THE FEASIBILITY OF ADDING CONTROLLED SUBSTANCE WASTE ASSAY TESTING TO A CURRENT DRUG PREVENTION PROGRAM

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Joseph Martin Bailon, titled The Feasibility of Adding Controlled Substance Waste Assay Testing to a Current Drug Prevention Program and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

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DEDICATION

I would like to thank my family and friends for their understanding and patience during the last year and a half. Mostly, I would like to express a very special thanks to my wonderful wife, and sons for their unstoppable support, help, and empathy. Thank you all, for providing me with continuous encouragement throughout my years of study and through the process of researching and writing this project. Without these wonderful people, I would not be where I am today. Thank you!

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ABSTRACT

Anesthesia care providers (ACP) are entrusted with enormous access to controlled substances and anesthetics of various types and strengths. This access enables them to perform a highly technical and stressful job. Many studies have determined that ACPs are at significant risk for drug abuse and drug diversion while at work. The current intervention of providing education on the high risk of drug use among anesthesia professionals has not decreased drug diversion, in fact it currently remains unchanged and has increased making it the most significant occupational safety hazard ACPs face daily. A thorough review of the literature about drug diversion and CS waste assay testing was performed and implications for practice and suggestions were summarized in a project proposal. This project focused on determining if implementation of a controlled substance (CS) waste assay testing program is a feasible option at a large level one-trauma center. To elicit feasibility for implementation of a new method for detecting drug diversion key stakeholders of this medical facility were recruited to participate in a focus group discussion the group consensus was that assay testing could be a reliable means for determining and preventing diversion of controlled substances. It becomes more difficult to divert with CS waste assay testing in place. The group had expressed confidence in assay testing as a more reliable process than the current two-person waste of CS. The key stakeholder consensus was implementation of CS waste assay testing would most likely protect patients, providers, and the healthcare institution from drug diversion.

INTRODUCTION

Numerous articles and studies have described the significant problem of drug diversion by healthcare workers (Berge, Dillon, Sikkink, Taylor, & Lanier, 2012; Bryson & Hamza, 2011). Compared to the general population, the rate of alcohol and drug abuse by healthcare workers is similar: 10% and 15%, respectively (Baldisseri, 2007; Berge et al., 2012). Unlike the general population, healthcare workers have easier access to controlled, often highly potent and addictive substances placing susceptible individuals at greater risk for diversion while at work.

The high number of anesthesia care providers (ACP) who have succumbed to drug dependence and abuse of controlled substances (CS), despite education and awareness of the potential for substance abuse has not decreased the rate of providers falling victim. As a result they are at significant risk for morbidity and mortality (Bryson & Hamza, 2011). Another unfortunate issue noted is that young ACPs appear to be the group at the peak risk for death and addiction to anesthetic agents and controlled substance medications (Tetzlaff, 2011). Opioids continue to show up as the primary drug of choice. It has been noted when an ACP enters treatment for substance abuse, opioids are generally the drug of choice, while misuse of ketamine, lidocaine, propofol, nitrous oxide, sodium thiopental, and volatile inhalation agents have also been identified (Bryson & Hamza, 2011).

The potential to abuse drugs is considered the most significant occupational safety hazard ACPs face on a daily basis (Tetzlaff, 2011). Due to this bitter reality, every healthcare institution is faced with implementing a wide-ranging drug diversion prevention program, which should meet both state and federal government laws and regulations (Brummond et al., 2017). A strong recommendation exists for hospitals to update and review procedures consistently for

compliance and effectiveness. This review will strengthen controls by use of surveillance technology to mitigate drug diversion (Brummond et al., 2017).

Controlled substance (CS) diversion within healthcare institutions is a significant problem that must be prevented before it leads to serious patient or diverter harm. This issue also places an enormous potential for liability on the organization. The organization must be prepared for critical issues that inevitably will occur due to drug diversion, which include: patient harm, fraudulent billing, liability for resulting damages, regulatory and legal risks, and diminished public trust in the healthcare system (Berge et al., 2012). When a provider decides to start using controlled medications and develops substance use disorder (SUD), it places patients at risk for poor care by their impaired provider, leading to insufficient pain relief, fraudulent documentation of medications received on their chart, and the possibility of a dirty needle or drug exposure to an infectious disease (Berge et al., 2012).

Background Knowledge and Significance

For ACPs to properly and efficiently care for patients undergoing surgery and other procedures, it is necessary and practical for them to have extensive access to considerable quantities of controlled substances. The typical clinical practice for ACPs both in and outside of the operating room (OR) grants them undisturbed access to acquire, utilize, and account for CS in vast quantities (Tetzlaff, 2011). Due to this enormous access to addictive medications a healthcare provider may decide to divert drugs for self-use. Once this choice has been made, the well-being and safety of patients and the providers becomes jeopardized leaving them susceptible to injury or harm (Berge et al., 2012). Many highly publicized patient infection cases have prompted public health and government officials to acknowledge the drug diversion risk

and exposure to patients, healthcare workers, healthcare facilities, the community, and healthcare workers suffering from substance use disorder (SUD) is a major issue (New, 2014). Situations have occurred when addicted healthcare workers used syringes on themselves and then used the same syringes on patients. Another situation is colleagues of addicted healthcare workers have used contaminated syringes unknowingly on patients after they were tampered with and this has led to patients contracting infections like hepatitis C and iatrogenic allergic reactions (Berge et al., 2012). Drug diversion by healthcare workers and ACPs is a very serious issue. Anytime patient safety and provider well-being are at risk, healthcare organizations may become liable (Berge et al., 2012).

To help combat drug diversion the American Society of Health-System Pharmacists (ASHP) has developed guidelines for institutions to use as a framework. The guideline (Appendix G) describes how an organization should go about developing a comprehensive controlled substance diversion prevention program (CSDPP). By implementing this prevention and safety program, patients, healthcare workers, the public, and the institution benefit. The development of a CSDPP that complies with all applicable federal and state laws and regulations remains the responsibility of the healthcare organization. To review process compliance and effectiveness, the institution should apply technology and diligent surveillance to strengthen controls and set out to be proactive versus reactive in drug diversion prevention (Brummond et al., 2017). Mayo Clinic in Rochester, Minnesota has led the way in initiating a high-level drug prevention program meeting the recommendations of the ASHP guidelines in an effort to prevent drug diversion in the workplace. They also have established the ability to identify and rapidly respond to any known or suspected CS diversion. Similar to the ASHP guidelines, their systems

are multi-faceted and have brought in all the needed stakeholders to ensure a successful drug diversion program. The stakeholders involved include human resources, security, nursing, anesthesiology, risk management, and pharmacy. The work by Berge et al. (2012) has found that diversion of CS is common and can result in a substantial risk to patients, the diverting healthcare worker, healthcare staff, and the institution. It is possible for drug diversion to take place at any time and point within a healthcare facility; therefore, all healthcare workers must be vigilant and aware of signs of possible drug diversion and provider impairment. If it is suspected that a healthcare worker is impaired or diverting drugs, workers must be trained to notify the drug diversion officer of their suspicion. Berge et al. (2012) from Mayo Clinic believes that all health care facilities should have systems in place to deter controlled substance diversion and to promptly identify diversion and intervene when it is occurring. In addition, strong policies and procedures should be in place for handling investigations and for the management of the many possible situations of a confirmed diversion (Berge et al., 2012).

Similar to the Mayo Clinic, the Cleveland Clinic Foundation (CCF), via the Anesthesiology Institute, decided to be proactive in the process of deterring drug diversion. CCF instituted specific mandatory education programs for all anesthesia department personnel on a repeated basis, enhanced procedures for the detection and prevention of diversion of CS and improved the ability of staff to detect impairment. CCF then applied a multifaceted drug testing program, which included random and for cause urine drug screening for ACPs. This enabled them to prevent and quickly detect abuse of CS and other drugs (Tetzlaff et al., 2010).

In sum, controlled substance assay testing could initially occur in the main operating room (OR) area and all anesthesia work sites throughout the hospital. Eventually, controlled

substance waste testing could move to every unit of the hospital that utilizes controlled injectable substances. Organizations that have implemented random drug testing have been able to demonstrate a positive deterrent effect (Bryson & Hamza, 2011). This includes the Federal Transit Administration, the Federal Aviation Administration, the Federal Railroad Administration, every branch of the United States military, as well as most constituents of the Department of Transportation (Bryson & Hamza, 2011).

Local Problem

ACPs have a professional obligation to their patients and themselves requiring they remain drug-free while at work when providing patient and anesthesia care (Fitzsimons, Baker, Lowenstein, & Zapol, 2008). When providers do succumb to substance abuse and diversion of drugs there is a potential for a decrease in staff morale, efficiency, possibly leading to feelings of betrayal, which can adversely affect safety and quality of patient care (Ramer, 2008). Many of the signs of substance use by ACPs are often initially subtle and difficult to distinguish or differentiate from fatigue, stress, or common life issues (Tetzlaff, 2011). Unfortunately, self-reporting by ACPs is rare, leaving the fact that coma, suicide, and accidental death are the likely outcome (Tetzlaff, 2011).

Valleywise Health Medical Center (VHMC), just like many other healthcare organizations, has experienced drug diversion by healthcare workers. In the past 5 years, two of our anesthesia colleagues have admitted to abusing and diverting controlled substance medications. The two ACPs were relatively new to the anesthesia profession and had both been practicing less than five years. Currently, VHMC has diversion mechanisms in place to deter providers from diverting CS; however, this could be strengthened. Institutional policies and

procedures for the detection and prevention of controlled substance diversion should include education on signs and symptoms of drug use for all hospital personnel, also random and for cause urine drug testing, which could possibly prevent and detect abuse of anesthetics and CS as described by Tetzlaff (2010).

Purpose and Intended Improvement

The purpose of this project was to determine the feasibility of implementation of random controlled substance waste testing and remove the two-person waste requirement at VHMC. Assay testing of medications is accomplished by using a refractometer. This method is considered a practical solution to monitor returned CS waste samples. The process is easy to perform and can alert the pharmacy staff if the returned sample does not match what the stated product should have been. Using this type of refractive index measurement pharmacy staff will be aware of potential drug diversion or tampering by providers and can place departments on alert for potential abuse. The ASHP guidelines and others have recommended this type of testing (Berge et al., 2012; Brummond et al., 2017).

The potentially devastating consequences of provider drug diversion led to this effort for the protection of the patients, the organization, and the diverting provider. Berge et al. (2012), anecdotally described reductions in diversions from 1 per year to 1 in 7 years at the Mayo Clinic, once random quantitative assays of CS returned to the pharmacy was implemented. Unfortunately, there is no other specific literature in regards to the impact of assay testing on drug diversion and the decrease of diversion expected; which leaves us to rely on expert opinion. This finding would indicate this is an area ripe for further inquiry and studies to determine the specific impact of CS waste assay testing.

