

June 24, 2015

## Drug Diversion: Protecting Your Patients and Organization

### *AT A GLANCE*

#### ***At Issue:***

Drug diversion, the diversion of legal drugs for illicit purposes, can cause serious harm to patients, the diverter, providers and the community. As prescription drug abuse continues to increase, drug diversion will become an increasingly significant issue. Hospitals need to have systems and procedures in place to detect and respond quickly in order to mitigate harm to patients.

#### ***Our Take:***

We urge hospitals to assess the steps they have taken to prevent drug diversion and adequately prepare to respond if it does occur. The most effective drug diversion prevention programs include a set of complex and technologically advanced systems and procedures specifically designed to monitor and manage controlled substances (CS) in health care facilities. Effective drug diversion prevention and response fundamentally depends on a culture of safety. Other important elements include educational initiatives, a prevention coordinator or CS manager, a CS code of conduct, a reporting system, state-of-the-art security and surveillance systems, employee screening and diversion investigation protocols and procedures.

This advisory provides an overview of the problem of drug diversion in context and outlines the essential aspects of a successful drug diversion prevention program.

#### ***What You Can Do:***

- ✓ Share this advisory with your chief medical officer, chief nursing officer, chief quality officer, hospital pharmacist, and directors of anesthesia, surgical services, human resources, risk management and patient safety.
- ✓ Contact your state health department to learn more about how you can collaborate with your state's Prescription Drug Monitoring Program.

#### ***Further Questions:***

Nancy Foster, vice president of quality and patient safety policy, at [nfoster@aha.org](mailto:nfoster@aha.org) or (202) 626-2337.

## **Drug Diversion: Protecting Your Patients and Organization**

### *At Issue*

#### **Overview**

Drug diversion, the diversion of legal drugs for illicit purposes,<sup>1</sup> can cause serious harm to patients, the diverter, providers and the community. In hospitals, drug diversion can result in patients not receiving intended care. When diversion does occur, hospitals need to have systems and procedures in place to detect and respond quickly in order to mitigate harm to patients. Many successful drug diversion prevention programs are interdisciplinary cooperative systems that involve providers, pharmacists, information technology (IT) professionals, safety, maintenance and security personnel, executive management, attorneys and other staff working together.

To protect patients, health care professionals must be held to high professional and ethical standards. The vast majority of clinicians and hospital staff provide high-quality hospital care and perform their duties with the integrity. Yet some hospital staff may engage in reckless or criminal behavior that can harm to patients. When this behavior involves the diversion of drugs, addiction is typically the main motivating factor.

The use of prescription opioids and other prescription narcotics outside of their intended clinical use is dangerous for patients and for users. Commonly diverted drugs such as fentanyl are several times more potent than drugs such as heroin and often used as a substitute for heroin in opioid-dependent persons. Employees who divert these drugs from their intended use may put their own health, life and career in danger. Further, the legal penalties for drug diversion can be severe. Offenders have received prison sentences of up to 30 years for exposing patients to disease by using and returning syringes drawn up with controlled substances prepared for patients. In such cases, the severity of the punishment will increase depending on the recklessness of the diverter's actions and the harm caused. When an employee's reckless act harms a patient, a hospital can be subject to legal liability for failure to prevent injury. It is critical to recognize and address signs of drug diversion.

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<sup>1</sup> Centers for Medicare & Medicaid Services, Get the Facts.  
<http://www.drugwarfacts.org/cms/Diversion#sthash.hat6GFsA.dpbs>.

This advisory identifies the regulatory and legal authorities that address drug diversion and describes technology, policies and procedures that hospitals can use to prevent and respond to diversion effectively.

### **Addiction, Prescription Drugs and Drug Diversion in Hospitals**

Over the past two decades, addiction to prescription drugs has increased dramatically and drug diversion has increased as well.<sup>2</sup> Within hospital facilities, drug diversion most often occurs among members of the anesthesiology department.<sup>3</sup> Opioids, such as fentanyl, are the most commonly diverted drugs from health care facilities, and these kind of psychotropic drugs are more readily available to anesthesiologists than other health care professionals.<sup>4</sup> Data confirm that clinicians in anesthesiology departments also have higher rates of opioid addiction than other clinicians.<sup>5</sup> Other drugs that are diverted frequently include antipsychotic medications and drugs used in the treatment of other psychiatric disorders, such as Xanax, Ativa, Risperdal and Abilify.<sup>6</sup>

A hospital's safety and security procedures also may have a significant impact on its employees' propensity to divert drugs. A survey by Trinkoff et al, suggests that, when nurses have easy access to prescription drugs, they are more likely to divert them.<sup>7</sup> Nurses at hospitals with reputations for poor medication management, are 1.5 times as likely to abuse substances.<sup>8</sup> While, the majority of diversions occur to feed addiction, the methods of diversion can differ.<sup>9</sup> Diverters may take unopened vials and syringes, or take partially used vials and syringes containing residual drugs. They may take discarded syringes with residual drugs from the waste bins and sharp containers. A more dangerous form of diversion occurs when a provider takes a vial or syringe containing a controlled substance from a cart or tray intended for a patient, uses the medication, refills the syringe with a readily available substance that is similar in

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<sup>2</sup> Public Policy Statement on Measures to Counteract Prescription Drug Diversion, Misuse and Addiction by American Society of Addiction Medicine, 2012.

