonate with a budget-conscious audience.

Avoiding Reputational Risk

Diversion events tend to make the local - and sometimes national - news. Health system reputations and success are built on a foundation of trust with the communities they serve, and diversion can disrupt that trust and put lifetime patient value at risk. Oftentimes, having a proactive program can prevent catastrophic diversion incidents from happening. Overall, more cases will usually be discovered, but it will happen at a point in which damage can be prevented or largely mitigated. These events will not typically reach the level of more complacent institutions that would rather take the attitude that it doesn't happen in their facility.

Patient Safety

Patients can be put at significant risk with diversion in a variety of ways. Examples include patients not receiving necessary drugs, having IV medications or fluids infused that have been contaminated with bloodborne

³ <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx>

Aligning the Organization *continued*

pathogens, or having patients treated by individuals who are impaired due to controlled substance abuse.⁴ Any organization with a focus on patient safety must have a concomitant focus on preventing controlled substance (CS) diversion. Failure to do so will put patients at risk, damage the reputation of the institution, and possibly even threaten its future business viability.

Workforce Safety

A major concern of many health systems relates to the occupational health risks associated with working with individuals who may be diverting, and are impaired at the workplace as a consequence. The inability to trust your colleagues puts all employees at risk and damages overall workforce cohesion. Also, workforce members can be put in an uncomfortable position if the only current means of detecting diverters lies with them reporting their own observations. Many employees and managers would rather rely on more advanced surveillance methods. This also helps to avoid a scenario in which employees may be providing conflicting reports.

Avoiding Regulatory Risk

It is undeniable that regulatory risks and fines abound when it comes to controlled substance (CS) diversion, and patterns of enforcement appear to be getting more aggressive. A notable \$2.3M fine was levied in 2015, and since then, there have been additional fines of \$4.1M and \$4.3M levied in 2018. There have been no indications that this increase in penalties will abate. The Drug Enforcement Administration (DEA) is primarily responsible for these levies, though in cases of wide-scale fraud, the FDA, the OIG, and many other agencies may become involved. It is important to note that the DEA Diversion Control Division has become more interested in health facility diversion over the past few years as they have become increasingly aware of the complacency of some in the industry. This scenario makes it even more important that the facility does all it can to comply with federal and state regulations and to develop a proactive drug diversion program that keeps diversion to a minimum.

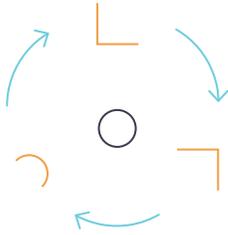
All teams and executives involved in the program should be closely aligned on all elements of this handbook - the degree of institutional alignment behind this initiative will determine its success or failure.

Keep in mind that the key institutional factors around which you align may have significant downstream effects. For instance, if you focus on patient and workforce safety, you will want to optimize the process for detecting as many incidents as possible. If it is about a workforce shortage, you will want to focus on how many FTEs are needed to run the program efficiently and effectively.

⁴ <https://www.nytimes.com/2010/02/25/us/25hepatitis.html>

Aligning the Organization *continued*

Step 2: Assemble the teams for successful monitoring



The success of the diversion monitoring program will lie with the competency of the assembled teams. At a minimum, core teams will need to include:

Pharmacy

Essential in any drug diversion program in healthcare facilities. They are the true gatekeeper when it comes to CS in your institution and the ones who safeguard the DEA license that allows health systems to administer CS. These individuals are on the front lines of CS administration for the facility and they are essential for monitoring supply and detecting anomalies that may indicate drug diversion.

Human Resources (HR)

As a critical component of any diversion team, HR advocates both for workforce members' rights, as well as the needs of the institution with regard to human capital. Ultimately, any serious diversion incident will involve HR, and so they should be included up-front as a key stakeholder. They are the initial gatekeepers for your facility, and it is imperative that they effectively screen any future employee that would have access to controlled substances.

Occupational Health

Occupational health employees are often essential when it comes to setting up a plan for drug testing and completing fitness-for-duty exams. They may also support a program for bloodborne pathogen testing in suspected diversion cases. These roles demonstrate their role on the drug diversion team.

Anesthesia

Anesthesiologists come from an area where they have access to both unique insights as well as unique risks. Across top institutions, teams that involve anesthesia and have physician champions are often more effective in advocating for additional resources to hospital leadership. Significant drug diversion activities can and do occur in the operating room (OR), making the anesthesiologist a great agent to spot potential diversion activities. The need for tight CS monitoring in the OR is essential, along with the monitoring of gas usage and symptomatic signs of the patient under sedation. These may be potential signs of drug diversion.