The implementation of controlled substance waste assay testing could potentially deter ACPs from deciding to misuse these highly addictive drugs knowing they themselves may be detected, prosecuted and have to deal with professional and legal issues (Brummond et al., 2017). If ACPs still decide to misuse drugs, the goal would be to catch and recognize the abuse so the provider can be sent for treatment before they injure themselves or any patients.

Unfortunately, the extent of drug diversion is likely larger than what is currently reported in the literature (Wright et al., 2012). There is high likelihood that some providers are impaired at work considering it is believed that one out of every ten actively practicing Certified Registered Nurse Anesthetists (CRNAs) misuses a controlled substance (Wright et al., 2012) This process could potentially help decrease or possibly alleviate the unfortunate risk of drug diversion among ACPs, indirectly improving patient safety and outcomes (Berge et al., 2012). This project aimed to determine if key stakeholders would deem controlled substance assay testing a feasible alternative/addition to the current drug diversion program at a local medical facility?

PICO Question for Synthesis of Literature

Among ACPs (P), can implementation of controlled substance waste assay testing (I) make an impact, compared to no change in the current waste procedure (C) to deter ACPs from drug diversion (O)?

Theoretical Framework

Deterrence theory was the primary theoretical framework behind this DNP project. The principal assumption made by this theory is to send a message to a target group (healthcare workers). When the target group receives the message and perceives it as a threat the group then

makes rational choices based on the information there are consequences for improper actions (Tomlinson, 2016). This project uses deterrence theory, which suggests when providers are aware there is an increased likelihood for drug diversion detection, an environment that encourages them to not divert is created.

A second model is required to operationalize and guide the project. Lewin's theory of planned change (Figure 1) was the chosen framework to guide the project to improve the identified problem from beginning to end. The first step of the theory of planned change is called the unfreezing stage. In this project, unfreezing the old process was the aim with intentions to complete the rest of the steps in the future. For this project, a literature review was performed, stakeholders were established and input was used to determine that a change was needed such as in this case, controlled substance waste assay testing. The chief CRNA was the clinical leader. Being in this position allowed the chief CRNA to drive, guide, organize, implement, and champion the process. Continuing in this phase, an appropriate team or person with the knowledge required to advance the implementation of controlled substance assay and waste testing will be determined and chosen. The lead pharmacists and pharmacy department are priority collaborators in this process. The controlled substance monitoring technician and the pharmacist in charge are especially essential and provided technical expertise in the proposed process. The pharmacist is capable of understanding the rules and regulations of the daily waste processes, which are necessary and easily accomplished. In-depth collaboration with the pharmacy department leader will be helpful to determine feasibility and, in the future, will be crucial with the implementation of the process, creation of measurement tools, and project design. Acquiring a sponsor with authority and access to hospital management was necessary.

The chief nursing officer (CNO) and chair of anesthesia fulfilled the role for this project. Getting the sponsor involved with the planned change now can help overcome barriers or issues that arise on behalf of the project.

The next step is called moving. Moving will be when education is presented to the ACPs and the pharmacy-controlled substance group on the new controlled substance waste process. Once controlled substance assay testing is deemed necessary and subsequently implemented, all ACPs will be required to return 100 percent of their controlled substance waste. The department workflow will require that all ACPs cap their syringes, document the waste in the Pyxis system, and return to the secure return bin. Once the waste is collected and returned to the pharmacy, the samples can be selected for random testing for actual medication type and concentration by quantitative drug assay testing with a refractometer. This testing establishes a positive monitoring system rather than a system based on assumptions about returned medications (Sharer, 2008). The pharmacy will ensure safe and controlled disposal of the returned waste. The final step is to refreeze the change process. The new process will become ingrained in the culture of the hospital; however, education and training of new staff must continue to keep controlled substance waste testing as part of the diversion program. Adding this practice change to our controlled substance prevention plan will provide another deterrent and potentially allow us to detect drug diversion sooner with the main goal being protection for our patients, the provider, and our organization.

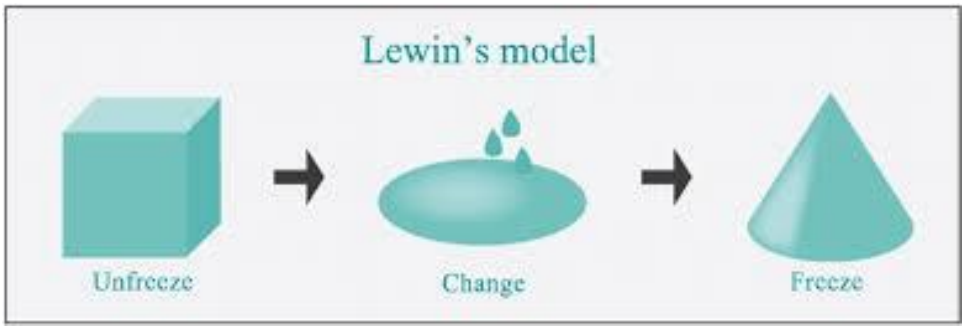

FIGURE 1. Lewin's model.

Lewin extended his theory of planned change by including "force field analysis" which offers direction for identifying situations and handling change within organizations (Shirey, 2013). Lewin believed that both driving and restraining forces influence the change that potentially may occur in any situation (Cathro, 2011). Driving forces are known as forces that impact a situation, moving it in a specific direction that will start the change and move it forward. The key stakeholders will be necessary to help drive and move the change forward. Key stakeholders will include the chief nursing officer, lead pharmacist, and chair of anesthesia.

Restraining forces are seen as barriers that may restrain or lessen the driving forces making it harder to implement the change and move it forward. For the change to occur the driving forces must be stronger and repel any restraining forces in order for the change to occur so whenever driving forces are stronger than restraining forces, the status quo or equilibrium will change (Cathro, 2011). Success can be achieved by either strengthening the driving forces or weakening the restraining forces to create change. Lewin's theory of planned change integrates well with force field analysis during the process of unfreezing the current equilibrium, advancing towards the expected change, and then refreezing the process so a new equilibrium exists, resistant to further change (Shirey, 2013).

Concepts

List of Concepts

- Anesthesia care provider (ACP): encompasses all anesthesia provider types. Certified Registered Nurse Anesthetists (CRNA), Anesthesiologist, Anesthesia residents, and Students Nurse Anesthetists (SRNA).
- Controlled substance waste assay testing: An assay test is an analysis done to determine the presence of a specific substance (medication) and the amount of that substance.
- Diversion: the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.
- Refractometry: A refractometer measures the refractive index of a substance and can be used to confirm the identity of an unknown substance or purity of a known substance, relative to the refractive index of a reference standard.
- Substance use disorder (SUD): substance use disorder describes a problematic pattern of using drugs or alcohol that results in impairment in daily life or noticeable distress.

Synthesis of Evidence

The PICOT question driving the literature review: ACPs at VHMC will have all of their controlled substance waste randomly tested by quantitative drug assay testing versus no change in the current waste procedure that feasibly should create a greater deterrent against drug diversion once implemented. Anonymous self-reporting by ACPs indicate the prevalence of diversion may be as high as 10% (Bryson & Hamza, 2011). The anesthesia provider rates of drug diversion detected due to death, severe injury, or entry into an inpatient treatment facility are

between 1% and 2%, leaving the likelihood that 8% to 9% of drug diversion taking place goes undetected (Bryson & Hamza, 2011).

Close examination of the literature provided the necessary reasons for a robust drug diversion program in every facility that handles CSs. The literature supports the use of controlled substance assay testing to deter drug diversion (Bryson & Hamza, 2011). To gather current knowledge on controlled substance diversion programs, numerous literature searches were completed employing the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Embase, and PubMed databases. Keywords used for drug literature search included drug diversion, substance abuse, nurse anesthetists, anesthesiologists, refractometry and prevention. Searches with related terminology were also performed using controlled substance, healthcare workers, statistics and hospitals. To decrease the amount of extraneous data the listed limitations were applied: English language, last 10 years, available abstract, human subjects, peer-reviewed, research articles, and full text. Included were numerous descriptive studies, some quasi-experimental research studies, and other related articles published between 2008 and 2019. I retained 98 articles with information suited for selection and use in this project describing four of them to demonstrate the risks ACPs are under in regard to drug diversion.

To develop and create an ideal and sophisticated drug diversion and prevention program will require gathering knowledge from behavioral and biologic sciences, information technology, law enforcement, pharmacy sciences, credentialing and licensure experts, and industry loss prevention sciences (Berge et al., 2012). A significant weakness of the literature is the lack of available data that precisely define the extent of drug diversion from the health care facilities (Bryson & Hamza, 2011). Improving the information reported when drug diversion occurs in

facilities could help with additional prevention strategies and increase the depth of knowledge about drug diversion. The majority of the literature in regards to drug diversion in hospitals is very similar in the fact that they are expert opinion and do not list any credible randomized control trial or meta-analyses. This noted limitation in the current literature on drug diversion provides an opportunity for further research in this area to provide evidence the suggested barriers work in reducing diversion. Improving the quality and updating the literature regarding drug diversion with current trends and statistics is needed.

The literature describes how easy it is for a single anesthesia provider without the knowledge or involvement of others, to divert drugs intended for patients. It is difficult to determine the exact incidence of substance abuse and dependency among ACPs due to the sensitive issue, legality, and patient care implications which may discourage disclosure; therefore, it is possible that reports underestimate the true scope of the problem (Wright et al., 2012). However, it is well recognized that ACPs, perhaps more than any other class of healthcare worker, have ready access to highly addictive psychotropic medications and have a higher rate of addiction to opioid drugs than physicians in other specialties (Wright et al., 2012). Furthermore, the drugs most commonly abused by ACPs are obtained through diversion (Tetzlaff et al., 2010). This diversion by ACPs suggest that easy and abundant access is a critical component of drug diversion from the health care facility workplace.