<sup>3</sup> Keith Berge, MD, et al. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention." Mayo Clinic Proceedings. July 2012;87(7):674-682 <http://dx.doi.org/10.1016/j.mayocp.2012.03.013681>

<sup>4</sup> "Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid" CMS, January 2012, page 1. Mayo Clinic 674-675.

<sup>5</sup> Keith Berge, MD, et al. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention." Mayo Clinic Proceedings. July 2012;87(7):674-682 <http://dx.doi.org/10.1016/j.mayocp.2012.03.013681>

<sup>6</sup> "Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid" CMS, January 2012, page 1.

<sup>7</sup> Trinkoff AM, Storr CL, Wall MP. Prescription-type drug misuse and workplace access among nurses. J Addict Dis. 1999; 18(1):9-17.

<sup>8</sup> Trinkoff AM, Storr CL, Wall MP. Prescription-type drug misuse and workplace access among nurses. J Addict Dis. 1999; 18(1):9-17.

<sup>9</sup> Keith Berge, MD, et al. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention." Mayo Clinic Proceedings. July 2012;87(7):674-682 <http://dx.doi.org/10.1016/j.mayocp.2012.03.013681>

appearance and replaces the vial or syringe or the cart or tray.<sup>10</sup> The patient who was intended to receive a drug at a certain dosage may then receive a diluted or contaminated dose, or an alternative substance.

On very rare occasions, there have been individuals who diverted drugs with the express intent of harming or killing patients. Hospitals' actions to prevent drug diversion can protect patients from these so-called "Angels of Death," too.

### **Reasons for Drug Diversion**

The majority of drug diverters do not do so with malicious intent; instead, the diversion is motivated by addiction. Still, their actions may pose significant risk for patients or other staff. One example involves a radiology technician at a hospital in Jacksonville, Fla. After an outbreak of Hepatitis C, investigators discovered that, from 2006-2008, the technician stole syringes of fentanyl during patient procedures and replaced them with syringes of saline contaminated with Hepatitis C.<sup>11</sup> The hospital's epidemiologist, the Florida Department of Health and the Centers for Disease Control and Prevention (CDC) worked for several years to track down the source of the outbreak and tested more than 3,000 patients who were determined to be at risk.<sup>12</sup> The hospital discovered that five people contracted Hepatitis C from the technician. The technician faced criminal charges and pled guilty to tampering with a consumer product resulting in death, four counts of tampering with a consumer product resulting in serious bodily injury, and five counts of stealing fentanyl by deception. He faced a maximum penalty of life in federal prison but received 30 years.<sup>13</sup>

In a similar incident, a surgical technician at a hospital in Colorado was convicted of diversion in 2009. The technician used syringes filled with fentanyl and replaced them with saline before they were used on patients. Hospital personnel caught the technician when they found her in a room she did not have authorization to be in with a syringe she should not have had.<sup>14</sup> Estimates suggest that her actions may have infected up to nine patients who received care at the center.<sup>15</sup> Another hospital in New Hampshire has been dealing with the repercussions from the actions of a past employee who diverted drugs and infected potentially dozens of patients with Hepatitis.<sup>16</sup>

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<sup>10</sup> Keith Berge, MD, et al. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention." *Mayo Clinic Proceedings*. July 2012;87(7):674-682 <http://dx.doi.org/10.1016/j.mayocp.2012.03.013> 681.

<sup>11</sup> Mayo Clinic Radiology Tech Pleads Guilty to Spreading Hepatitis C, <http://www.fbi.gov/jacksonville/press-releases/2012/mayo-clinic-radiology-tech-pleads-guilty-to-spreading-hepatitis-c>.

<sup>13</sup> Mayo Clinic Radiology Tech Pleads Guilty to Spreading Hepatitis C, <http://www.fbi.gov/jacksonville/press-releases/2012/mayo-clinic-radiology-tech-pleads-guilty-to-spreading-hepatitis-c>.

<sup>14</sup> HEP-C case in Denver has hospitals examining preventive strategies by Geri Aston, *AHA News*, Vol. 45, No. 16, August 13, 2009, <http://www.aha.org/content/00-10/HEPC%20Denver080309.pdf>.

<sup>15</sup> Hospital worker may have exposed patients to hepatitis by Jim Spellman, *CNN-Crime*, July 3, 2009 <http://www.cnn.com/2009/CRIME/07/03/hospital.employee.arrest/>.

<sup>16</sup> NH Report Criticizes Hospital in Hep C Outbreak by Holly Ramer, *ABC News*, June 22, 2013, <http://abcnews.go.com/Health/wireStory/nh-report-criticizes-hospital-hep-outbreak-19459945>.