Security

Diversion often involves both physical security as well as law enforcement or complex interviewing techniques. Placing security on the core team provides an important skill set to the group that can enhance the capabilities of a diversion team to investigate and resolve potential incidents of diversion. In some cases, security is sworn law enforcement and can be used for criminal investigations and prosecutions. If not, security should have a good relationship with local law enforcement to be able to integrate them into the investigation when needed and be the liaison for the institution.

Aligning the Organization *continued*

Compliance

As the department that is ultimately responsible for avoiding major regulatory fines and ensuring procedures and education for institutional compliance, some organizations have Compliance take a point position in a diversion team, bringing together all stakeholders under a unified authority. Drug diversion can fall under their wide umbrella of compliance, and the inclusion of these experts can help the entire team understand the range of issues and their various potential outcomes.

Legal

Most diversion incidents will also have to involve the legal team of a hospital, given the potential institutional risk and complexity around liability that can come about from diversion that might involve patients. Having these individuals present for all team activities can help to inform the group on potential legal issues that may arise,

Risk Management

This team may want to be involved in diversion decision-making and/or provide resources on this front, given the significant institutional liability represented by CS diversion.

Patient Safety

This team is an important addition to an integrated diversion team, given the significant safety impact diversion events can have on patient outcomes.

Nursing

Nursing staff are very likely to have team members who are diverting drugs. Nurses represent the largest group of employees who have direct access to controlled substances. They are also the individuals with the most essential on-the-ground knowledge to know if a given prescribing practice was appropriate given the clinical context of the situation. This means that nurse managers, and sometimes, nurses themselves, should serve on the core team.

In assembling these teams, it is also important to take into account your organization's unique structure.

For instance, if you are a multi-facility organization, each facility may have its own Director of Pharmacy, and centralized pharmacy leadership may or may not have direct oversight concerning CS diversion. In these situations, it is important to involve all necessary stakeholders from all facilities, and to the best of the system's ability, standardized rules and principles across the entire organization.

This standardization aids in reporting, coordination, and ultimately, fairness, creating a unified culture that grows stronger and more effective over time.

Forming these teams is also your first opportunity to analyze the workflows that you'll need to run through to detect and resolve diversion incidents. All of these team members are certainly stakeholders, but deciding which of them are involved in the diversion investigation workflows will have real trade-offs. Each additional step adds "friction," but may contribute a key piece of the puzzle, so optimizing each team's participation is key.

Aligning the Organization *continued*

Step 3: Develop KPIs for your diversion program

KPI	Description	Why is this important?
% of transactions reviewed	% of ADM/ADC transactions explicitly determined to be appropriate or inappropriate	Provides a sense of how comprehensive your program by seeing what "lies beneath the surface"
% of users reviewed	% of monitored total workforce members using CS	Ensures all roles and individuals at an institution handling CS are equally held accountable
Number of cases reviewed	Total number of flags or alerts you have to review and rule in or out with human judgment	Volume of work and FTEs required to get to a given level of results
Diversion incidents detected per year	Number of true diversion events that you detect every year	A measure of true "productivity" and comprehensiveness of a diversion surveillance program
Workflow improvement opportunities ("good catches") detected per year	Number of non-diversion, but poor practice, events that are detected per year	A measure of the diversion surveillance team's role in driving process and operational improvements
False positive rate	% of investigations yield false positives, or individuals who are ultimately cleared	A measure of the effectiveness and sophistication of the surveillance software being utilized
Time spent per case	Time spent (in hours) from event detection to final disposition determination	Time and FTEs required to get to a given result, a measure of workflow efficiency
Time to detection	Amount of time that elapses between an event occurring and it being detected by a system	Holding the institution accountable for patient safety, ensuring diverters have minimal exposure to patients
Time to resolution	Amount of time that elapses between a system reporting on a potential event and it being resolved	Holding the institution accountable for patient safety, ensuring diverters have minimal exposure to patients, ensuring efficient investigatory workflows

The first step in developing Key Performance Indicators (KPIs) is going to be deciding who is ultimately responsible for evaluating the success of the program. It is recommended that a single group is accountable for the totality of the diversion program's achievements and improvements. This ensures someone is held accountable for overall performance. However, individual KPIs can have joint owners to isolate opportunities and challenges, as well as rally teams around shared goals.

It is an axiom of quality control and management that you improve what you observe.

