# PROFESSIONAL AFFAIRS:

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## Members Only! HOME STUDY CE

## NO MORE GAPS – A CONTROLLED SUBSTANCE DIVERSION PREVENTION GOAL!

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## HEADLINES

**"Former Missoula RN sentenced for felony diversion of drug charges."** [1]

**"Texas medical center to pay $4.5mln over fentanyl diversion."** [2]

**"A hospital staffer diverted drugs, which gave me hepatitis C. That happens more often than you think."** [3]

**"DHMC Doctors Accused of Stealing Drugs."** [4]

### INTRODUCTION, PURPOSE & GOALS OF THE PROGRAM

The headlines listed are a few examples of controlled substance diversion in healthcare settings. It is estimated that 10%-15% of healthcare staff divert controlled substances (CS).[5] A survey of healthcare professionals showed that 85% agreed that it occurs in US Hospitals, but only 20% believe it is a problem in their own institution.[6] CS diversion affects the staff member and patient, and also has financial, regulatory, and reputational consequences. Diversion occurs throughout the health system for any group in contact with controlled substances and requires a multidisciplinary approach to prevention.

The American Society of Health-System Pharmacists (ASHP) created guidelines to help health systems establish CS diversion prevention programs.[7] Our multi-state health system used the ASHP framework along with existing organizational initiatives and practice standards to create policies and a set of best practices that meet local, state and federal regulatory requirements. Using these guidelines along with other tools and resources available, we started a Controlled Substance Diversion Prevention Program (CSDPP) for the Illinois hospitals of the system, also known as our market.

The purpose of our comprehensive CSDPP is to close the gaps for diversion for our hospitals in a Just Culture environment, helping our patients, our associates and ultimately our community. Goals include achievement or progress toward completion of all controlled substance best practices; regulatory readiness; standardized utilization of diversion surveillance software; and dispensing transaction monitoring.

### PROGRAM DESCRIPTION

Our structured CSDPP started around September 2021, with the onboarding of a Medication Safety Manager and Diversion Analyst. These individuals implement

best practices across the market, create reporting mechanisms, review operational processes, and oversee the diversion surveillance software functions and findings. Quality dashboards and metrics, policy and procedures, and diversion surveillance report-outs are brought to the market Controlled Substance Diversion Prevention Committee (CSDPC) as well as regional committees and are shared with each hospital's Drug Diversion Response Team (DDRT).

## PROGRAM OUTCOMES & EXPERIENCE

Though the CSDPP was started by Pharmacy, the program now reaches all professionals in the organization. Our Controlled Substance Best Practice list (CSBP) contains over 120 best practices organized into categories, such as Regulatory, Procurement, Storage & Security, Automation, Prescribing, and Data Management. An example of what is included in a category is "Regulatory: DEA license is up to date". The CSBP is updated periodically, with an annual compliance review completed by the end of each fiscal year. Each hospital pharmacy leader reviews each best practice and attests compliance or provides a status update. If not currently compliant, the facility will have 90 days to identify the primary barrier that hinders compliance and define a corrective action plan, including the responsible individual for corrective action. The goal is to have all best practices in full compliance or with clear action plans before the end of the fiscal year.

This effort is coordinated and led by the System CS Diversion Analyst who provides subject matter expertise and ongoing auditing. When meeting with pharmacy leaders to support action plan progress, the analyst clarifies what defines compliance, discusses references or policies and shares practices within the market. Once follow-ups are completed, the gap analysis for each hospital is discussed with the Medication Safety Manager and reported to the System Pharmacy leadership. As in **Table 1**, compliance percentage is tallied to see our current standing and where we will need to concentrate and gain compliance, as well as any process gaps. At the end of the fiscal year, compliance, barriers, and action plans are reported to the national pharmacy team and Diversion Steering Committee to determine areas where additional support or system standards are needed.