## **Core Elements of a Drug Diversion Prevention Program**

An effective drug diversion prevention program should be built upon a culture of safety and include staff education, a code of conduct, a reporting system, a surveillance system, periodic employee screening and an effective investigation protocol.

### **1. Culture of Safety**

Programs, systems and technology are necessary, but the hospital staff's overall attitude toward safety, or "just culture," is equally, if not more, important.<sup>17</sup> While medical errors, oversights and adverse events may occur, a strong safety culture can help prevent medical errors or adverse events from claiming lives.<sup>18</sup> A number of programs aimed at teaching safety fundamentals exist. For example, David Marx founded Outcome Engineuity, which teaches elements of Just Culture. The Agency for Healthcare Research and Quality (AHRQ) Patient Safety Culture survey<sup>19</sup> and Brian Sexton's "Safety Culture" survey<sup>20</sup> both query employees on safe culture fundamentals.

### **2. Educational Programs**

Education programs should begin during orientation and continue throughout an employee's tenure with a hospital. Each staff member should be educated on the dangers of drug diversion and the hospital's policies and procedures, including policies concerning the reporting of suspicious behavior by other employees, volunteers and staff. Hospitals also should teach their employees how to detect drug diversion and other unusual events. This should include teaching them how to screen a patient's pain level during surgery and treatment, and how to detect discrepancies in electronic health records (EHRs).

### **3. Medication Diversion Prevention Coordinator and Drug Diversion Response Teams**

Diversion prevention coordinators are important and act as the initial point of contact for all suspected diversions. They also coordinate preliminary investigations in suspected cases of drug diversion and initiate and coordinate meetings with the drug diversion response team (DDIRT). The diversion prevention coordinator also acts as a crucial link with law enforcement, when needed. In addition, the coordinator oversees the surveillance program and maintains a database of cases.

### **4. Code of Conduct that Sets Standards to Prevent Non-criminal and Criminal Acts or Omissions**

Codes of conduct provide concrete rules and guidelines on how the hospital will handle cases of suspected or confirmed drug diversion. The code of conduct defines the nature of remedial action taken against employees who commit intentional acts and reckless

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<sup>17</sup> Singer, Sara J., and A. Tucker. "Creating a culture of safety in hospitals." *Abstr Academy Health Meet* 22 (2005): 1-41.

<sup>18</sup> Institute of Medicine. 2000. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press.

<sup>19</sup> <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html>

<sup>20</sup> JB Sexton, et al. "Safety Attitudes Questionnaire: psychometric properties, benchmarking data and emerging research," *BMC Health Services Research*. V6, 2006.



acts that violate codes of conduct, ethics or laws. The code of conduct also should outline and address patient and organizational risks from drug diversion.

## **5. Suspicious Act Reporting**

To prevent drug diversion and to respond appropriately when it occurs, hospitals need to get reports of suspicious activity promptly. A reporting system is a valuable tool that can enable staff to report suspicious activity and enable security and the administration to respond by investigating further and taking action, if appropriate.

## **6. Drug Security and Surveillance Techniques**

Drug security and surveillance techniques, such as one-use syringes and EHR bar codes linked to an alert system, can be useful as well. EHR bar codes that are connected to a surveillance and alarm system flag unusual behavior and help administrators catch suspicious acts as they occur. Another surveillance and drug security measure involves the monitoring of patient pain levels. Higher-than-expected pain levels can be a sign that the patient's drugs have been diverted.

## **7. Employee Screening and Substance Abuse Treatment**

Early detection programs include initiatives that encourage colleagues to hold one another accountable. Some hospitals have found that because the focus of an early detection program is restorative and less punitive, employees are more willing to share information because they feel like they are helping a colleague in need and not reporting him/her for disciplinary action. Peer review assessments also have been recognized as effective tools. The American Organization of Nurse Executives' (AONE) culpability chart has been used as a form of peer review for nurses with satisfactory results. In addition, some hospitals have found that offering substance abuse treatment is an effective way of preventing employees from diverting drugs to feed their addiction.

Drug screening, criminal background checks and searching national provider practitioner databanks are ways of identifying prospective employees who may be at increased risk of committing drug diversion or have committed diversion in the past.

Truthful references can provide employers with information on a prospective employee's past job performance, past employment misconduct and remedial action taken by his/her previous employers. They also can help prevent would-be serial diverters from moving from hospital to hospital. However, references have not been fully utilized in many states because many employers are dissuaded from providing truthful references out of fear of being sued for defamation by a past employee.<sup>21</sup> Thirty-eight states have job reference shield laws that provide protection for employers who provide honest performance information to future employers. The District of Columbia and 12 states have no such protection. A summary of the existing provisions is available at:

<https://www.crimcheck.com/resources/job-reference-shield-laws>.

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<sup>21</sup> Please reference the job reference shield laws chart in Appendix D for more information about each state's laws on truthful references.