The importance that Key Performance Indicators (KPIs) hold becomes evident when measuring the effectiveness of your diversion program over time. Though each organization must determine their unique blend of KPIs that will lead to the intended outcomes, here are some recommendations that may help evaluate the success of your diversion program:

Percent of Transactions Reviewed

Many organizations presently achieve far below the ideal 100% review and documentation of transactions of controlled substances. This may be due to resource, technology, or personnel limitations. Report-running and periodic reviews only generally result in capturing perhaps 1-5% of total transactions, which provides an opportunity to catch some events, but is ultimately an

Aligning the Organization *continued*

unacceptable portion of transactions. Striving for the ability to prove that 100% of all transactions have been audited is crucial.

Percent of Users Reviewed

This KPI is related to the percent of transactions reviewed, but measures coverage across your organization's personnel to ensure that all clinical environments are being monitored. For instance, if you are reviewing 100% of electronically-logged transactions, but still have a paper-and-pencil policy on anesthesia and no review of anesthesiologists, you may have a significant gap, and one that could easily be exploited.

Number of Cases Reviewed

A reasonable measure of the team's capacity and workflow efficiency is the number of cases reviewed in a given month. A "case" may have a variety of definitions, but it is traditionally defined as an event that has some degree of suspiciousness to it, that requires it be investigated, documented, and a resolution state (diversion, inconclusive, not diversion, etc.) be provided. Increasing the numbers of cases reviewed can be either a good or bad thing, depending on the proportion of them that end up being true diversion events.

Diversion Incidents Detected Per Year

This is a critical metric for any diversion monitoring program, if not the most critical one. Currently, it is generally accepted that an increase in this number usually comes from improvement in monitoring, rather than an actual increase in diversions. The more diversion incidents you are detecting and resolving, the more you are able to create accountability and foster culture change at your institution.

False Positive Rate

The false positive rate for traditional diversion monitoring programs is unacceptably high, yet simultaneously a necessary evil. A false positive result from any investigation is neither an opportunity for improvement nor an identified diversion incident. High false positive rates are very common with report-based methodologies for detection, which focus on looking at items like volume discrepancies, high volumes of opioids dispensed, or similar broad metrics that often have reasonable explanations.

Good Catch Rate

An organization's rate of "good catches" results from legitimate opportunities for quality or practice improvement that come about due to one's diversion detection methodology. How much a program wants to focus on "good catches" can depend on the resources that exist for an institution, but incidents like inappropriate batches of wasting, delayed administration or documentation, or questionable waste witnessing practices all fall under the umbrella of cultural norms or individual performance that should be improved.

Aligning the Organization *continued*

Time Spent Per Case

This critical metric is currently at troubling levels for many health systems. Right now, many health systems report spending dozens of hours to resolve complex cases. This is time spent reviewing reports, gathering data, making requests from different departments for resources, and ultimately writing up conclusions. Driving improvement in these statistics not only allows diversion teams to focus on more strategic goals but also speeds time to resolution, another KPI with safety implications.

Time To Detection

This metric is all about patient and workforce safety; the longer it takes to detect a diverter, the more damage they can do. Right now, detection times are abysmal, averaging 24 months based on a recent analysis.⁵ In such a long period of time, a considerable number of patients can be exposed to an impaired diverter, continuously increasing the health system's liability. In addition to this, the diverter becomes more susceptible to an overdose death of their own. Even if this does not occur, the likelihood of successful rehabilitation may drop as their addiction levels increase over this time period.

Time To Resolution

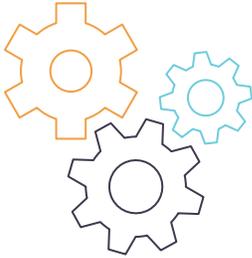
The amount of time that it currently takes to resolve a case after detection is largely a measure of workflow efficiency in case resolution. This efficiency is reduced when diversion teams have to pass cases back and forth between departments. For instance, if a diversion workflow needs pharmacy review, then is handed off to nursing, security, then back to pharmacy, this process will likely take weeks (if not longer). However, if all of the information generated by those handoffs is presented up-front, a timely resolution may be reached within minutes, or possibly hours if an interview is required.

The key for your program is to review all of the above KPIs in a historical context (when possible) and using your current methodologies, decide which ones you want to focus on improving. Once this has been done, you can then create actions to ensure improvement. Some interventions, like standardized documentation, might reduce time to resolution in a targeted sense. Others, like implementing a Healthcare Compliance Analytics platform, might improve several KPIs simultaneously. Whatever you choose to do, the key is to start tracking and reporting on these metrics to show progress and hold all teams involved accountable.

Operationalizing our Goals

This section focuses on the steps required to put the policies, procedures, and technologies in place that allow us to achieve the established Key Performance Indicators (KPI) goals.

Step 4: Evaluate workflows



Now that we've covered KPIs, let's discuss how to achieve them. As with any operational process, the achievement of KPIs can be done in many different ways, but we think about three primary workflows that characterize your typical diversion program, albeit workflows that have significant variance program-by-program.