Bryson (2018) describes a significant link between other forms of impairment and substance abuse. ACPs with a history of substance abuse, anxiety, depression, and burnout may develop substance use disorder (SUD), placing the provider and their patients at greater risk for injury (Bryson, 2018). The development of a proactive drug diversion program at the Cleveland

Clinic included mandatory SUD education for all department staff on a periodic basis, improved detection and prevention capability of drug diversion. This program boosted training of staff in the signs and symptoms of impairment, and employed random and "for cause" urine drug screens for early detection and prevention of abused substances while on the job. (Tetzlaff et al., 2010). Warner et al. (2013) studied the frequency of SUD occurrences among anesthesiology residents from 1975 through 2009. While performing this retrospective cohort study of 44,612 anesthesia residents throughout the United States 384 (0.86%) were identified as positive for SUD during their training over a 34-year time span (Warner et al., 2013). A national survey looking into SUD in Canada was completed on anesthesia residency programs using directors and site chiefs associated with the university anesthesia departments. After surveying and counting, the incidence of SUD was found to be 1.6% among anesthesia residents and 0.3% among fellows; unfortunately, the incidence among practicing anesthesia attending physicians could not be determined (Boulis, Khanduja, Downey, Friedman, & Khanduja, 2015). The study by Boulis et al. (2015) reported opioids were the primary drug of abuse by ACPs similar to the study presented by Warner et al. (2013). In both studies, alcohol abuse was considerably higher than SUD by physicians in the United States and Canada. The thought is that physicians who abuse prescription and illicit drugs seek treatment while the vast majority of physicians abusing alcohol do not (Bryson, 2018). Authors of both studies have implied that by limiting the examination to known cases of SUD, the actual prevalence was most likely underestimated in these groups (Bryson, 2018). Studies which have investigated the frequency of anesthesiologists referred for treatment have reported a lower incidence, between 0.86 to 1.6%, and a much greater

inclination for opioid use, which many times results in identification and referral to treatment centers, unlike alcohol abuse, which typically does not (Bryson, 2018).

Brozimowski et al. (2014) over a 5-year period from 2008 to 2012 studied the incidence, outcomes, demographic factors, and preventative measures for substance abuse experienced by nurse anesthesia students (Bozimowski, Groh, Rouen, & Dosch, 2014). Electronic surveys were sent to nurse anesthesia program directors of 111 programs in the United States. Twenty-three programs of the 111 responded for a response rate of 21.7%. The data contained information on 2,439 students. Over the 5-year period, sixteen incidences of substance abuse were documented for an incidence of 0.65%. Similar to other studies, opioids were the drug of choice of Student Registered Nurse Anesthetists (SRNAs) (n = 9). There were no identifiable predisposing risk factors noted in 50% of the occurrences. Outcomes related to abuse included voluntary entry into treatment (n = 10), loss of nursing license (n = 2), dismissal from the program (n = 7), and a single death was reported by program directors (Bozimowski et al., 2014). The incidence of substance abuse in the two groups was higher in CRNAs versus SRNAs (Bozimowski et al., 2014). In the survey responses, program directors reported wellness promotion education was the primary prevention strategy utilized along with drug testing "for cause" and pre-enrollment background checks.

METHODS

Design

This DNP project aimed to determine the feasibility of implementing CS waste assay testing at VHMC. The proposed intervention would utilize the addition of controlled substance waste assay testing to deter and prevent potential drug diversion at VHMC. Currently, VHMC

does have a prevention program with mechanisms of prevention and detection but lacks controlled substance waste assay testing. The current processes include education on signs and symptoms of drug use for all department personnel, policies and procedures for the detection and prevention of diversion of CSs, and a urine drug testing program, which can be random and "for cause" (Tetzlaff et al., 2010).

The target outcome of this DNP project is to develop a process map for CS waste assay testing and present it to key stakeholders for approval to move forward. This process required two steps. The first step was recruitment of key stakeholders to participate in a focus group. The second step was to have each member answer questions about the need for CS waste assay testing and if the implementation would be deemed feasible at VHMC. The stakeholders could ultimately implement a program change for controlled substance waste assay testing among ACPs. Results of the project were presented to key leaders in the form of a white paper (Appendix F) how the institution could benefit from this knowledge and approve the change.

Ethical Considerations

As the project investigator I adhered to ethical principles by providing: a) informed consent to the project participants; (b) minimized the risk of harm to participants; (c) protected their anonymity and confidentiality by keeping data secured via a password protected recording device and the REV website requires email address and password to obtain transcription data; (d) avoided using deceptive practices; and, (e) gave participants the right to withdraw from the project at any time. Focus group participants included the CNO, lead pharmacist, and chair of anesthesia. The participants were emailed an invitation to participate in the project by this author. This email informed the participants of their option to participate or not. Attendance at the focus

group meeting was considered agreement to participate in the project. The participants were informed they could leave the study at any time. There were no known physical or psychological risks associated to the project. There was no cost to the focus group members and no compensation was provided to the participants.

Institutional Review Board (IRB)

This project was a ceded IRB application to VHMC. This DNP project focused on interviewing three key stakeholders to determine if they believe ACPs are at risk for drug diversion and if there is feasibility for implementation of CS assay testing at VHMC (Appendix C & H).

Setting

The setting for the quality improvement project was a large level one-trauma center in Phoenix, Arizona. The aim for this project was to determine if responses by the focus group and the driving forces indicated that CS assay waste testing was feasible.

Participants

The project participants included key stakeholders: the chair of anesthesia, the chief nursing officer, and the pharmacy lead on drug diversion. Each of them received an email from the author of the project requesting their presence to discuss the topic of drug diversion and controlled substance waste assay testing. The key stakeholders were sent literature emailed to them in preparation for the focus group. This literature review required approximately two hours of their time prior to the meeting, in addition to one hour forty minutes for the focus group interview. These expectations were included in the email that was sent to the participants.

Data Collection

The clinical practice guidelines from the American Society of Health-System Pharmacists Guidelines on Preventing Diversion of CSs and references to additional articles were provided to the group members. These items were intended to prepare the group on the topic of drug diversion and prevention. A one hour and forty-minute focus group was held on Tuesday, October 29, 2019. The first 40 minutes were dedicated to participant introductions as well as a brief introduction and discussion of the topic. During the hour of questions and answers, an audio recording of the session was obtained, along with written notes. Following the focus group, a transcription was created from the recording of the session. After review of the data, the author and DNP project chair created a list of common concepts derived from the answers given.

Data Analysis

A transcription of the question and answer portion of the focus group session was created from the recording taken during the focus group interviews using the REV software. The REV transcription service allowed the audio recording of the session to be converted into text. The author reviewed the transcription raw data to generate common topics, which evolved from the questions each provider was asked during the open discussion. The apparent common topics uncovered were reviewed and agreed upon by the chair of the DNP committee as well as a second committee member.

TABLE 1. *Conceptual analysis.*

	Seriousness of Drug Diversion Problem	**Feasibility of Changing to a New System to Identify Diversion**
Stakeholder #1	... And listening to your numbers of just the two, over a period of time, it doesn't sound like it's a huge issue, but that's just the people you know, and when you talk about patient safety, even when I look at just health care workers in general, that's when you start to see that impact and that becomes important to us. I still think that impacts patients because I think about it. Are they diverting it from the patient and taking it? Are they just taking it? If you never really know, and so in my mind, those are all harms to the patient. If you're taking it from the patient and utilizing it where you won't get caught but the patient's not getting what they may need. So, that's where I always feel like one is too many." I think it's probably two-fold. One really is the patient that, if we, let's say we are compromised, we could have a mishap that would normally happen if you weren't using something. Then the other thing is just what ultimately is going to happen to that individual as, I think it gets back to us saying, how do we make the environment healthy for people where they can be healthy and then ultimately, we're human. We'll make mistakes, but that the patients are going to get what they need and you're going to be focused. I just can't imagine if you're taking certain levels of drugs, regardless of whatever your tolerance is, you're not going to be at your best game. I think that's probably the biggest worry is that and I do think sometimes before it becomes known, I think it does lead to some disruption in the work and in the team. I think people start to know something's not right but they don't call it out. Cause we're all sometimes afraid to say something and so we'll think something's not right. Then, you become part of that problem too and that's hard to recover a team from."	"I'm thinking it's (CSA testing) probably the most reliable means of knowing for sure what is being wasted. Because even if I am diligent and watch you, I don't know if you drew up something else cause you usually come to me saying I'm going to- you're going to watch me waste this, but I don't know if you hadn't already done something with it. So, I'm not going to be able to discern if it's really that drug." "I would say probably what like maybe once a month we drill down on people anyway, but then we drill down on people because we have concerns. Then it's, it's a little bit more resources because we pull everything. We really start to look at the charts, look at what they've documented and what their colleagues have documented. So, I mean, I guess if you just figured like it could be $50,000 a year that we're doing and just the, data pieces of it." "I don't see barriers in the sense of a philosophy, like a philosophical barrier in doing, I think one, it's just really what it takes to put it in play and that, it's something that's quick and easy. It's more of making sure that process is in place before you move forward with it. Put the right resources and what that takes and it might end up taking less resources than what we do today."

TABLE 1 – *Continued*

	Seriousness of Drug Diversion Problem	Feasibility of Changing to a New System to Identify Diversion
Stakeholder #2	Yes. For me, I mean ever since I've been in the pharmacy profession, it's always been a, significant issue. Doesn't matter one or you know, one is too much. Yeah, to kind of add that it's just more of the, anesthesiologist are to me as you know, in their work area are very much pretty much the controlling of the environment, and if they can't really truly control their environment, a lot of things can happen and they need to be at the top of their game all the time. It's a very stressful job."	"Yeah, I mean, I've been at facilities, we've used some spectrum assay testing. With pharmacy, we didn't do it our self. We send it to the lab. So, it was something that we used and, and it worked well when we had to, we didn't do it often. It was more of that found type medications and we wanted to make sure it was, we can trace it back to see where, you know, how it was found. I think the assay will help out and, and it has its place to help with that diversion." "The only other barrier I would say, yeah. Letting people know why. Then we just need to make sure that you give them a little bit more of a background so that way they don't feel that we're just testing or we're doing a project for someone. It's more of a why we want to do it, just to help out, help them out in the long run." "So, if you think about it, for us it's like I said, a monthly report. So, you're looking at employee or technician who you know, a certain dollar amount, you know per an as a portion of their job. So, you know, I would say costly wise, you're looking at 20% of the salary. I would say, and I don't know, I can't tell you the numbers of those assessments, but 20% of the salary just on the pharmacy part and then it goes up to the nursing areas and that's a certain percentage of their day looking, verifying all that, the medications that we are saying about this individuals are in."