Building regulatory readiness into our CSDPP, we created a primary resource for all our hospitals in the market by establishing a Table of Contents shown in **Figure 1**, that lists all documentation for required state and federal regulatory requirements. This is stored in a binder, secure file cabinet or electronic shared file. The purpose is to have the required information available in one location and have clear instructions how to access information not immediately available. This is designed to help managers retrieve information quickly and ensure prompt access to required

## TABLE 1

| | % Compliant | % Compliant + N/A | % Responded |
|---|---|---|---|
| Medical Center | 77% | 96% | 97% |
| Medical Center | 92% | 95% | 100% |
| Medical Center | 82% | 92% | 94% |
| Medical Center | 92% | 95% | 99% |
| Medical Center | 90% | 93% | 100% |
| Medical Center | 91% | 95% | 98% |
| Medical Center | 89% | 93% | 99% |
| Medical Center | 88% | 93% | 99% |
| Medical Center | 89% | 92% | 95% |
| Medical Center | 92% | 95% | 100% |
| Medical Center | 93% | 97% | 99% |
| Medical Center | 92% | 96% | 100% |
| Medical Center | 93% | 97% | 100% |
| Average/Total | 89% | 95% | 99% |
| ***Current Standing before end of FY23 | | | |

## FIGURE 1

**MEDICAL CENTER NAME**
**Pharmacy Department**
**Controlled Substance Diversion Prevention**
**Regulatory: Pharmacy Practice Act & DEA**

**TABLE OF CONTENTS**

1. **Certificates:**
   - Current Pharmacy State License
   - Current PIC License
   - Current Power of Attorney Authorization Forms
   - Current DEA Registration Certificate
   - SAMHSA - if applicable
2. **Locations of Information Readily Available**
   - CSOS Registrant & Coordinator certificate
   - Pharmacist (Pharmacy staff) Signature Log
   - Electronic Records of Purchase, Invoice, Perpetual Inventory
   - Receiving Records: DEA-222 Forms; invoices from POM / EMS*
   - Distribution Records
   - Disposal Records
3. **Inventory Records:** Annually, after Initial Inventory, and kept for rolling required years minimum for State Regulation
   - Change of PIC Initial C2 INVENTORY of Actual Amount in the Facility
   - Change of PIC Initial C3-C5 INVENTORY of Approximate Amount in the Facility (Unless it comes in bulk container)
   - C2 Annual INVENTORY of Actual Amount
4. **Completed Forms**
   - CSBP Annual Attestation
   - DFPR - Annual Self Inspection
   - DEA 41 - Destruction of Controlled Substances
   - DEA 106 - Report of Theft or Loss of Controlled Substances
   - DEA 222 - Manual Orders
5. **Contact Reference**
   - Local Off-Site Record Storage Facility
   - Location of In-House Storage
6. **Important Links, Addresses and Phone Numbers**
   - IDFPR Professional Licensing
   - DEA Professional Support
   - DEA Address and Phone Number
7. **Blank Forms**
   - IDFPR Self Inspections
   - DEA 41, 106
   - DEA 222 and Log

documents if the primary manager is not available for a regulatory visit. This resource will be reviewed regularly to make sure that the information and location of information are up to date. In addition, this will be reviewed to verify that required regulatory files needed for inspections are readily available upon request.

Our health system utilizes a diversion surveillance software with advanced analytics. This software interfaces with the electronic health record (EHR), Automation Dispensing System (ADS), and human resources systems. All hospitals use an ADS except one, which uses a manual dispensing process. Because three different EHRs are used within our market, this software helps to streamline diversion monitoring at the system level. The software settings are based on regulatory requirements, best practices and healthcare system policy. Any configuration changes must go through a Steering Committee via request form. To maximize the utility of this software, as many individual dispensing cabinets as possible are monitored. For any excluded devices or manual dispensing, the local hospital is required to establish a procedure for manually auditing a set number of sample transactions based on policy, including who will complete the audits. The Diversion Analyst confirms completion of these audits during site visits for CSBP compliance.

The surveillance software identifies issues with ADS transactions and notifies a designated pharmacy leader when enough issues arise to suggest deviation from policy or potential diversion. Any incomplete CS documentation identified by the software is validated and reported in the safety event reporting system. There is also a set amount of user reviews required for each hospital to complete monthly. User review metrics are reported to the CSDPC and national Pharmacy and Diversion Prevention Committees. **Table 2** provides recent data on the number of reviews created and closed by each hospital.

Another part of our CSDPP is to measure and report transactions in the ADS that may increase diversion risk. The initial report is the ADS CS Discrepancy report of transactions where a count of controlled substances does not match the expected quantity. These numbers are collected monthly and are the basis of the metrics collected for the CSDPP Dashboard (**Table 3** on page 20). Calculating discrepancies per 100 controlled substance dispenses allows for comparison between sites. Discrepancies not resolved in 24 hours per policy are reported daily during safety huddles and are tracked on the dashboard. Other metrics include the number of CS override dispenses and the percent of CS Medication waste completed at the time of dispensing. All CS metrics are reported at the CSDPC and local DDRT meetings.