Step one in operationalizing the goals was laid out in the first half of this paper; this also involves identifying which model your institution is currently operating in, which could be any of the following:

The Reactive Model

In a reactive model, the only monitoring of diversion events relies on individuals reporting their colleagues' suspicious behavior, which may then be used as a justification for a deeper investigation. In this model, reports may be pulled, workflows investigated, and interviews done in order to reach a determination. The drawback is that the process is highly manual, very time and labor intensive, and it is only initiated after the fact.

The significant challenge with the reactive model is that it depends on human reporting, which is highly inefficient, provides no investigatory leverage (as bringing together data sources is highly time-consuming) and usually finds events after it is far too late to intervene helpfully. Furthermore, it may lead to conflicting accounts of events by different employees, which can frustrate or stall the investigation.

This model occurs all too frequently, and in these cases, there is typically no diversion team in place and likely, no upper management buy-in, meaning that the success rate will be marginal. This model fosters many patient safety issues and risks massive regulatory fines when the complacency is identified.

The Report-Based Model

In a report-based model, a health system has attempted to evolve somewhat from a reactive posture by putting in place a series of reports, such as:

- Mismatches between the automated dispensing cabinet (ADC) and medication administration record (MAR)/anesthesia record
- Individuals who have high volumes of distributed opioids
- Individuals who have abnormal numbers of ADC discrepancies
- Individuals or pairs of individuals who witness waste
- Individuals pulling CS on discharged patients

Operationalizing our Goals *continued*

Advanced reports may have helpful graphs, and they may check to ensure that volumes dispensed equal those administered and wasted. Through regular review of such reports, the theory suggests, some events can be proactively detected.

However, in reality, while the report-based model adds helpful data and some level of institutional proactivity, it comes with significant trade-offs. Many health systems report that, after an institution implements this model, the reports can become so voluminous and “noisy” that exceedingly small amounts of new diversion events are actually caught, and significant additional work is created due to false positives. This work revolves around a central team running reports, and discipline-specific teams reviewing them for clinical context, security investigating them, and more.⁶ Given that reports are only looking at one angle at a time, this can lead to a lot of work for little yield.

This is certainly a better model than the Reactive Model, but it still has massive gaps in efficiency. Usually in these models there are some good reports, but they are only coordinated and analyzed with great difficulty among the different parties. They also give many institutions the false sense of security that they are “doing something” while it is technically true that they are in fact doing something, the follow up and successful resolution of diversion cases will not be near as good as it could be with a different model.

The Healthcare Compliance Analytics (HCA) Model

Also known as a “case-based” model, this approach focuses on bringing together a wide array of relevant data sources, reviewing 100% of transactions, and accurately reporting ONLY on those events that have a very high likelihood of being a diversion. In stark contrast to a report-based model, there is no data collection, fact-gathering, or manual review of reports, but rather, facts are presented up-front after a daily and complete review of all of the tens of thousands of transactions that flow through a hospital.

Notably, there are no regular reports that are run and reviewed in this model (though they can be run if necessary), as cases are only generated when suspicious behavior has been detected and examined by an Artificial Intelligence (AI) system, which has determined that there is no reasonable explanation for the employee’s behavior. In addition, the results of this AI investigation are presented in natural-language descriptions, for easy review and resolution, as well as clear data provenance and explainability. By incorporating rich clinical information from the electronic health record (EHR) - such as patient diagnoses and encounters - minimal additional nursing staff is needed to review cases, saving time on the wards, and increasing the speed with which cases can be resolved.

⁶ Note: Security involvement can vary from institution-to-institution, with some health systems handling these investigations through integrated diversion teams, and some leveraging security teams for most of the investigatory work. We recommend a model where this investigatory effort is a team effort, and led by the integrated diversion team.

Operationalizing our Goals *continued*

So what are the types of risks that each of these models might detect? Let's take a look at some of the best-in-class guidelines from ASHP that discuss various areas of diversion.