TABLE 1 – *Continued*

	Seriousness of Drug Diversion Problem	Feasibility of Changing to a New System to Identify Diversion
Stakeholder #3	"Yeah, definitely. In my opinion, I do see the diversion as a significant issue. During the years of my practice, even just here at this institution, I've witnessed quite a few diversions resulting in harm to the particular individual. We, in this particular institution, at least in the anesthesiology department." "The patient outcomes and also provider outcomes. But I'd add on top of either one of those is the risk, and liability outcome, legal outcomes that, can be imposed on an institution."	"Yeah, I think the assay would definitely have an impact at least in two areas. I should say a pleaser for all providers it would probably be more threatening to a person's diverting because they know now they've got to have the real stuff in there and so it's going to take more discipline on their part to make it the real stuff that they're wasting. I very strongly think that we need to have an assay, whether it's every drug that comes back or whether it's just randomly and with target, once there's some clinical suspicion." "I think, some of my barriers are probably more imagined than real. I just see it so positive now. I wonder how could there be any barriers? And I think, you're right, although nice to hear you say it, that there was no philosophical issue with it." "Once we hear a little bit more, it's probably moved from the expense side of it so that's not so severe."

RESULTS

The primary objective was to determine the feasibility of adding CS waste assay testing to the current drug prevention program at VHMC. Questions were directed in a manner to first identify if the participants believed that the topic holds any significance and then to evaluate and determine if CS waste assay testing was something, they think could be implemented at VHMC. Additionally, the participants who believed CS waste assay testing was feasible were also asked what specific recommendations they would make and what barriers would impede this effort.

The common concepts along with quotes from the focus group are listed in Table 1 and Appendix E.

Conceptual Analysis

During our focus group discussion, the consensus was each of the three participants were clearly aware of drug diversion activities prior to participating in the focus group or receiving information on the need for a drug prevention program. The three participants all described drug diversion as a significant issue. Primarily noting that patient and provider safety were at significant risk for harm if drug diversion was occurring. The group was in agreement that drug diversion has been a problem for a very long time. The primary consensus is that patient and provider safety and wellbeing are at risk. Furthermore, there is high potential for mishaps or injury to patients or the diverting provider. The group believed there is a need for providers to remain drug free to care for patients. The last take away regarding the seriousness of drug diversion was the potential for major liability and legal risks to the institution if drug diversion is taking place. A more effective system for preventing and detecting drug diversion was seen as a necessary change.

The group consensus is assay testing can be a reliable means for determining possible diversion of drugs. It becomes more difficult to divert with CS waste assay testing in place. The group believe assay testing is more reliable than current two-person waste of CS. They also concur that it will be an impactful process in the prevention of drug diversion within the institution. The consensus of the group agree that barriers may not be overly formidable allowing implementation of CS waste assay testing at VHMC. The group would like to take the time to figure out the process before implementation as well as educate the staff on the CS waste process. The group also spoke of imagined barriers that people may think are present but truly will not impede the process of implementing CS waste assay testing and it being successful.

Group members voiced that the current drug diversion process may be more expensive than implementing CS assay testing. CS waste assay testing may be more efficient than the current process and associated staff costs to look at records and data if a healthcare worker is suspected of drug diversion.

DISCUSSION

The participant/stakeholders of the focus group all acknowledged that drug diversion is a problem, although the scale of the problem was not as well known. The participants deemed the use of CSA program as a feasible deterrence for potential drug diverters. Deterrence theory demonstrates it is an effective way to influence providers by making them aware there is an increased likelihood for drug diversion detection, thus creating an environment that encourages providers not to divert.

Aims of the study were to determine a process for CS waste assay testing and for key stakeholders in leadership positions at VHMC to evaluate the feasibility of adding CS waste assay testing to the existing drug prevention program then removing the two-person witnessed waste. These key leaders will be vital members in determining if the recommended change is possible at VHMC and could make recommendations and assist with driving and championing the practice change.

Creating a focus group of key leaders was helpful in determining the need for CS waste assay testing, and defining potential barriers to the implementation of the change process. The focus group came together as a group and discussed drug diversion and what their thoughts were in regards to the occurrence and outcomes at VHMC and other institutions they had worked at in the past. The question and answer period was semi-structured but allowed the participants to

speak freely at any time with responses they wanted to share. The findings indicate that while the stakeholders agreed CS assay testing would be beneficial to the institution and that the cost of implementing the process may ultimately decrease cost compared to the current process of determining if someone is or has been diverting drugs. The pharmacy will have an increased burden of performing the assay testing and monitoring their technicians that gather the CS waste and perform the assay testing for diversion in their department. It was also the consensus of the group that knowledge of drug diversion has been an ongoing issue and it is the institution's job to protect patients, employees, and the institution from the potential harm caused by drug diversion. Furthermore, the group decided that staff education about drug diversion and education on the barriers to protect them and their patients is necessary.

Impact of Results on Practice

The most significant safety hazard in the field of anesthesia is the potential for chemical dependency (Tetzlaff, 2011). ACPs or healthcare workers who decide to divert drugs create an enormous danger for themselves, the organization, co-workers, and patients they serve (Berge et al., 2012). Of note, drug use and diversion among ACPs is disturbingly high and tends to peak early in anesthesia careers (Tetzlaff, 2011). The execution and installation of CS assay waste testing is essential to keep patients, healthcare providers, and the organization protected from drug diversion by healthcare workers. Diverting drugs is a criminal activity that healthcare institutions have a duty to minimize within their organization (New, 2014). All healthcare institutions have the responsibility to maintain policies and procedures capable of preventing, detecting, and responding to controlled substance diversion within their organization (New, 2014). Healthcare innovation core concepts place the needs of patients, healthcare providers and

caregivers who deliver care as the priority (Omachonu & Einspruch, 2010). There are six concepts that healthcare organizations attempt to meet: outreach, prevention, education, research, treatment, and diagnosis (Omachonu & Einspruch, 2010). To effectively manage these concepts, a healthcare organization must control safety, costs, quality, outcomes, and efficiency (Omachonu & Einspruch, 2010). When implementing new technology into a facility that is capable of detecting medication type and concentration from a waste syringe helps meet the concept of placing patients and healthcare workers as a priority. The focus of the DNP change concept is on controlled substance waste surveillance. The process change requested will be tested, modified and eventually adopted at VHMC. ACPs will be involved and instructed by leaders in regards to the new waste process and reason behind the change. This change then will impact the provider's ability to divert medication for self-use. Ultimately, this improvement project is important to protect patients, providers, and the organization from drug diversion by healthcare workers. Preventing or making drug diversion more difficult should help protect patients and providers from harm by identifying diverters sooner and creating another obstacle (Berge et al., 2012). Implications for nursing practice in drug diversion prevention has shown ACPs have a high potential for abusing opioid medications, and research has provided evidence that actual use among this group is extremely difficult to assess (Wright et al., 2012). Due to the need for quick medication availability, coexisting psychological disorders, and a history of family substance abuse stand as key factors noted to increase the risk of developing substance use disorder. A question to ask is how the presence of the previously listed factors in ACPs, students, and residents may contribute to the development of substance use disorder during their anesthesia careers.

Study Strengths, Limitations and Future Endeavors

There undoubtedly would be several potential barriers faced when attempting to implement CS waste assay testing. Resistance to change by the institution and staff must be considered. Another possible issue would be the perceived costs of implementing a program for randomized CS drug testing with tight hospital budgets. The pharmacy will incur the cost of a technician retrieving CS waste, performing the random assay testing, and disposing of returned medications. There could be arguments against random CS assay drug testing due to the potential for complaints of unfair testing procedures and protocols. Through use of evidence and the literature and cost benefit analysis, prospective obstacles may be avoided when actual implementation is attempted. The potential change could significantly affect work performance, decrease medication errors related to impaired providers, and improve patient safety and outcomes throughout the health system.

Determining the specific impact using surveillance technology like refractometry to proactively mitigate drug diversion is a future area of study. Other than Berge et al. (2012), who anecdotally described reductions in diversions from 1 per year to 1 in 7 years at the Mayo Clinic, once random quantitative assay testing of CS waste returned to the pharmacy was implemented not much else is available showing the effectiveness of this technology. The need for more studies in this area is necessary to help drive the use of assay testing to prevent drug diversion, therefore, this area is in need for further inquiry and studies to determine the specific impact of CS waste assay testing. Further research can also be considered as a result of the white paper presented to stakeholders, including further studies related to risk factors associated with drug diversion.

Dissemination and Future Implications for Practice

A white paper regarding a CSA program for preventing and detecting drug diversion was disseminated to the key stakeholders (Appendix F). Results of a study like this could provide the basis for research, risk identification, substance-abuse prevention strategies, and counseling during anesthesia education with identification of high-risk providers also becoming possible (Wright et al., 2012). If VHMC leadership chooses to implement CS waste assay testing, a refractometer or an enhanced photoemission spectrometer must be purchased. The cost would depend on the type of model purchased, additional supplies and maintenance. The cost can influence how often the random controlled substance waste testing would occur. By adopting and sustaining practice changes, the development of supportive protocols, cost, and the equipment availability will be potential barriers or facilitators to the project (Stange & Glasgow, 2013). This DNP improvement project was necessary to be able to do a better job of detecting drug diversion, which in turn will protect patients, providers, and the healthcare organization from drug diversion by ACPs and other hospital staff.

APPENDIX A:

FOCUS GROUP GUIDELINE AND QUESTIONS

Focus Group Guideline

Total meeting time: 1 hour 40 minutes estimated.

- Meeting and introductions (5 minutes)
  - Author introduction (5 minutes)
  - Each participant will introduce them self, state their title, role, and specialty (10 minutes)

- A brief overview of the topic (5 minutes)
  - The author will detail their experience with drug diversion programs (5 minutes)
  - The group will be asked general questions based on their experiences with drug diversion and random assay testing and an open discussion will follow (10 minutes)

- Focus Group Discussion (60 minutes)
  - The group will be asked open-ended questions and each participant will be given time to respond.

Focus Group Questions

1.) Were you aware of drug diversion prior to agreeing to participate in this focus group?

2.) In your opinion, do you see drug diversion as a significant issue as it pertains to anesthesia? Why, or why not?

3.) If you feel drug diversion is a significant issue pertaining to anesthesia, what concerns you most about this issue?

4.) Do you believe the implementation of CS waste assay testing of returned medication will help decrease drug diversion or help detect misuse sooner? Is CS waste assay testing feasible for this facility?

5.) What barriers do you foresee to implementing this type of testing?

6.) What is the current cost of the drug diversion program at VHMC? What do you think the cost would be if CS waste assay testing were implemented?

APPENDIX B:

PROCESS MAP

The movement and use of CSs have been typically checked by various accounting systems, but these systems can be misled because the returned medications rarely are tested to verify that they have not been diluted or replaced (Sharer, 2008). The pharmacy at VHMC will obtain controlled substance waste information using a refractometer. It is one of the most common practices for assessing the purity of CSs that have been returned to the pharmacy (O'Neal, Bass, & Siegel, 2007). A refractometer measures the refractive index of a substance and can be used to confirm the identity of an unknown substance or purity of a known substance, relative to the refractive index of a reference standard.