## INNOVATIVE ASPECTS & ACHIEVEMENT OF GOALS

We have realized successes small and large in the short time this diversion program has been active. A great achievement is having a multidisciplinary market CSDPC, which took nearly one year to be established after the start of the CSDPP. In addition, each hospital has a DDRT that meets regularly. Some small achievements with big impact are finding a secure cabinet to store controlled substances and identifying how to monitor prescription pads and papers. Our larger achievements are in our pillars of best practice implementation, regulatory readiness, diversion surveillance software, and ADS transaction monitoring.

In 2020, before the CSDPP, average CS Best Practice compliance for the system was 94.2%. With the attention of the Diversion Analyst, compliance for the fiscal year ending June 2022 increased to 99.8% by addressing practices which had been self-reported as non-compliant. This year, 10 CSBP were added to reflect the updated ASHP guidelines, and compliance with all practices was validated. The compliance rate decreased to 95.6% but is the most accurate assessment yet. Action plans are in place for all areas of non-compliance. Regulatory readiness improved with the implementation of the CS Table of Contents in January 2023. This process identified gaps in document availability and record retrieval

## TABLE 2

| ***Review Created*** | 2023 | | | | | ***Review Resolved*** | 2023 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Jan** | **Feb** | **Mar** | **Apr** | **May** | | **Jan** | **Feb** | **Mar** | **Apr** | **May** |
| Medical Center 1 | 10 | 8 | 8 | 8 | 9 | Medical Center 1 | 11 | 4 | 4 | 7 | 10 |
| Medical Center 2 | 5 | 1 | 4 | 4 | 6 | Medical Center 2 | 33 | 29 | 7 | 4 | 4 |
| Medical Center 3 | 10 | 4 | | | | Medical Center 3 | 9 | 3 | 2 | | |
| Medical Center 4 | 9 | 6 | 4 | 2 | | Medical Center 4 | 8 | 7 | 3 | 4 | 3 |
| Medical Center 5 | 9 | 7 | 6 | 1 | | Medical Center 5 | 8 | 6 | 6 | 4 | 1 |
| Medical Center 6 | 9 | 7 | 1 | 1 | 2 | Medical Center 6 | 10 | 7 | 1 | 4 | |
| Medical Center 7 | 4 | | | | 7 | Medical Center 7 | | 10 | | | 3 |
| Medical Center 8 | | 3 | | | | Medical Center 8 | 2 | 2 | | | |
| Medical Center 9 | | | | | 4 | Medical Center 9 | 2 | 1 | | | 3 |
| Medical Center 10 | 8 | 3 | | | | Medical Center 10 | 10 | | | 1 | 2 |
| Medical Center 11 | 4 | 4 | | | 1 | Medical Center 11 | 1 | 3 | | | 2 |
| **Grand Total** | **68** | **43** | **23** | **16** | **29** | **Grand Total** | **94** | **72** | **23** | **24** | **28** |