Step 5: Identify gaps and prioritize risks



ASHP Guidelines⁷ suggest that there are five potential areas that diversion predominantly occurs:

1. Procurement
 - Purchase order and packing slip removed from records
 - Unauthorized individual orders for CS on stolen DEA Form 222
 - Product container is compromised
2. Preparation and Dispensing
 - CS are replaced by product of similar appearance when prepackaging
 - Removing volume from a premixed infusion
 - Multi-dose vial overfill is diverted
 - Prepared syringe contents are replaced with saline solution
3. Prescribing
 - Prescription pads or printer paper are diverted and forged to obtain CS
 - Prescriber self-prescribes CS
 - Verbal orders for CS is created but not verified by the prescriber
 - Written prescriptions are altered by patients
4. Administration
 - CS are withdrawn from an automated dispensing cabinet (ADC) on discharged or transferred patient
 - Medication documented as given, but not administered to patient
 - Waste is not adequately witnessed and subsequently diverted
 - Substitute drug is removed and administered while CS is diverted
5. Waste and Removal
 - CS waste is removed from an unsecured waste container
 - CS waste in syringe is replaced with saline
 - Expired CS are diverted from holding area

While diversion can happen in any of these areas, this piece focuses primarily on clinical diversion, a combination of the prescribing, administration and waste/removal categories. Questions of procurement diversion are often a separate issue, focusing more on operational and financial controls in shipping and payment. Clinical diversion is also presently one of the most opportune spaces for diversion, given the lack of controls and surveillance, and high personnel turnover in front-line clinical staff.

In order to evaluate gaps in existing controls, we recommend systematically examining each class of controlled or high-value substance that enters your facility, and tracking its path from delivery to patient administration (and any subsequent disposal). This workflow analysis can identify areas where exploitation may be possible.

⁷ <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx>

Operationalizing our Goals *continued*

This 2013 paper by Martin, et al. excellently catalogs the various methods by which large-scale diversion can occur in a health system.⁸

Table 2.

Steps to minimize the risks for large-scale controlled substances diversions [adapted from Martin, 2013]

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. 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. 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. 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.
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.

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3839459/>

Operationalizing our Goals *continued*

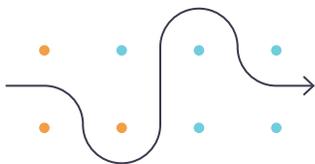
Excellent work from such specialists in the field as Kim New, also addresses methods of clinical diversion, such as:⁹

- Removal of fentanyl patches
- Too-frequent removal
- Giving less than ordered
- Removal when not needed
- Withdrawal for discharged patient
- Removal of a duplicate dose
- Removal without an order
- Frequent null transactions and discrepancies
- Removal of larger doses than necessary
- Failure to waste
- Frequent wasting of an entire dose
- Removal under sign-on of colleague
- High instances of PRN administration

While a complete inventory of every possible step in identifying diverted drugs would be impossible, thinking about common use cases and methodologies can help you cover as many bases as possible. Drawing on past records, case studies, and the resources noted in this paper are a great first step in identifying where your vulnerabilities might be.

Critically, any systems put in place should look for behavioral patterns like those identified above on a continuous basis. Examining for each of these manually could be laborious, even with robust reports, but a Healthcare Compliance Analytics system should readily be able to address such challenges.

Step 6: Determine and implement necessary controls



After you identify vulnerabilities in your current workflow, it is important to build controls that can address those vulnerabilities. A variety of controls are currently discussed as potential best practices and are all worth considering.

The key for any system of controls is to have many layers of accountability and protection, unified under a system that can ensure a 100% review of all CS transactions. Some key components to such a holistic system include:

ADCs

Controlled substances must be universally locked in some form of automated dispensing machine to provide maximum control over CS administration. Wards with substances not contained in a trackable, ADC-monitored format represent significant diversion risk to an institution and make monitoring these medications a challenge.

⁹ https://www.ncsbn.org/0613_DISC_Kim_New.pdf

Operationalizing our Goals *continued*

Drug Screenings

While some organizations may have random screenings, these can certainly be controversial and frequently have a negative impact on workforce morale. This process can require the workforce to submit to a drug screen upon suspicion of the diversion committee, with clear expectations that failure to do so will result in termination. The most conservative policy would only initiate drug screens after a comprehensive body of evidence and probable cause was established. When drug screens are utilized, witnessing the sample is crucial. The cases of “clean” urine being concealed on the diverter’s body are more commonplace than imagined. Pre-employment drug screenings are also a must for the institution.

Cameras

The use of cameras near any ADC can be a powerful deterrent and investigatory tool for drug diversion. Individuals are much less likely to divert if they know that they are being directly observed, though this will not stop all diversion activity [as not all activities are captured by cameras]. The most powerful argument for cameras lies in their ability to exonerate individuals in cases of accidental loss or practice deviation, since a lack of intent can often be inferred from cameras [and not in reports]. This may be the case in instances where a syringe or pill rolls away or becomes jammed in a machine, a scenario that many drug diversion investigators have encountered. Although cameras do provide a deterrent effect, it’s worth noting that a significant amount of diversion acts do not occur at the ADM, such as with PRN diversion or wastage, meaning cameras will be ineffective in discovering these acts of diversion.