## 8. Investigation Protocol

The investigation process is a crucial element in drug diversion. Without a thorough and detailed investigation, many diverters will not be identified and their acts will continue.

### **Guidance for Hospitals**

AONE has created [guiding principles](#) to help providers review their preparedness to deal with drug diversion and other bad acts. Effective recruitment, screening and hiring is the first crucial element. It is important to involve health care human resource (HR) professionals, nurse directors, medical staff and executives in the screening and hiring process. In addition to the usual process for verifying professional credentials and screening for drugs, HR should conduct reference checks with past employers and inquire whether or not the former employer would rehire the candidate and, if not, why.

Hospitals also should ensure that each new clinical staff member is effectively oriented. Successful onboarding is a proactive, transparent and flexible process. It also should engage those involved in the process, such as HR, nurse managers, executives, risk managers and other staff. Onboarding should provide support and consistently communicate the processes essential to creating a safe patient and work environment.

Once hired, AONE recommends that staff are monitored for high-risk or reckless behavior. The monitoring process should include the following: the establishment of appropriate job performance criteria; behavioral performance reviews; evaluations of clinical staff transfers to ensure that employees with a history of high-risk or reckless behavior do not move around in an organization to avoid detection; ensuring that there are multiple channels available through which employees can report suspicious behavior; ensuring that there are ongoing quality and safety assessment mechanisms available to review staff; and that a system is in place to identify and alert staff of discrepancies in medication administration and adverse events.

When there is a reason to suspect that an adverse event may have been the result of malicious behavior, AONE recommends the following actions be taken: 1) respond to the patient first, and then determine if there is an ongoing threat and take the appropriate actions needed to mitigate or stop harm; 2) notify the risk manager; 3) remove the suspected clinician from the unit or environment; 4) contain the environment; 5) ensure staff have the appropriate support; 6) conduct a thorough, objective, valid, confidential and timely investigation; 7) take appropriate actions to ensure the clinician is dealt with; 8) take corrective actions to prevent further diversion of drugs; 9) refer to “workplace violence” or “fitness for duty” policies; 10) report the incident in accordance with applicable state and federal laws and regulations, and accrediting body standards.

### **What States Are Doing**

State wide drug diversion initiatives include prescription drug monitoring programs (PDMPs) and continuing medical education (CME). PDMPs are statewide electronic databases that collect information regarding legally dispensed controlled substances in the state. Research indicates that, when fully utilized, PDMPs are useful tools against

drug diversion. PDMPs may provide patient care toolkits, drug epidemic early warning systems and drug diversion investigative tools to providers.<sup>22</sup> Professional licensing boards may use PDMPs to identify medical professionals with improper prescribing and dispensing practices. PDMPs also help law enforcement investigate and prosecute cases of drug diversion and reduce the amount of time required to investigate cases of diversion or suspected diversion.<sup>23</sup>

Currently, 49 states and the District of Columbia have enacted legislation establishing a PDMP, and all of them are active except the one in the District of Columbia.<sup>24</sup> Only a few PDMPs provide their physicians with real-time information and function within the normal workflow of the physician.<sup>25</sup> The majority of states allow licensed physicians and prescribers, law enforcement and medical boards to access PDMP information.<sup>26</sup>

Lastly, 10 states require courses on the prescription of controlled substances as part of continuing medical education. These courses can increase awareness of drug diversion among clinicians and keep them abreast of new technologies, strategies and best practices with respect to prevention, detection and response.

**State Laws, Regulations and Initiatives.** A variety of state laws and regulations apply to drug diversion. Many of the laws are criminal and penal in nature; others perform regulatory functions. Because of the depth and breadth of the many state laws that could apply, this advisory will highlight only a few notable state statutes that specifically deal with drug diversion.

The Oklahoma Anti-Drug Diversion Act (63 O.S. Section: 2-309) requires all dispensers of controlled substances to submit prescription dispensing information to the appropriate agency within 24 hours of dispensing a scheduled narcotic. The act also created the state's PDMP. The Oklahoma Interventional Pain Management and Treatment Act (SB 479) limited the practice of interventional pain management to licensed doctors of medicine or osteopathy. This act also prohibited nurse anesthetists from operating a freestanding pain management facility without the direct supervision of a board-certified interventional pain management physician or equivalent.

Utah's Controlled Substance Database Amendments (HB28) provided for the stricter enforcement of drug laws targeted at prescription drug abuse. The law aimed to increase public awareness of the dangers of prescription drug abuse, provided harsher sanctions for those who abuse prescription drugs, and created a network for the disposal of unwanted prescription drugs.

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<sup>22</sup> <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>, March 2015.

<sup>23</sup> Prescription Drug Monitoring Programs, Congressional Research Service, January 3, 2013.

<sup>24</sup> <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>.

<sup>25</sup> Advocacy Resource Center, American Medical Association, <http://www.ama-assn.org/ama/pub/advocacy/topics/combating-prescription-drug-abuse-diversion.page>.