Once controlled substance assay testing is implemented, all ACPs will be required to return 100% of their controlled substance waste. The department workflow involves all ACPs capping their syringes, documenting the waste in the Pyxis system, and returning to the secure return bin. This type of drug diversion prevention has been found to be successful in deterring drug diversion at other large hospitals (Berge et al., 2012). Once the waste is collected and returned to the pharmacy, the samples can be selected for random testing for actual medication type and concentration by quantitative drug assay testing with a refractometer. This testing establishes a positive monitoring system rather than a system based on assumptions about returned medications (Sharer, 2008). The final step is safe and controlled disposal of the returned waste by the pharmacy department. The pharmacy will play a pivotal role in the implementation of controlled substance assay testing throughout this project.

The target measure will be identifying wasted drugs that are not determined to be the correct controlled substance or a diluted down version of the medication. The outcome measure of decreased provider diversion will help determine if our new process has created

deterrence to drug diversion amongst healthcare providers and allow us to provide earlier detection. We will measure the selected outcome and process measures over time utilizing a process map. This type of flow chart or map is a pictorial demonstration of the sequential steps involved in our process (Picarillo, 2018). The hospital team members will provide an understanding of how each step may be influenced by the preceding or subsequent steps in the controlled substance testing process. By utilizing a process map, the whole team is able to visualize how each member performs a step in a certain procedure, allowing for an improved understanding of each other's roles and responsibilities during clinical situations (Picarillo, 2018). The value of using a map created in a stakeholder's meeting allows for discussion, understanding, and appreciation of everyone's role in the process. This will help establish a baseline knowledge of the controlled substance waste assay testing process for all team members and once completed, the team can decide what steps were useful and what steps were not (Picarillo, 2018).

APPENDIX C:

MARICOPA INTEGRATED HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD

APPROVAL LETTER

MIHS
MARICOPA INTEGRATED HEALTH SYSTEM
Maricopa County Special Health Care District

September 26, 2019

TO: Joseph Bailon, CRNA
Department of Anesthesiology

FROM: William Dachman, MD
Chair, Institutional Review Board (IRB)

RE: QI2019-014: *The Viability of Adding Controlled Substance Waste Assay Testing into a Current Drug Prevention Program*

On September 26, 2019, the above project was determined by the MIHS Institutional Review Board (IRB) to be exempt from IRB Review. This project is considered a quality improvement activity and therefore is not human subject research.

Date of Exemption
September 26, 2019

WD/mtg

*If there are changes to the protocol from that described in your submission, the changes must be submitted to the IRB for review to assure that the activities qualify as exempt.

APPENDIX D:

SYNTHESIS OF EVIDENCE

Synthesis of Evidence

Author/Article	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
Bell, D. M., McDonough, J. P., Ellison, J. S., & Fitzhugh, E. C. (1999). Controlled drug misuse by Certified Registered Nurse Anesthetists. *American Association of Nurse Anesthetists Journal, 67*(2), 133.	What is the prevalence of controlled drug misuse among actively practicing Certified Registered Nurse Anesthetists (CRNAs)? Secondly what variance in controlled drug misuse by variables of age, sex, population and geographic area of residence, type of anesthesia position currently held, and a number of years in anesthesia practice?	Comparative study	**Sample:** mailed to 2,500 actively practicing CRNAs rate of 68.4% (1,709 of 2,500), n=1,709 Predominantly female 54% in the 36- to 40-year-old age group with average clinical practice longevity of 11 to 15 years represented the largest numbers. **Setting:** Throughout the United States, predominantly urban-dwelling midwestern CRNAs.	The research data were obtained through self-administered surveys. The survey instrument allowed for stratification according to admitted misuse of controlled drugs commonly used in the clinical practice of anesthesia. All CRNAs randomly selected to receive a questionnaire were members of the American Association of Nurse Anesthetists (AANA) at the time of the study and could be classified as "certified" or "recertified." This allowed for representation of 11% of all actively practicing AANA members.	The established prevalence of drug misuse in the target population was found to be 9.8% of the sample (167 of 1.709 respondents), with the majority indicating a distinct proclivity for polydrug misuse. The survey results were compared with those of studies involving anesthesiologists and registered nurses with the notable exception of the preferred drugs for misuse. A strong relationship existed between sex, a number of years in clinical anesthesia practice, and the likelihood for controlled drug misuse, thus indicating a potential predictor of which CRNAs may misuse controlled drugs. In addition, a significant relationship existed between recency of controlled drug misuse and drug(s) of choice (P = .05).

Boulis, S., Khanduja, P., Downey, K., Friedman, Z., & Khanduja, P. K. (2015). Substance abuse: a national survey of Canadian residency program directors and site chiefs at university-affiliated anesthesia departments. *Canadian Journal of Anaesthesia*, *62*(9), 964-971.	What is the prevalence of substance abuse cases among Canadian anesthesiologists at university-affiliated hospitals? A secondary aim was to describe the current management of confirmed cases, rehabilitation procedures being offered, and preventative strategies being employed.	Cross-sectional electronic survey	**Sample:** Canadian anesthesia residency program directors and site chiefs **Setting:** University-affiliated hospitals.	An electronic survey was sent via e-mail to all 17 Canadian university-affiliated departments of anesthesia.	The survey response rate was 54% (53/98). Substance abuse was reported as 1.6% for residents and 0.3% for clinical fellows over a ten-year period ending in June 2014. Fentanyl was abused in nine of 24 reported cases. At present, one of 22 respondents (4.5%) reported a formal education program on substance abuse for faculty members, and 72% described mandatory education for residents. The majority of participants did not perceive substance abuse as a growing problem. Seventy-one percent of respondents indicated that methods for controlled-drug handling had changed in the previous ten years; however, 66% did not think that the incidence of controlled substance abuse could be decreased further by more stringent measures. Only 21% of respondents supported the introduction of random urine drug testing.
Boulton, M. A., Apos, & Connell, K. A.	What is the relationship of student nurses'	Quantitative, cross-sectional,	**Sample:** Members of the	Two groups mean age 26 years. Participants were	<u>Primary</u> A one-unit increase in

(2018). Relationship of Student Nurses' Substance Misuse to Perceptions of Peer Substance Use and Harmfulness. *Archives of Psychiatric Nursing, 32*(2), 310-316.	perceptions of peer substance misuse, perceptions of harmfulness of substance misuse to their own substance misuse?	correlational design.	National Student Nurse Association (NSNA). Membership includes 60,000 nursing students in 50 states and territories of the U.S. 4452 participants of the almost 60,000 responded to the Internet survey. 419 participants were removed because they did not complete the survey. Female (n = 3743, 93%), between the ages of 17 and 27 years (n = 2783, 69%, M= 26 years), and White (n = 3195, 79%) **Setting:** Internet survey	given a short demographic questionnaire, a self-reported personal use survey, and a survey of their beliefs about substance use, which included their beliefs about harmfulness and perception of peer use. Descriptive statistics were performed on the demographic characteristics of the participants.	perception of peer illegal drug use, students were 3.6 times more likely to use illegal drugs ($p < 0.001$). A one-unit increase in perception of harmfulness, students were 41% < likely to use illegal drugs ($p < 0.001$). The current rate of alcohol misuse (61% in the last year) appears higher than the rates of 15–29% alcoholic drinking reported in earlier surveys of student nurses. <u>Secondary</u> None
Bozimowski, G., Groh, C., Rouen, P., & Dosch, M. (2014). The Prevalence and Patterns of Substance Abuse Among Nurse Anesthesia Students. *American Association of Nurse Anesthetist Journal, 82*(4), 277-283.	What is the prevalence, demographic factors, outcomes, and preventative measures for substance abuse among nurse anesthesia students over a 5-year period from 2008 to 2012?	Cross-sectional, retrospective study	**Sample:** Program directors (PD) of 111 accredited nurse anesthesia programs **Setting:** Accredited nurse anesthesia programs in the United States.	An electronic survey sent to the program directors. Survey items inquired about known incidents of substance abuse including the drugs abused and student outcome (termination, readmission, loss of licensure, or death).	<u>Primary</u> 23 programs (RR = 21.7%) reported data 2,439 students. 16 incidents of substance abuse reported 5-year prevalence of 0.65%. <u>Secondary</u> Opioids primary drug of choice (n = 9). Programs listed no predisposing RF in 50% of the incidents. Students, reported outcomes: voluntary entry into

					treatment (n = 10), dismissal from the program (n = 7), loss of nursing license (n = 2), and 1 death.
Chipas, A., & McKenna, D. (2011). Stress and burnout in nurse anesthesia. *American Association of Nurse Anesthetist Journal, 79*(2), 122.	What are the current level of stress and its physical manifestations in Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs)	Cross-sectional study	**Sample:** 28,000 CRNAs and SRNAs who had email addresses on file with the AANA. Data were collected between February and May 2008. There were 7,537 respondents or 26.9% of all eligible ACPs. CRNAs responding, 40% were male and 60% females. **Setting:** Email questionnaire to U.S. CRNAs and SRNAs	The study used data collected between February and May 2008 using a Stress and Burnout Survey on an online survey tool (SurveyMonkey).	Response rate was less than 27%, the resulting sample size was 7,537 Substance abuse: Weekly % = 2.0 Monthly % = 4.0 Intermittent % = 2.4 Not applicable % = 91.6
Fitzsimons, M. G., Baker, K., Lowenstein, E., & Zapol, W. (2008). Random drug testing to reduce the incidence of addiction in anesthesia residents: Preliminary results from one program. *Anesthesia Analgesia, 107*(2), 630-635.	Does random drug testing reduce the incidence of addiction in anesthesia residents?	Quasi-experimental	**Sample:** All incoming anesthesia residents **Setting:** MGH	Urine drug testing is performed at an outside facility. The sample is initially screened for substances by enzyme immunoassay. Confirmatory analysis of a positive immunoassay is via gas chromatography ± mass spectroscopy. An independent certified medical review officer (MRO) receives,	Primary Overall, the incidence of substance abuse 1% 403 resident-years during the 6 yrs. before testing began. During this same time, in the most highly vulnerable CA-1 residents, the incidence of drug abuse in the 138 resident-years was 2.2% (3 events). During this time period, one event occurred in a