Hiring Controls

HR is likely the entity that will authorize the hiring of agency [temporary] healthcare workers. These workers, unfortunately, are disproportionately represented among healthcare workers found to be diverting medications. Therefore, it is important to make it clear to the agency that their hiring and monitoring practices must equal or exceed your own institution’s. This requirement will hopefully result in the agency providing you with top quality employees. If HR understands the importance of closely screening new hires that have access to CS they will be especially vigilant when an opening is being filled. The basics of good licensure checks, background checks, and reference checks can also be extraordinarily effective in preventing serial diverters from entering your system.

Mass Spectrometry/Volumetric Monitoring

Without going into a detailed technical analysis, many systems [such as Mayo Clinic]¹⁰ have begun to implement volume tracking and, indeed, analysis of residue and concentration in very high-risk classes of substance, like

¹⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538481/>

Operationalizing our Goals *continued*

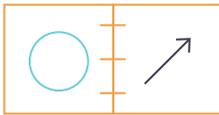
fentanyl. Such methods, while costly and time-consuming, can help ensure that potential diverters are not able to dilute IV bags or syringes, or divert even closer to the point of preparation. In addition to this, volumetric analysis can ensure that amounts of waste that are recorded match up with what is actually being discarded.

Healthcare Compliance Analytics

The challenge in determining whether the entirety of a given transaction is appropriate or not, is a laborious and often-inaccurate process. All of the above measures are somewhat limited in their effectiveness without a mechanism for 1) bringing all necessary data together, 2) proactively reviewing every transaction and 3) documenting the appropriateness or inappropriateness of every CS transaction.

While the previous strategies provide a “spot check,” or a retroactive look at past behavior, only through detailed behavior monitoring can a health system hope to fully close the loop and actively manage the risk associated with CS diversion.

Step 7: Establish reporting protocols



A necessary part of any diversion monitoring and prevention program is knowing which organizations require reporting from your institution.

DEA

Per ASHP guidelines, “The organization defines, in accordance with the law, when a DEA Form 106 should be completed for discrepancies that remain ultimately unresolved. There are clear responsibilities for completion of DEA Form 106 for a theft or significant loss, who is to be notified, and when. Even if the loss cannot be quantified due to the nature of the diversion method, DEA should still be notified.” However, beyond this, top health systems should also ensure that their relationships with their local DEA office are established before diversion events occur, creating open lines of communication and shared trust. This simple approach can yield significantly improved cooperation and optimal results over time. Although reporting to DEA Diversion is mandated, do not anticipate or notify them with the impression that a criminal investigation will occur. DEA Diversion is a regulatory federal entity only, and use of local and state law enforcement for criminal prosecutions is advised.

Local Law Enforcement

If criminal diversion activity is suspected, proactively establishing good relationships with local law enforcement and involving them in a timely manner in case of incidents of likely diversion, can be a tremendous organizational asset. While involving law enforcement can often be viewed as

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adding complication to a case, it also brings resources to bear and provides helpful investigatory assistance for these complex cases. In ideal situations, local or state law enforcement personnel are part of your diversion team. Good relationships with these individuals can aid in investigations; this is true even in situations where criminal prosecution is not pursued.

State Licensing Boards

Depending on the case, the organizational policies, and applicable state laws, you may have obligations to report diversion incidents to state nursing boards, physician certification boards, or other professional/regulatory bodies. Familiarizing yourself with these requirements and setting internal protocols for communication is helpful. Most state boards also have no law enforcement powers, although they can be crucial in your investigation. Becoming familiar with each of the professional boards and knowing individuals on them with whom you can rely on at a moment's notice is ideal. These organizations will likely also be able to guide the addicted health professional to an effective drug rehabilitation program.

FDA

In cases of potential package tampering or early-pipeline diversion, the FDA may have jurisdiction. It is commonly said that FDA-OIG also has significant technological resources at their disposal that can be of great assistance in extremely difficult investigations. FDA criminal investigators, and sometimes the FBI will become involved in these cases. Ideally, the federal and local law enforcement agencies will work the case together if possible, along with input from the State Boards.

State Health Departments

Many local or state health departments have requirements for reporting confirmed diversion cases and will assist with investigations where the potential for bloodborne pathogen exposure is present.

A Note on HIPAA

Note that many organizations feel that HIPAA might serve as a barrier to reporting. In actuality, this is rarely the case. 45 CFR 164.512 allows clear exceptions¹¹ for the purposes of:

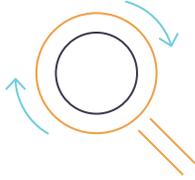
- Disclosure required by law
- Public health activities
- Health oversight activities
- Law enforcement

Each of the above categories provides a reason for PHI disclosure when it comes to suspected or confirmed CS diversion. Of course, without these exclusions, no one would be able to report drug diversion, which can result in untold catastrophes.