<sup>26</sup> Drug diversion survey results, Advocacy Resource Center, American Medical Association, <http://www.ama-assn.org/resources/doc/washington/drug-diversion-state-survey-results.pdf>.



Florida law S 2272 provided state officials with the authority to increase oversight of pain-management clinics. The law tightened regulations on clinics, increased potential penalties, limited cash-paying patients to a 72-hour supply for dispensation, and banned the advertising of certain treatments, such as opiate oxycodone

Massachusetts has created a Drug Diversion Control unit.<sup>27</sup> This unit develops security and accountability standards for controlled substances in health care facilities, ensures that providers and suppliers of care comply with these standards, and educates health care providers and the general public.<sup>28</sup> In August 2010, Massachusetts policymakers enacted a new detection system designed to stop “doctor shopping” by patients addicted to prescription narcotics. The prescription reporting system updates weekly, allows physicians to review and identify patients with a history of abuse and provides physicians with reports on patients who are flagged by the monitoring system.<sup>29</sup>

### ***What the Federal Government Is Doing***

**Federal Initiatives.** The federal government has launched several initiatives to address drug diversion. The most important are:

- 1) The Drug Enforcement Administration (DEA) and Department of Justice (DOJ) established the Office of Diversion Control in 2005 to investigate and prevent the diversion of drugs.
- 2) The DEA’s Automation of Reports and Consolidated Order Systems (ARCOS) database, which monitors the flow of DEA controlled substances from their point of manufacture to their distribution to hospitals, retail pharmacies, practitioners and other providers;
- 3) Through a 2013 regulatory change, the DEA expanded the opportunities for hospitals and other health care facilities to serve as prescription drug take-back sites. Hospitals can collect unused controlled substances from patients who did not need to use the entire amount of the drugs prescribed for them can now return them to participating hospitals for safe disposal.
- 3) The consolidation of information about providers into the National Practitioner Data Bank (NPDB). The Affordable Care Act authorized the Secretary of Health and Human Services to transfer all information from the Healthcare Integrity and Protection Data Bank to the NPDB. The NPDB now contains information on adverse licensure, clinical, professional board actions, as well as civil judgments and criminal convictions, against select health care professionals for health care-related offenses.

**Federal Statutes and Regulations.** There are a variety of statutes and regulations that govern the management of controlled substances. Examples include requiring providers

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<sup>27</sup> Drug Diversion Overview, Massachusetts Department of Health and Human Services, <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-diversion/>.

<sup>28</sup> Drug Diversion Overview, Massachusetts Department of Health and Human Services, <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-diversion/>.

<sup>29</sup> Drug Diversion in the Medicaid Program, <http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf>.

to use storage and distribution systems, record keeping and use of tamper resistant prescription pads as a condition of participation in the Medicare program. Other regulations outline how employers should handle suspected drug diversion and define the appropriate action to be taken against employees who have diverted drugs. There also are regulations that require health care employees with knowledge of illegal drug activity to report such activity. The abuses and losses of controlled substances must be reported to the pharmaceutical services officer and chief executive officer.

**Federal Initiatives.** A synopsis of relevant federal initiatives is shown in Appendix A.

## **Next Steps**

Drug diversion is a potential problem for any hospital and, thus, hospital leaders must put safeguards in place to protect patients and staff members. Please share this advisory with your organizational leadership team and those who head departments where opioids and other dangerous drugs are commonly used for patient care. Ask your staff to assess the protections already in place in your organization against the core elements of a drug diversion program described in this advisory and to make suggestions for improvements, if needed.

If you have further questions, please contact Nancy Foster, vice president of quality and patient safety policy, at [nfoster@aha.org](mailto:nfoster@aha.org) or (202) 626-2337.

## Appendix A: State and Federal Initiatives

<b>Federal Initiatives</b>	
Office of Diversion Control (DEA & DOJ)	The agencies have established the Office of Diversion Control to investigate, detect and prevent the diversion of drugs. <sup>30</sup>
PPACA 6403	Requires the Secretary to transfer all information in the HIPDB to the NPDB. As a result, the NPDB can now collect information on adverse licensure, clinical, professional board actions as well as civil judgments and criminal convictions against select health care professionals for health care related offenses.
ARCOS (Automation of Reports and Consolidated Order Systems)	This program monitors the flow of DEA controlled substances from their point of manufacture to their distribution to hospitals, retail pharmacies, practitioners, and other providers <sup>31</sup> .
<b>Federal and State Initiatives</b>	
Harold Rogers Prescription Drug Monitoring Program (DOJ) Federal and State	This program seeks to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data through a centralized database administered by an authorized state agency. Improve the efficiency of PDMPs to allow the early detection of abuse and possible sources of diversion, including: building a data collection and analysis system at the state level, enhancing existing programs' ability to analyze and use collected data, facilitating the exchange of collected prescription data between states, and assessing the efficiency and effectiveness of the programs funded under this initiative. <sup>32</sup>
National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) grant (HHS)	Provides grants to states to establish PDMPs. This system and its reporting requirements help providers more appropriately prescribe controlled substances and identify illicit use and abuse.