				interprets, and reports all results of the workplace urine drug-testing program.	resident during the second year. No events occurred during 330 resident-years since testing began in 2004. The data are associated with a p= 0.13 Fisher's exact test. <u>Secondary</u> None
Hyman, S. A., Shotwell, M. S., Michaels, D. R., Han, X., Card, E. B., Morse, J. L., & Weinger, M. B. (2017). A Survey Evaluating Burnout, Health Status, Depression, Reported Alcohol and Substance Use, and Social Support of Anesthesiologists. *Anesth Analg, 125*(6), 2009-2018.	Is burnout is associated with physical health issues, mental health issues, and substance abuse?	A cross-sectional, convenience sample	**Sample:** 221 respondents began the survey, and 170 (76.9%) completed all questions. There were 266 registrants total (31 registrants for the live webinar and 235 for the archived event), yielding an 83% response rate. Among respondents providing job titles, 206 (98.6%) were physicians and 2 (0.96%) were registered, nurses. **Setting:** Webinar participants.	The American Society of Anesthesiologists and the journal Anesthesiology cosponsored a webinar on burnout. As part of the webinar experience, we included access to a survey using MBI-HSS, 12-item Short Form Health Survey (SF-12), Social Support and Personal Coping (SSPC-14) survey, and substance use questions. Results were summarized using sample statistics, including mean, standard deviation, count, proportion, and 95% confidence intervals. Adjusted linear regression methods examined associations between burnout and	The frequency of high-risk responses ranged from 26% to 59% across the 3 MBI-HSS categories, but only about 15% had unfavorable scores in all 3. Mean mental composite score of the SF-12 was 1 standard deviation below normative values and was significantly associated with all MBI-HSS components. With SSPC-14, respondents scored better in work satisfaction and professional support than in personal support and workload. Males scored worse on DP and personal accomplishment and, relative to attending physicians, residents scored worse on DP. There was no significant association between MBI-

				substance use, SF-12, SSPC-14, and respondent demographics.	HSS and substance use.
Oreskovich, M. R., Shanafelt, T., Dyrbye, L. N., Tan, L., Sotile, W., Satele, D., . . . Boone, S. (2015). The prevalence of substance use disorders in American physicians. *American Journal on Addictions, 24*(1), 30-38. doi:10.1111/ajad.12173	What is a current substance use disorder in a large sample of all specialty physicians in the U.S?	Cross-sectional study	**Sample:** A National Study of Substance Use Disorder (SUDS) in a large sample from all specialty disciplines using the AMA Physician Masterfile. E-mails were sent to 89,831 physicians. Of the 27,276 physicians who received an invitation to participate, 7,288 (26.7%) completed surveys. **Setting:** Survey of U.S. physicians	Substance Use Disorders (SUDS) were measured using validated instruments WHO Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) that has been modified for this use by the National Institute of Drug Abuse (NIDA)	12.9% of male physicians and 21.4% of female physicians met diagnostic criteria for alcohol abuse or dependence. Abuse of prescription drugs and the use of illicit drugs was rare. Factors independently associated with alcohol abuse or dependence were age (OR¼.985;p<.0001),hours worked(OR¼.994;p¼.0094), male gender (OR¼.597;p<.0001), being married (OR 1.296; p¼.0424) or partnered (OR 1.989; p¼.0003), having children (OR .745; p¼.0049), and being in any specialty other than internal medicine (OR 1.757; p¼.0060). Specialty choice was strongly associated with alcohol abuse or dependence (p¼.0011). Alcohol abuse or dependence was associated with burnout (p<.0001), depression (p<.0001), suicidal ideation (p¼.0004), lower

					quality of life (p<.0001), lower career satisfaction (p¼.0036), and recent medical errors (p¼.0011).
Warner, D. O., Berge, K., Sun, H., Harman, A., Hanson, A., & Schroeder, D. R. (2013). Substance use disorder among anesthesiology residents, 1975-2009. *Journal of the American Medical Association, 310*(21), 2289-2296. doi:10.1001/jama.2013.281954	To describe the incidence and outcomes of substance use disorder (SUD) among anesthesiology residents.	Retrospective cohort study	**Sample:** 44,612 anesthesiology residents contributing 177,848 resident-years to analysis. Follow-up for incidence and relapse was to the end of training and December 31, 2010, respectively **Setting:** Physicians who began training in United States anesthesiology residency programs from July 1, 1975, to July 1, 2009	Cases of SUD (including initial SUD episode and any relapse, vital status and cause of death, and professional consequences of SUD) ascertained through training records of the American Board of Anesthesiology, including information from the Disciplinary Action Notification Service of the Federation of State Medical Boards and cause of death information from the National Death Index	<u>Primary</u> 384 residents had evidence of SUD during training, with an overall incidence of 2.16 (95% CI, 1.95-2.39) per 1000 resident-years 2.68 (95% CI, 2.41-2.98) men and 0.65 (95% CI, 0.44-0.93) women per 1000 resident-years. During the study period, an initial rate increase was followed by a period of lower rates in 1996-2002, but the highest incidence has occurred since 2003 (2.87 [95% CI, 2.42-3.39] per 1000 resident-years). <u>Secondary</u> The most common substance was iv opioids, followed by alcohol, marijuana or cocaine, anesthetics/hypnotics, and oral opioids. 28 residents (7.3%; 95% CI, 4.9%-10.4%)
Warner, D. O., Berge, K., Sun, H., Harman, A., Hanson, A., &	What risk factors and outcomes for substance use disorder (SUD) in	A nested, matched case-cohort design	**Sample:** 384 anesthesia residents who developed (SUD)	For each of 384 individuals with evidence of SUD while	Receiving medical education within the United States, but not

Schroeder, D. R. (2015). Risk and Outcomes of Substance Use Disorder among Anesthesiology Residents: A Matched Cohort Analysis. *Anesthesiology, 123*(4), 929-936.	physicians enrolled in anesthesiology residencies approved by the Accreditation Council for Graduate Medical Education. Using a comparator group of anesthesiology residents who did not develop SUD, this		and 768 controls who did not, receiving medical education in the United States, but not anesthesia knowledge early in residency, was associated with risk of developing SUD. **Setting:** The primary data sources for this ascertainment process included the training records of the American Board of Anesthesiology (Hussain et al.), the National Death Index, and the Disciplinary Action Notification Service (DANS) of the Federation of State Medical Boards	in primary residency training in anesthesiology from 1975 to 2009, two controls (n = 768) who did not develop SUD were identified and matched for sex, age, primary residency program, and program start date. Risk factors evaluated included location of medical school training (the United States vs. other) and anesthesia knowledge as assessed by In-Training Examination performance. Outcomes (assessed to December 31, 2013, with a median follow-up time of 12.2 and 15.1 yr. for cases and controls, respectively) included mortality and profession-related outcomes.	performance on the first in-training examination was associated with an increased risk of developing SUD as a resident. Cases demonstrated a marked increase in the risk of death after training (hazard ratio, 7.9; 95% CI, 3.1 to 20.5), adverse training outcomes including failure to complete residency (odds ratio, 14.9; 95% CI, 9.0 to 24.6) or become board certified (odds ratio, 10.4; 95% CI, 7.0 to 15.5), and adverse medical licensure actions subsequent to residency (hazard ratio, 6.8; 95% CI, 3.8 to 12.2). As of the end of follow-up, 54 cases (14.1%) were deceased compared with 10 controls (1.3%); 28 cases and no controls died during residency.

APPENDIX E:

COMMON CONCEPTS WITH EXAMPLES: ANSWERS TO QUESTIONS 1 – 6

Question 1: Common concepts with examples.

Question 1: Were you aware of drug diversion prior to agreeing to participate in this focus group?	
Common Concepts	**Examples**
Each of the three participants agreed that they were aware of drug diversion prior to the focus group.	Participant 1- "Yes." Participant 2- "Yes, totally do." Participant 3- "Yes."

Question 2: Common concepts with examples.

Question 2: In your opinion, do you see drug diversion as a significant issue as it pertains to anesthesia? Why, or why not?	
Common Concepts	**Examples**
Drug diversion seen as a significant issue among key stakeholders. *1) Patient and healthcare provider safety and potential harm issue* *2) Always has been a significant issue*	Participant 1- "Yeah. And listening to your numbers of just the two, over a period of time, it doesn't sound like it's a huge issue, but that's just the people you know, and when you talk about patient safety, even when I look at just health care workers in general, that's when you start to see that impact and that becomes important to us. I still think that impacts patients because I think about it. Are they diverting it from the patient and taking it? Are they just taking it? If you never really know, and so in my mind, those are all harms to the patient. If you're taking it from the patient and utilizing it where you won't get caught but the patient's not getting what they may need. So, that's where I always feel like one is too many." Participant 2- "Yes. For me, I mean ever since I've been in the pharmacy profession, it's always been a, significant issue. Doesn't matter one or you know, one is too much" Participant 3- "Yeah, definitely. In my opinion, I do see the diversion as a significant issue. During the years of my practice, even just here at this institution, I've witnessed quite a few diversions resulting in harm to the particular individual. We, in this particular institution, at least in the anesthesiology department."

Question 3: Common concepts with examples.

Question 3: If you feel drug diversion is a significant issue pertaining to anesthesia, what concerns you most about this issue?	
Common Concepts	**Examples**
Patient and provider safety and wellbeing. *1) Potential mishaps or injury.* *2) Need to remain drug free to care for patients.* *3) Liability and legal risks to institution.*	Participant 1- "I think it's probably two-fold. One really is the patient that, if we, let's say we are compromised, we could have a mishap that would normally happen if you weren't using something. Then the other thing is just what ultimately is going to happen to that individual as, I think it gets back to us saying, how do we make the environment healthy for people where they can be healthy and then ultimately, we're human. We'll make mistakes, but that the patients are going to get what they need and you're going to be focused. I just can't imagine if you're taking certain levels of drugs, regardless of whatever your tolerance is,

	you're not going to be at your best game. I think that's probably the biggest worry is that and I do think sometimes before it becomes known, I think it does lead to some disruption in the work and in the team. I think people start to know something's not right but they don't call it out. Cause we're all sometimes afraid to say something and so we'll think something's not right. Then, you become part of that problem too and that's hard to recover a team from." Participant 2- "Yeah, to kind of add that it's just more of the, anesthesiologist are to me as you know, in their work area are very much pretty much the controlling of the environment, and if they can't really truly control their environment, a lot of things can happen and they need to be at the top of their game all the time. It's a very stressful job." Participant 3- "The patient outcomes and also provider outcomes. But I'd add on top of either one of those is the risk, and liability outcome, legal outcomes that, can be imposed on an institution."

Question 4: Common concepts with examples.