¹¹ <https://www.hollandhart.com/pdf/DHCP-drug-diversion-webinar.pdf>

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Step 8: Establish investigation protocols



A great investigation workflow is well articulated by a recent presentation by Heidi McNeely, of Children's Hospital Colorado. Other highly-detailed procedures for analysis have been proposed by experts like Berge, et al.¹² We offer here a simplified workflow that might provide a starting point for new diversion programs or an opportunity for existing programs to see if any significant gaps might exist in their practices.

- Develop organizational policies around reporting and investigating diversion with the expectation that all employees are required to report any suspected or confirmed cases of diversion.
 - Establish a consistent process to address all suspected diversion cases: see below example.
1. Notification of Diversion Response Team (consistent process for reporting diversion), outline how all key stakeholders on the response team will be notified once the report made
 2. Mitigate any immediate risks: remove the suspected employee(s) from duty if immediate risk is identified
 - Secure evidence and engage security for chain of custody support
 - Ensure safe patient care procedures
 3. Schedule a briefing with response team members within 24 hours of the initial report and define the investigation's process and responsibilities
 - Notification of additional team members based on the specifics of the case
 4. Review any analytics/data available related to case
 5. Pull additional data, including: time card data, room/door access reports, work history, etc.
 6. Schedule interviews and engage leadership to help cover for an employee when they are removed from duty for the interview, if they have not already been suspended from work
 7. Arrange for drug testing and bloodborne pathogen testing to be completed after the interview
 8. Interview the suspect using a customary methodology and a consistent team
 9. Have security search the employee's locker/belongings based on organizational policy
 10. Determine if patient harm resulted from diversion or if there was an impact to patient care
 11. If termination of the employee is necessary, ensure ID badge, keys and other organizational belongings are collected promptly
 - Remove access to ADC and buildings immediately
 12. Determine what reporting is necessary. This can include:
 - State Health Department
 - DEA
 - FDA
 - Licensing Board in the State
 - Law Enforcement
 - Peer Assistance program in state or Employee Assistance Program

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538481/>

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Another critical element of any investigation workflow is the platform that you used to detect and resolve threats. These investigation workflows are rooted in our previous discussion of the difference between reactive investigation protocols, report-based investigation protocols, and case-based investigation protocols.

In a reactive model, the diversion team is limited only to what events are detected by diverters' peers or patients. This tends to occur after the symptoms of addiction become quite severe, which suggests that a diverter may have been impaired for quite a while, putting colleagues and patients at risk. The above investigatory steps will likely take an enormous amount of time, as each step requires additional information and resources that must be drawn on, and as the case and new facts unfold, more individuals and resources must also be brought into the investigation.

In a report-driven model, regular reports are run based on ADC and/or EHR and/or time card data, in order to determine if any employees have odd patterns of activity, such as high drug volumes, incorrect shift locations, or missing administrations of CS when compared to what was pulled from a machine. In this model, the diversion team is constantly viewing exception or anomaly reports, which are mostly comprised of false positives, meaning that there is a huge amount of information to sift through in exchange for the proactivity granted by this approach. While some of the above steps may be streamlined by this model, the reality is that there is still a significant amount of data collection and investigation to be done post-report, as reports only tell one piece of the story, and the rest of the information must be gleaned from interviews, additional reports, or special data requests. This is still a very time-intensive and labor-intensive approach.

In the modern, case-based method, an entirely different approach is taken. In this model, only "cases" are ever reviewed by a human being, which are detailed descriptions of high-risk events that have been examined from multiple angles. There is no need to run reports, as the system is constantly running reports on all activities, and only those activities that have multiple risk factors and no reasonable explanation are raised to the level of "case" status. In this model, diversion specialists have all of the facts at their fingertips in the form of a natural-language report, giving them the ability to review and explain 100% of transactions, but only focus on those that pose real risk to the organization. Critically, this means that teams can generally jump immediately to the interview step, and get to in-person reactions within minutes, rather than days or weeks. This reduction in time-to-action is a critical benefit of the case-based approach.

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Whenever any case is encountered, regardless of the outcome, it is important that the team debrief. This means taking a critical look at the case investigation and asking hard questions.

- What did the team do right?
- What could the team have done differently and better?
- Do we have the right people on the team, or should we add or reduce the team size?
- Was the best possible outcome for the patients, diverter, and facility realized?