<sup>30</sup> Inside Diversion Control, U.S. Department of Justice, Department of Drug Enforcement, Office of Diversion Control, [http://www.deadiversion.usdoj.gov/prog\\_dscrpt/index.html](http://www.deadiversion.usdoj.gov/prog_dscrpt/index.html); "Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid" CMS, January 2012, page 2.

<sup>31</sup> Automation of Reports and Consolidated Orders System (ARCOS), U.S. Department of Justice, Department of Drug Enforcement, Office of Diversion Control, <http://www.deadiversion.usdoj.gov/arcos/>.

<sup>32</sup> Harold Rogers Prescription Drug Monitoring Program, Bureau of Justice Assistance, Department of Justice, <https://www.bja.gov/Publications/PDMP.pdf>.

Education Medicaid Contractor	CMS and states are working together to provide educational resources on drug diversion through the Education Medicaid Contractor. This initiative is helping providers identify drug seeking behavior in beneficiaries and how to report suspicious or fraudulent behavior in health care facilities. <sup>33</sup>
<b>State Initiatives</b>	
Diversion Investigation Unit	Several states have these specialized units staffed to investigate diversion.
State Prescription Drug Monitoring Programs	<p>Store and distribute prescription drugs and controlled substances. Interstate sharing mechanisms vary from state to state and some states do not share any information with other states.<sup>34</sup> PDMPs can help monitor the dispensing of controlled substances prescribed. States are given a wide range of discretion in deciding how each PDMP will function. Often included information on dispense and use of prescribed controlled substances, who is addicted. Some suggested improvements include:</p> <ul style="list-style-type: none"> <li>• Make PDMPs data accessible by clinicians, administration and oversight committees.</li> <li>• Make PDMPs Accessible in real time.</li> </ul>

As of March, 49 of the 50 states have operational prescription drug monitoring programs. Missouri is the only state that does not. The District of Columbia has passed legislation to establish a PDMP, but it is not yet operational. Further information about the fundamentals of each of the state programs is available at: <http://www.pdmpassist.org/content/state-profiles>.<sup>35</sup>

<sup>33</sup> “Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid” CMS, January 2012, page 2.

<sup>34</sup> Prescription Drug Monitoring Programs, by Kristin M. Finklea, Erin Bagalman, Lisa N. Sacco, Analyst in Illicit Drugs and Crime Policy CRS Report for Congress, January 3, 2013; “Drug Diversion in the Medicaid Program State Strategies for Reducing Prescription Drug Diversion in Medicaid” CMS, January 2012, page 4.

<sup>35</sup> Prescription Drug Monitoring Program Training and Technical Assistance Center at The Heller School for Social and Policy Management at Brandeis University.

## Appendix B: Federal Statutes and Regulations

Federal Implementing Organization	Federal Statute	Regulatory/Legal Requirements
HHS	CFR 42 §482.25(b)(7)	Must report abuses or losses of CSs to head of pharmaceutical services and CEO.
FDA	Title 18 U.S.C. Sect 1365 Tampering with Consumer Products	Confidential/protected nonpublic for active/pending investigations. Public for inactive investigations, unless it would jeopardize another pending action.
FDA	Title 21 U.S.C., Sections 331 (a) and 331 (k) Misbranded/adulterated Drug	Confidential/protected nonpublic for active/pending investigations. Public for inactive investigations, unless it would jeopardize another pending action.
DEA	The Comprehensive Drug Abuse Prevention and Control Act of 1970 21 U.S.C., Section 800 to end	222 form and record keeping, registration, eligibility, location and security.
DEA	Title 21 U.S.C., Sect 843 Obtaining a Controlled Substance by Fraud	Confidential/protected nonpublic for active/pending investigations. Public for inactive investigations, unless it would jeopardize another pending action.
DEA	Title 21 U.S.C., Sect 841 Distribution	Confidential/protected nonpublic for active/pending investigations. Public for inactive investigations, unless it would jeopardize another pending action.
DEA	21 CFR Part 1300	Regulations relating to security, records, inventories, orders, prescriptions, disposal, wasting, return and accounting for the controlled substances.
DEA	21 CFR Part 1301.92 regulations (all of 1300) Regulations Promulgated Pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970	Employees who possess, sell, use or divert controlled substances will subject themselves not only to state or federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.



DEA	21 CFR 1301.91 Employee responsibility to report drug diversion	An employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.
DEA	(21 CFR 1301.75(b))	CS must be stored in "a securely locked, substantially constructed cabinet....pharmacies and institutional practitioners may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substance."
DEA	(21 CFR 1301.90)	The conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry in employee screening.