Question 4: Do you believe the implementation of CS waste assay testing of returned medication will help decrease drug diversion or help detect misuse sooner? Is CS waste assay testing feasible for this facility?	
Common Concepts	**Examples**
Reliable means for determining possible diversion of drugs *1).....* *ore difficult to divert with CS waste assay testing in place.* *2).....* *ore reliable than current two-person waste of CS* *3).....* *ill be an impactful process*	Participant 1- "I'm thinking it's probably the most reliable means of knowing for sure what is being wasted. Because even if I am diligent and watch you, I don't know if you drew up something else cause you usually come to me saying I'm going to- you're going to watch me waste this, but I don't know if you hadn't already done something with it. So, I'm not going to be able to discern if it's really that drug." Participant 2- "Yeah, I mean, I've been at facilities, we've used some spectrum assay testing. With pharmacy, we didn't do it our self. We send it to the lab. So, it was something that we used and, and it worked well when we had to, we didn't do it often. It was more of that found type medications and we wanted to make sure it was, we can trace it back to see where, you know, how it was found. I think the assay will help out and, and it has its place to help with that diversion." Participant 3- "Yeah, I think the assay would definitely have an impact at least in two areas. I should say a pleaser for all providers it would probably be more threatening to a person's diverting because they know now they've got to have the real stuff in there and so it's going to take more discipline on their part to make it the real stuff that they're wasting. I very strongly think that we need to have an assay, whether it's every drug that comes back or whether it's just randomly and with target, once there's some clinical suspicion."

Question 5: Common concepts with examples.

Question 5: What barriers do you foresee to implementing this type of testing?	
Common Concepts	**Examples**
Barriers may not be formidable to implement CS waste assay testing *1).....* *ut time in to figure out the process* *2).....* *ducate staff on the process* *3).....* *magined barriers*	Participant 1- "I don't see barriers in the sense of a philosophy, like a philosophical barrier in doing, I think one, it's just really what it takes to put it in play and that, it's something that's quick and easy. It's more of making sure that process is in place before you move forward with it. Put the right resources and what that takes and it might end up taking less resources than what we do today." Participant 2- "The only other barrier I would say, yeah. Letting people know why. Then we just need to make sure that you give them a little bit more of a background so that way they don't feel that we're just testing or we're doing a project for someone. It's more of a why we want to do it, just to help out, help them out in the long run." Participant 3- "I think, some of my barriers are probably more imagined than real. I just see it so positive now. I wonder how could there be any barriers? And I think, you're right, although nice to hear you say it, that there was no philosophical issue with it."

Question 6: Common concepts with examples.

Question 6: What is the current cost of the drug diversion program at VHMC? What do you think the cost would be if CS waste assay testing was implemented?	
Common Concepts	**Examples**
Expense for current process may be more than if CS waste assay testing is implemented *1) Staff costs to look at records and data if a healthcare worker is suspected of diversion* *2) Potential cost saving with CS waste assay testing*	Participant 1- "I would say probably what like maybe once a month we drill down on people anyway, but then we drill down on people because we have concerns. Then it's, it's a little bit more resources because we pull everything. We really start to look at the charts, look at what they've documented and what their colleagues have documented. So, I mean, I guess if you just figured like it could be $50,000 a year that we're doing and just the, data pieces of it." Participant 2- "So, if you think about it, for us it's like I said, a monthly report. So, you're looking at employee or technician who you know, a certain dollar amount, you know per an as a portion of their job. So, you know, I would say costly wise, you're looking at 20% of the salary. I would say, and I don't know, I can't tell you the numbers of those assessments, but 20% of the salary just on the pharmacy part and then it goes up to the nursing areas and that's a certain percentage of their day looking, verifying all that, the medications that we are saying about this individuals are in." Participant 3- "Once we hear a little bit more, it's probably moved from the expense side of it so that's not so severe."

APPENDIX F:

WHITE PAPER PROPOSAL

University of Arizona
Doctor of Nursing Practice

THE FEASIBILITY OF ADDING CONTROLLED SUBSTANCE WASTE ASSAY TESTING TO A CURRENT DRUG PREVENTION PROGRAM

Protect Patients and Healthcare Staff from Drug Diversion

Joseph Bailon, MNA, CRNA

Background

- Numerous articles and studies have described the significant problem of drug diversion by healthcare workers (Berge et al., 2012; Bryson & Hamza, 2011).
- The potential to abuse drugs is considered the most significant occupational safety hazard Anesthesia Care Providers (ACP) face on a daily basis (Tetzlaff, 2011).
- The organization must be prepared for critical issues that inevitably will occur due to drug diversion, which include: patient harm, fraudulent billing, liability for resulting damages, regulatory and legal risks, and diminished public trust in the healthcare system (Berge et al., 2012).
- To review process compliance and effectiveness, the institution should apply technology and diligent surveillance to strengthen controls and set out to be proactive versus reactive in drug diversion prevention (Brummond et al., 2017).

Purpose and Methods

- The purpose of this project was to determine the feasibility of implementation of random controlled substance (CS) waste testing and remove the current two-person waste requirement at VHMC.
- A focus group of key stakeholders met to determine the feasibility of CS waste assay testing at VHMC.
- Assay testing CS waste is accomplished by using a refractometer. This method is considered a practical solution to monitor returned CS waste samples. The process is easy to perform and can alert the pharmacy staff if the returned sample does not match what the stated product should have been. Using this type of refractive index measurement pharmacy staff will be aware of potential drug diversion or tampering by providers and can place departments on alert for potential abuse. This type of testing has been recommended by the American Society of Health-System Pharmacists (ASHP) guidelines and others (Berge et al., 2012; Brummond et al., 2017).
- The literature supports the use of controlled substance assay testing to deter drug diversion (Bryson & Hamza, 2011).

Results

- The implementation of controlled substance waste assay testing could potentially deter ACPs from deciding to misuse these highly addictive drugs knowing they themselves may be detected, prosecuted and have to deal with professional and legal issues (Brummond et al., 2017).
- There is high likelihood that some providers are impaired at work considering it is believed that one out of every ten actively practicing Certified Registered Nurse Anesthetists (CRNAs) misuses a controlled substance (Wright et al., 2012).
- This process could potentially help decrease or possibly alleviate the unfortunate risk of drug diversion among ACPs, indirectly improving patient safety and outcomes (Berge et al., 2012).
- Berge et al. (2012), anecdotally described reductions in diversions from 1 per year to 1 in 7 years at the Mayo Clinic, once random quantitative assays of CS waste returned to the pharmacy was implemented.

Implications and Change Proposal

- The focus group consensus was there is a need for providers to remain drug free to care for patients. There is a high potential for major liability and legal risks to the institution if drug diversion is taking place. A more effective system for preventing and detecting drug diversion was seen as a necessary change.
- The group consensus was assay testing could be a reliable means for determining possible diversion of drugs. It becomes more difficult to divert with CS waste assay testing in place. The group believe assay testing is more reliable than current two-person waste of CS. They also concur that it will be an impactful process in the prevention of drug diversion within the institution.
- Group members voiced that the current drug diversion process may be more expensive than implementing CS assay testing.
- The group would like to take the time to figure out the process before implementation and educate the staff on the CS waste process.

November 2019

APPENDIX G:

ASHP GUIDELINES ON PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

ASHP Guidelines on Preventing Diversion of Controlled Substances

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Purpose

Controlled substances (CS) diversion in health systems can lead to serious patient safety issues, harm to the diverter, and significant liability risk to the organization. Diversion driven by addiction puts patients at risk of harm, including inadequate relief of pain, inaccurate documentation of their care in the medical record, exposure to infectious diseases from contaminated needles and drugs, and impaired healthcare worker (HCW) performance.[1,2] In addition to patient harm, there are regulatory and legal risks to the organization, including fraudulent billing and liability for resulting damages, and decreased community confidence in the healthcare system. These guidelines provide a detailed and comprehensive framework to support organizations in developing their CS diversion prevention program (CSDPP) in order to protect patients, employees, the organization, and the community at-large. Ultimately, each organization is responsible for developing a CSDPP that complies with applicable federal and state laws and regulations but also one that applies technology and diligent surveillance to routinely review process compliance and effectiveness, strengthen controls, and seek to proactively prevent diversion.[3,4]

Diversion of CS is common, but it is rarely discussed openly. Some recent high-profile events are raising new awareness to the prevalence of this issue and its implications. It is estimated that 10–15% of HCWs misuse alcohol or drugs at some point in their careers, which is similar to the general population.[5] With the role HCWs have in taking care of patients and the accessibility of CS in the work environment, organizations must routinely evaluate their employees, systems, and patient care environments.[6,7] It is imperative that healthcare organizations develop CSDPPs that include support systems for the work force (e.g., employee assistance programs, professional monitoring programs), methods to monitor effectiveness of diversion prevention efforts, and patient safety considerations. Education on the signs and symptoms of impaired HCWs—supported by rigorous monitoring and surveillance, human resources management, awareness of state and national diversion reporting requirements, and substance abuse treatment programs—is paramount for healthcare organizations. In addition, healthcare organizations are not immune to the larger societal issues associated with substance abuse, including the recent exponential rise in accidental overdoses, and should therefore ensure that there are systems in place to positively influence prescribing, procurement, dispensing, administration, and proper disposal and wasting of CS.[8-15]

There are many points where diversion may occur and many methods of diversion (Figure 1). CSDPPs that build in tight control through process checks and balances, diligent surveillance, and prompt interventions are required to prevent, promptly identify, and investigate suspected diversion. Such programs require a rapid response by key stakeholders, using established processes and time frames as defined by the organization. Clear policies, procedures, and lines of accountability should be in place for dealing with such investigations and reporting in a timely and thorough manner.