This kind of critique is valuable and helps to ensure mistakes are not repeated. It also demonstrates the successful parts of the investigation so that they may be expanded. The critique must be honest, while also minimizing any hard feelings that can occur during a debrief. The team must realize that no investigation is perfect, so discussing what they can do better and then implementing those elements creates a better investigation and better team in the long run.

Step 9: Establish resolution protocols



Diversion investigations can have a variety of resolution states that one might plan for up-front, of varying levels of severity. The need to submit a DEA Form 106 should, of course, always be adhered to in any situation with either the theft or a “significant loss” of controlled substances.¹³

However, different levels of severity might indicate different levels of response, based on laws in your state and your institution’s policies.

No Action, Error

In some cases, an error might have been made early in an investigation, or a piece of data that seemed suspicious has a perfectly reasonable explanation.

No Action, Watchlist

In some cases, information may suggest something may be awry with a particular user, but the results are inconclusive. Perhaps the trends of opioid use are “moving in the wrong direction,” or they are broadly regarded as suspicious, though their documentation is impeccable. These individuals may represent a risk to the institution, or they may not. A good program continues to carefully and thoughtfully monitor their actions. Very close monitoring of these individuals is crucial. Although it is possible that diversion is not occurring, there are as many of these situations that end up as criminal diversions.

Education

In some cases, poor practice or rule infractions exist, such as lack of documentation, poor documentation, batch wasting, or falsifying witness records. Depending on the severity of the infraction and the intent of the individual, severe disciplinary action may be necessary. However, in

¹³ https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

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many cases, a thoughtful approach that includes education and increased accountability may be sufficient. Education may take the form of mentorship, formal classes, or a simple reminder on relevant laws and policies. When used appropriately, education can be a powerful tool that can be delivered quickly, definitively, and clearly. The amount and type of education involving drug diversion lets the employee know that the facility is serious about these issues and will not tolerate deviations. Employees need to have clear, simple, and direct policies around acts that are ripe for drug diversion and then have them enforced when violated.

Remediation and Restricted Practice

In some cases, an individual's actions require some significant penalty, up to and including a period of not being able to work on high-risk wards. Education and treatment programs can be a compassionate way to provide early intervention to otherwise-good clinicians. Some states¹⁴ have programs by which individuals can enter programs where they can receive treatment, supervision, and eventual restoration of their license, such as Michigan's Health Professional Recovery Program.

Termination without Reporting

In some cases, infractions may be serious enough to warrant termination or a request to resign. This common category can, in fact, lead to more problems in the future. It is all-too-common that individuals are "asked to leave" quietly, in a seeming act of compassion towards the diverter. However, examples abound of individuals who have moved from facility to facility, state to state, continuously diverting without any facility ever knowing why they left their previous location. This type of situation is one that rarely does a service to anyone. It can continually put patients at risk and ignore the abuser's need for treatment. Other options are often preferable. The bottom line is that all drug diversion incidents need to be reported. This not only requires some action with regard to the diverter, but it can successfully reduce the civil liability of the institution.

Law Enforcement/Nursing Board Reporting

In situations where either an institution chooses a "zero tolerance" policy or when clear, repeated, unremediable infractions or incidents of diversion have been observed, termination may be necessary. This is ideally done in conjunction with law enforcement and/or board reporting. It is important to take action to prevent these types of events from occurring at another facility. Allowing an offender to merely resign or to fire them without proper reporting, is opening up the facility for huge liability issues, endangering future patients of the offender, and reducing the chance of successful rehabilitation of the diverter.

¹⁴ <http://hprp.org/>

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Note: Drug Testing

A somewhat ambiguous, “twilight” area of resolution can be a request for drug testing that an employee refuses, followed by their resignation, which depending on policy and state law, may either be reportable or not reportable. This situation leaves a diversion program in a difficult ethical situation - sometimes these individuals may go on to continue practicing. The lack of nationwide standards and reporting creates a significant gap in this regard that remains unfilled. The recommended best practice would be to report all suspicions in lieu of resignation with refusal to drug test.

Critically, all of these resolution states require a thoughtful, before-the-fact analysis of how an institution will treat different situations. Deciding, and agreeing upon, standards for each of the above resolutions avoids dealing with personal loyalties, uncomfortable compromises, and ambiguous responsibility. By aligning all diversion-involved executives on these protocols, expectations can be clearly set, and resolution of these incidents can be streamlined. Drug testing of all known drug diverters for blood borne pathogens (e.g., HIV, HepC) is essential. This needs to be a required procedure when drug diversion is discovered to be able to immediately notify those possibly infected to seek treatment. Follow-up reporting with local or state Health Departments is also then mandatory if infection is identified.