## **Appendix C: Case Studies – What Hospitals Are Doing**

### **Mayo Clinic’s 77 Best Practices**<sup>36</sup>

Mayo Clinic has outlined 77 elements of best practice in their CS diversion, detection and prevention program. The elements are grouped into 10 categories and two priority tiers. The following is a summarized list of these 77 elements.

#### **1. Core Principles**

The core principles of Mayo Clinic’s 77 elements of best practice are: 1) maintaining the chain of custody and individual accountability of CSs at all times; 2) ensuring that organizational policies that address all aspects of CS medication use processes are in place at all times; and 3) ensuring that the all staff members adhere to these policies.

#### **2. Storage & Security**

CSs are always securely stored in a locked location, with automated safe technology (i.e. ADM, safe, locked cabinet/drawer), and CSs are under the direct control of authorized personnel. Access to CS storage areas are minimized and limited to authorized personnel. CSs are not placed in an area where their view can be obscured or they cannot be under direct observation at all times.

#### **3. Procurement**

Procurement policies and procedures should require that all CSs are obtained from the pharmacy and are acquired by authorized pharmacy or clinical staff. The number of personnel authorized to order CSs are minimized and the ordering and receipt of CSs is divided into two separate duties. Multiple personnel are involved in the checking-in of CSs and the counting of CSs received and ordered, and a system is in place to identify unusual peaks in the quantity and frequency of CSs ordered. Inventory levels are based on usage which will help minimize excess stock. Hospitals use electronic CS ordering systems and have eliminated paper DEA 222 forms.

#### **4. Ordering/ Prescribing**

CSs are only ordered by licensed and DEA-authorized personnel. Range orders for CSs are eliminated and orders are generated by an electronic system with controlled access, except in emergencies.

#### **5. Preparation & Dispensing**

CSs are dispensed in unit dose packaging when possible. CS waste disposals are randomly examined, especially in the pharmacy. CSs are delivered using secure, lockable, non-transparent delivery carts. ADM technology is used whenever possible, especially in patient care areas. Instead of passwords, BIO-ID (biometric thumbprint entry) ADM technology is used for access. CS storage cabinets that are not equipped

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<sup>36</sup> [https://www.premierinc.com/safety/topics/drug\\_diversion/index.jsp](https://www.premierinc.com/safety/topics/drug_diversion/index.jsp);  
<http://www.nhha.org/files/whatsnew/NH%20Forum%20on%20Drug%20Diversion10-25-12%20%28Dillon%29.pdf>.

with ADM technology are secured using an electronic lock and the delivery of CSs to non-ADM areas require co-signature for delivery and return.

## **6. Administration**

No CSs are administered without a valid order from an authorized prescriber. CSs should only be administered by licensed or registered health care providers within their scope of practice. CSs should be retrieved as close to the time of administration as possible and the package size of CSs should be as close to the dose to be administered as possible. The person retrieving CSs from ADM storage also should be the person administering the medication.

When CSs are drawn into syringes, that are not for immediate use, the syringes are labeled with the person's name that drew up the drug. Just before administration, providers verify that the initials on prepared syringes are correct and that syringes have not been switched. The facility has established procedures for wasting CSs and all wasting requires an independent witness and documentation. Universal precautions are used when handling CS waste and CS waste from high risk medications and high-risk areas are given heightened scrutiny. Unused ADM managed CSs are returned to a bin and not the original ADM container. All CSs returns to the pharmacy require a co-signature from personnel in the patient care area and the pharmacy. All CSs administered are documented in the medical record.

## **7. Inventory & Record Keeping**

The hospital keeps an inventory of all CSs maintained. Using ADM technology, CS counts should be verified each time a CS drawer is accessed. ADM managed CSs are also manually inventoried by two authorized pharmacy providers on a routine basis. All non-ADM managed CSs are manually inventoried by two authorized health care providers every shift. A biennial physical inventory of all CSs is completed and documented, per DEA requirements.

## **8. Surveillance**

CS waste is randomly tested for content. ADM CS discrepancies are resolved by at least two authorized providers and within the same shift/business day in which the discrepancies arise. If discrepancies are not resolved, the facility has a process in place for further investigation. Surveillance reports are created and reviewed on routine basis. Inventory, order and administration sheets and documentation are also routinely reviewed and audited. Surveillance cameras are installed in pharmacy storage and preparation areas and other high-risk/high-use areas.

## **9. Investigation and Response**

The facility has a 24/7 medication diversion hotline available for employees to report suspected drug diversion and be able to do so anonymously, if desired. The hospital has a multidisciplinary "Drug Diversion Response Team," or its equivalent, in place to provide consultation, direction and oversight for suspected incidents of drug diversion. There is a standardized process and guidelines for handling, interviewing and drug testing suspected CS diverters. There is an established protocol for the internal and external reporting of incidents of drug diversion incidents.

## **10. Education**

Hospital staff is required to participate in an education program on diversion and CS policies and procedures before being authorized to access. The facility has established an ongoing drug diversion education program to promote the safe handling of CSs and increase awareness of diversion among staff.