## TABLE 3: CSDPP DASHBOARD

| | Month: May 2023 | Health System Pharmacy Services - System View | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Safety and Compliance** | **GOAL** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** |
| ***Raw # of CS Discrepancies*** | *Value used for trending purposes* | 21 | 47 | 36 | 37 | 57 | 136 | 129 | 60 | 44 | 20 | 76 |
| ***Number of MedStations used for "Per Station" Calculation*** | | 15 | 50 | 56 | 39 | 61 | 85 | 78 | 36 | 39 | 29 | 84 |
| ***Avg. # of CS Discrepancies per station*** | *Value used for trending purposes* | 1.4 | 0.9 | 1.2 | 0.9 | 0.9 | 1.6 | 1.7 | 1.7 | 1.1 | 0.7 | 0.9 |
| ***CS discrepancies are unresolved within 24 hours (%)*** | *0* | 4.8 | 17 | 16.2 | 10.8 | 7 | 9.6 | 16.3 | 3.3 | 0 | 15 | 7.9 |
| ***Calculated discrepancies unresolved within 24 hour (=total x %unresolved)*** | *Represents # of possible diversion events for review* | 1 | 8 | 11 | 4 | 4 | 13 | 21 | 2 | 0 | 3 | 6 |
| ***CS doses dispensed*** | *Value for calculation* | 4819 | 7691 | 12181 | 8623 | 11000 | 21289 | 12303 | 5857 | 6303 | 5220 | 17253 |
| ***CS discrepancies per 100 CS doses dispensed*** | *Goal <0.7* | 0.44 | 0.61 | 0.56 | 0.43 | 0.52 | 0.64 | 1.05 | 1.02 | 0.70 | 0.38 | 0.44 |
| ***Profile Override %*** | *Best Practice < 5%* | 4.5 | 1.8 | 2.9 | 2.3 | 7 | 3.33 | 2.4 | 3.1 | 1.6 | 1.8 | 1.4 |
| ***Profile CS % Override (% =total# CS Override/total# CS Dispenses) x100*** | *Value used for trending purposes* | 0.54 | 2.68 | 5.63 | 3.99 | 3.10 | 2.47 | 2.12 | 1.88 | 1.30 | 1.38 | 1.48 |
| ***Total #CS Override*** | *ADC CS Override Report: No Non-Med & EMS* | 26 | 206 | 686 | 344 | 341 | 525 | 261 | 110 | 82 | 72 | 255 |
| ***Total #RX Pads Override*** | *ADC CS Override Report: RX Pads* | 4 | 6 | 0 | 3 | 6 | 263 | 212 | 192 | 72 | 277 | 19 |
| ***CS Waste per 100 CS doses dispensed*** | *Value used for trending purposes* | 15.1 | 19.3 | 21.0 | 19.7 | 18.6 | 12.6 | 14.7 | 12.3 | 14.0 | 14.3 | 11.1 |
| ***Integrated Waste% (%=total# INT Waste/total# Waste transactions) x 100*** | *ADC CS Waste Report* | 71.9 | 25.6 | 33.9 | 35.5 | 39.9 | 11.1 | 14.7 | 11.8 | 22.8 | 29.5 | 17.9 |
| ***Total# Waste*** | *ADC CS Waste Report* | 729 | 1483 | 2555 | 1698 | 2046 | 2682 | 1803 | 718 | 883 | 746 | 1922 |
| ***Total# Integrated Waste*** | *ADC CS Waste Report* | 524 | 380 | 867 | 602 | 816 | 298 | 265 | 85 | 201 | 220 | 344 |

expectations. Managers are now better prepared to present required information in the event of a DEA visit.

The diversion surveillance software was implemented in phases starting in August 2021. In total, over 20,000 transaction issues have been individually reviewed by pharmacy staff. Approximately 1,100 user reviews have been completed, with violations found in over 60%. The CSDPP leaders convened a workgroup in summer 2022 to create standard procedures for reviewing findings from the diversion software. This effort plus ongoing configuration enhancements is increasing our ability to detect diversion and advise leaders on how to reduce diversion risk behaviors in their staff.

At the start of the CSDPP, discrepancy metrics were presented at the Medication Safety Committee. An awareness campaign in summer 2021 kicked off a downtrend, but a target was unclear. There are no benchmarks established in the literature, so the committee used the results of a 2016 study[8] and internal discrepancy data to set an FY23 goal of less than 0.7 discrepancies per 100 CS dispenses. This goal was met within the first 4 months and has persisted, along with a 40% decrease in total discrepancies since tracking began (**Figures 2 & 3**).

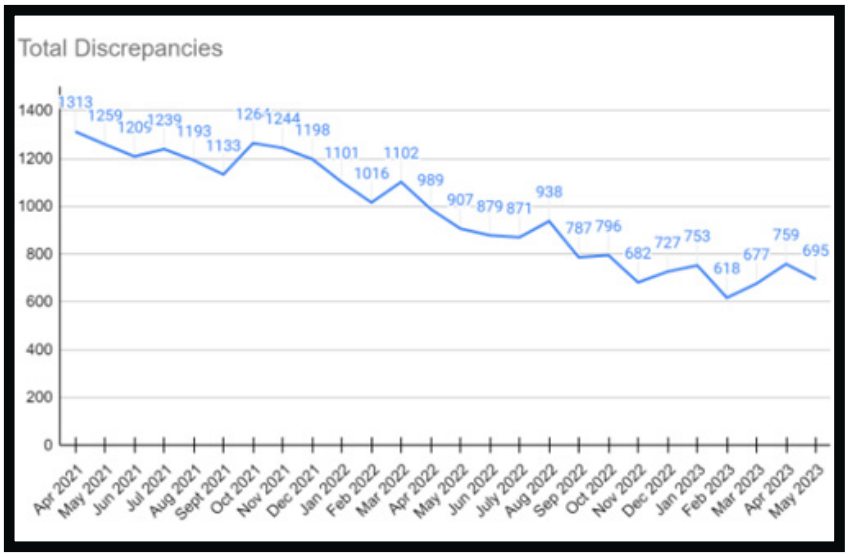
These successes have come with several challenges. The first is working with multiple hospitals within one system. Each hospital has an established culture of practice, including operational standards and habits, patient population, and infrastructure. Another challenge is getting the professional team together to understand diversion prevalence and importance, at a time when leaders and front-line staff are already stretched to their limits. Finally, some of the best

practices in preventing CS diversion require capital investments that executives may not be prepared to support in this financial climate.

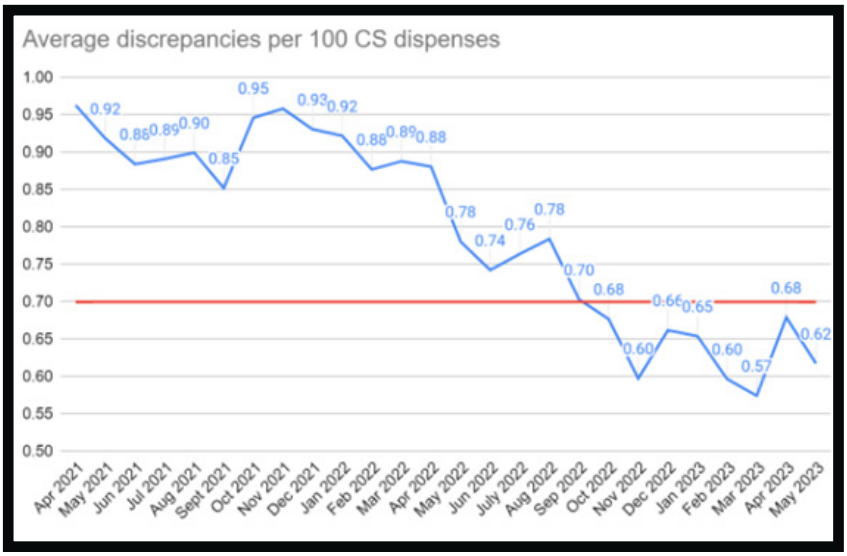
## CONCLUSION

There seems to be no end to the articles and news reports about controlled substance abuse and diversion. Setting prevention goals is not only required by law but is important for the well-being of our patients, our associates, and our communities. ASHP's guidelines help our health systems establish best practices and checklists to close many gaps, but a dedicated team conducting active monitoring is necessary to prevent, detect, and intervene to reduce the harm of diversion events. We celebrate each achievement and see challenges as opportunities to create new processes that protect our resources without interfering with patient care. A future target for the program is expanding beyond acute care to other settings that handle controlled substances. With the greater goal to protect our communities, we are looking forward to that challenge. ▪

## FIGURE 2




## FIGURE 3

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DETAILS ON PAGE 22

# BEST PRACTICE
## TEST QUESTIONS & CPE INSTRUCTIONS

## NO MORE GAPS – A CONTROLLED SUBSTANCE DIVERSION PREVENTION GOAL!

**HOME STUDY:** Journal Article
**TARGET AUDIENCE:** Health-System Pharmacists and Pharmacy Technicians
**LEARNING OBJECTIVES FOR PHARMACISTS & PHARMACY TECHNICIANS:**

1. Identify effects of Controlled Substance Diversion in Healthcare system.
2. Identify processes that can help Prevent Controlled Substance Diversion in Healthcare system.

This program is provided by the Illinois Council of Health-System Pharmacists (ICHP). The Illinois Council of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is equivalent to 0.5 contact hour (0.05 CEU) of pharmacy continuing education.

**ACTIVITY TYPE:** Knowledge-based
**ACPE UNIVERSAL ACTIVITY NUMBERS:** 0121-0000-23-101-H04-P and 0121-0000-23-101-H04-T
**INITIAL RELEASE DATE:** November 1, 2023 **PLANNED EXPIRATION DATE:** November 1, 2026

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## HOME STUDY TEST QUESTIONS:

**1. What percentage of healthcare workers reported diversion of controlled substances?**

a. 10% - 15%
b. 80% - 85%
c. 20% - 22%
d. None of the above

**2. What are two examples of categories listed in the Controlled Substance Diversion Best Practice?**

a. Procurement & Prescribing
b. Storage & Signage
c. Automation & Regulatory
d. Both A & C

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