### **Rose Medical Center (RMC)**

RMC dealt with a repeat diverter and subsequent Hepatitis C outbreak in its facility between 2008-2009. While RMC had policies in place prior to this event, it took more aggressive steps after the incident. The following is a timeline of RMC's drug diversion prevention, detection and response initiatives both before and after it dealt with a major incidence of drug diversion.

#### **1. Medication Security 2003-2009**

In 2003, RMC installed Accudose cabinets, which provide controlled medication security, in all 27 operating and supply rooms. Later, RMC placed secondary anesthesia carts for supplies and non-controlled medications in each operating room (OR). Carts were stocked daily and carts could be locked by Anesthesiologists.

#### **2. Immediately After 2008-2009 Incident**

RMC created a 24/7 incident command and patient support line. They setup a team of medical experts to help with patient inquiries related to Hepatitis C incident. A clinical team also began calling all patients impacted by the event. A team also was organized to provide media support and hold press conferences.

#### **3. 2010**

In 2010, RMC installed Pyxis A-stations and access to these stations is contingent on employees completing cabinet orientation, signing a safe practices acknowledgement form. RMC also determined that medications must be removed from the Pyxis in that procedural area (closest proximity cabinet). RMC established several other policies and procedures, including: treating propofol as a controlled medication; establishing new wasting practices that require a timely RN witness; loss of CS related privileges for lack of compliance or failure to respond to discrepancies; making pharmacy staff responsible for stocking all patient care and procedural areas in the hospital; standardizing policies and procedures in all procedural departments of the hospital; implementing diversion detection software; and RMC expanded their employee drug screen panel from seven to 10 substances in order to include select pharmaceuticals in addition to drugs of abuse.

#### **4. Cultural Changes**

Mangers at RMC now conduct routine direct observation of medication disbursement and administration practices in the OR. RMC holds hospital-wide diversion education sessions taught by addiction experts and an RN who is recovering from substance

addiction. At the beginning of each course, the importance of safety and a culture of safety is heavily emphasized.

## **5. Hiring Practices**

RMC has adopted new hiring practices that are used to screen potential employees. All candidates must participate in standardized behavioral-based interviews with at least two levels of management. Hiring staff also reviews applicants' social media. Lastly, candidates that make it past the interview stage must undergo a 10-panel drug test and an executive must approve each new hire.

### **McClure et al., Hospital Survey**

A 2011 survey by McClure et al., reports that there is an appreciable variation among facilities' use of best practices for the prevention, detection and response to drug diversion.<sup>37</sup> Some of this variation is associated with the size of the hospital. The respondents were surveyed on their hospital's practices in pharmacy, OR and nursing units. Sixty-three percent of large hospitals (400> beds) reported that they always reconciled the quantity of CSs dispensed for an OR case against the quantity CSs documented as administered or returned to the pharmacy for disposal. While only 44 percent of smaller hospitals (400<) do the same. CSs that were not used in the OR were only returned to the pharmacy for wasting 20 percent of the time in smaller hospitals, but 57 percent of the time in larger hospitals.

The practices within the hospital nursing units were more symmetrical. The vast majority (around or above 90 percent) of the hospitals polled use decentralized ADMs for CS distribution. Virtually all institutions "always" or "sometimes" investigated explanations for ADM discrepancies. Almost all use a system capable of electronically identifying discrepancies between central pharmacy vault withdrawals and nursing unit ADM receipts. Also, almost all institutions that used diversion detection software "sometimes" or "always" investigated flagged individuals. Seventy-two percent of larger hospitals and 67 percent of smaller hospitals analyzed ADM discrepancies to identify individuals most frequently involved in discrepancies. Just over half of the institutions investigated ADM stock outages for potential diversion. Just over half of the hospitals used biometric fingerprint scans or ADM access. Eighty-seven percent of large hospitals and 68 percent of smaller hospitals use diversion software that flags users for CS ADM transaction counts significantly above their peer group's mean. Very few (less than a third) of nursing units use email, voice mail, or pager alerts to notify pharmacy leaders when a specified ADM transaction threshold has been exceeded.

Responses on pharmacy practices within large and small hospitals were somewhat closely aligned. More than 95 percent of hospitals surveyed require a witness and documentation when wasting controlled substances. Around 85 percent of the hospitals audit CS purchases against the quantity of CS added to the pharmacy inventory on a quarterly basis. Ninety-seven percent of larger hospitals and 75 percent of smaller

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<sup>37</sup> McClure et al., Compliance with Recommendations for Prevention and Detection of Controlled-substance Diversion in Hospitals, *Am J Health Syst Pharm*. 2011;68(8):689-694, <http://www.medscape.com/viewarticle/740560>.



hospitals use automated vaults to store CSs. Seventy-three-percent of larger hospitals and 55 percent of smaller hospitals have cameras directed at CS storage areas. However, only 24 percent of smaller hospitals ban personal belongings from drug storage areas and only 37 percent of larger hospitals do.