The purpose of these guidelines is to provide guidance to health systems on planning for and implementing best practices when establishing a comprehensive CSDPP. Establishing a comprehensive CSDPP will require engaged leadership oversight that promotes a culture of organizational

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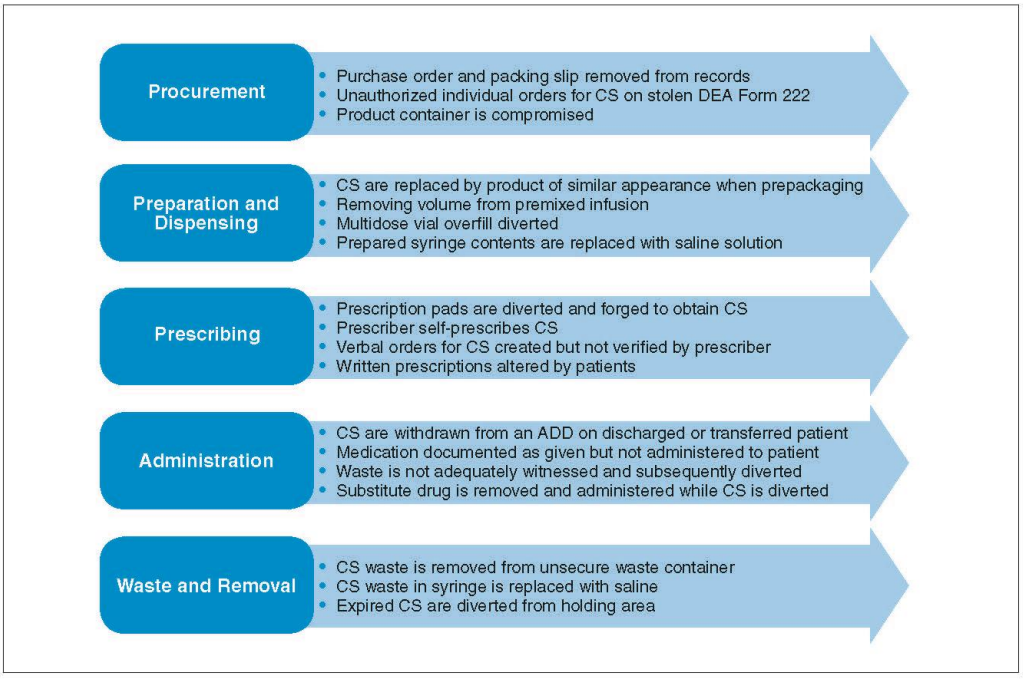
awareness, implements and evaluates the effectiveness of systems and processes, and works toward continuous improvement. The guidelines provide recommendations on developing CS diversion prevention strategies and a framework for integrating those strategies into a comprehensive organizational program that ensures successful implementation. The recommendations outline a collaborative, interdisciplinary approach to and accountability for CS diversion prevention and response within the organization. Some topics outlined in these guidelines are the subjects of other ASHP Best Practices documents, which should be referred to for additional information and guidance. Pharmacy leadership and other key stakeholders within healthcare organizations should use their professional judgment when determining applicability to their own needs and circumstances.

Scope

These guidelines address all settings in which health-system pharmacies typically have responsibility for purchasing, procuring, and distributing CS, including, but not limited to, inpatient settings, outpatient and community pharmacies, organization-owned clinics, and physician practices. The broad range of CS diversion prevention strategies recommended in this document supports a culture of safety for patients and HCWs and includes a suggestion that healthcare organizations define how to address impaired HCWs. To encourage dissemination and adoption of the strategies and recommendations outlined in this document, Appendix A provides a list of definitions of terms used in this document and in diversion prevention generally. Appendix B provides additional guidance regarding implementation strategies, examples of best practices, and key action steps described within the guidelines

Figure 1. Examples of common risk points and methods of diversion. CS = controlled substances, DEA = Drug Enforcement Administration, ADD = automated distribution device.



that can assist in self-assessment. Some of these approaches are relatively straightforward and can be implemented within the pharmacy. Other approaches are more complex and require collaboration throughout the organization and, in some cases, with vendors. Successful diversion prevention requires systematic attention to and integration of both types of approaches. When selecting and implementing these strategies, it is essential that the organization remains mindful of patient safety and the quality of patient care; patients must still be ensured access to timely care and effective pain management.

Core elements of a CSDPP

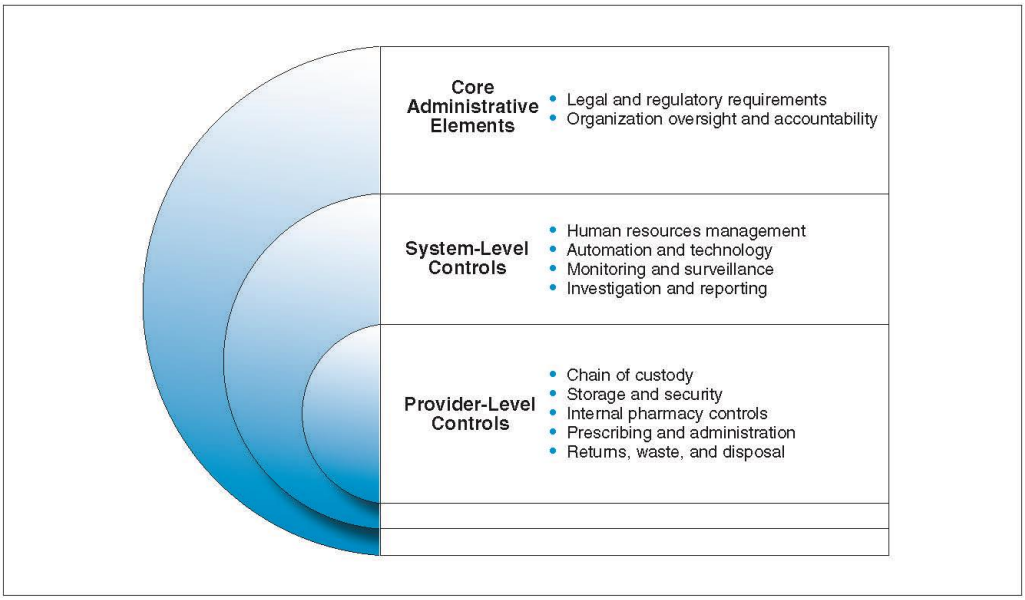
A comprehensive CSDPP includes core administrative elements (e.g., legal and regulatory requirements, organization oversight and accountability), system-level controls (e.g., human resources management, automation and technology, monitoring and surveillance, and investigation and reporting), and provider-level controls (e.g., chain of custody; storage and security; internal pharmacy controls; prescribing and administration; returns, waste, and disposal) (Figure 2). This framework is driven by key principles that include a collaborative approach, setting clear lines of accountability and responsibility, implementation of standard processes, and a culture of continuous readiness and quality improvement. When an organization has multiple Drug Enforcement Administration (DEA) licenses, all organization policies and procedures related to the CSDPP should be applied consistently.

Legal and regulatory requirements

The procurement, prescribing, administration, and transfer of CS are highly regulated by federal and state laws and regulations, as well as compliance standards (e.g., those of the Joint Commission and Centers for Medicare and Medicaid Services), and these requirements must serve as the foundation for the organization's policies and procedures.[6,7,16,17] Whether implemented manually or through the use of technology, policies and procedures must reflect current legal and regulatory requirements, including, but not limited to, records retention, biennial inventory, DEA registration and power-of-attorney designations, procurement requirements and forms, prescription authentication, surveillance, investigation and reporting of CS diversion or loss, authorization to access CS (i.e., to procure, prescribe, handle, transport, dispense, or administer), waste, and transfer. When applicable, the CSDPP integrates requirements for state-level CSDPPs and procedures, such as those required by professional licensure boards.

Billing and fraud implications. CS diversion also has billing fraud implications. When there are diversions

Figure 2. Controlled substances diversion prevention program.



with known documentation or processes that have impacted the integrity of the billing process, additional actions may be required. Organizations, with input from pharmacy, should take the initiative to self-monitor practices to prevent, identify, and correct potential fraud, waste, or abuse in collaboration with relevant departments (i.e., corporate compliance, finance, and internal audit).[18]

DEA registrations. The organization should be aware of applicable DEA registrations under its control and appoint a registrant who will be accountable for enforcement of requirements. Powers of attorney issued by a DEA registrant should be current and reevaluated on a regular basis (i.e., at least annually). There should be procedures in place for reporting suspected or known diversion to DEA and other appropriate local authorities, with the appropriate person submitting reports in accordance with requirements. Local DEA and law enforcement may vary in their requirements and preferences for how and when to report suspected diversion or theft. Furthermore, states vary in their requirements for who may handle and transport CS, for licensure and registration of providers, and for provider assistance programs. Those responsible for their CSDPP should be familiar with local and state requirements and work collaboratively to minimize risk to the organization and ensure public safety. Organizations should ensure completeness and integrity of required documentation, required elements in manual and electronic forms of documentation (i.e., procurement and disposition records and inventories), surveillance findings and actions, discrepancy investigations, and reports to DEA and other authorities; such documentation should be readily retrievable.

Patient's own medications, medical cannabis, marijuana, and illicit substances. Healthcare organizations should develop procedures for the disposition of patients' CS, medical cannabis, marijuana, and illicit substances brought into a facility.[19] Procedures should address notification of the local authorities when patients bring illicit substances into the organization, as required by law.[20] Pharmacy leaders, representatives of other affected HCWs, and the security department should work closely with the organization's legal counsel to interpret and weigh legal, regulatory, and accreditation requirements regarding these substances, as well as the rights of individual patients, in developing the organization's policies. It should be noted that, especially in the cases of medical cannabis and marijuana, possession and prescription laws vary from state to state.

Organization oversight and accountability

It is imperative that organizations establish a CSDPP that discourages diversion and strengthens accountability, rapidly identifies suspected diversion and responds to known or suspected diversion incidents, and continually seeks to improve controls. Strong organization oversight with broad HCW participation and a clear accountability structure provide a framework for a capable program.

Organizations should support the CSDPP by providing adequate resources, including human resources, facility controls, and technology. The pharmacy executive, whose central role is responsibility for the organization's medication-use system, will be an essential resource for a successful CSDPP. Key elements for organization oversight and accountability include the following (See Appendix B for additional guidance.):

- The organization establishes an interdisciplinary CS management program in compliance with statutory and regulatory requirements and with systems that discourage diversion and enhance accountability. Established policies and procedures address all points of access, reflect a segregation of duties where there are overlapping processes for diversion risk, and ensure that the chain of custody and individual accountability are maintained and verifiable at all times. To ensure that they are current, meet applicable practice standards, reflect best practices when possible, and are consistent with other organization policies, CS-related policies are reviewed at regular intervals and when there is a notable change in the organization's circumstances.
- HCWs authorized to access or handle CS are trained and competent in established policies, procedures, and regulatory requirements.
- As part of its CSDPP, an organization defines a structure that identifies and supports specific organization accountabilities with respect to oversight and implementation of the program.
- The organization establishes an interdisciplinary CSDPP committee to provide leadership and direction for developing policies and procedures and for overseeing the CSDPP. The CSDPP committee is proactive in its prevention efforts and addresses prevention control, diversion detection, incident investigation, and reporting procedures.
- The CSDPP committee is led by a designated diversion officer who coordinates all aspects of the program. The functions of this committee are integrated with existing compliance management programs, and the committee reports at least quarterly directly to the senior leadership of the organization.
- Committee members are identified and have clear roles with defined expectations. Suggested committee membership includes staff from the following departments: medicine, anesthesia, pharmacy, nursing, security, human resources, compliance, risk management, administration, legal, media/communications, information technology, and employee health. Pharmacy should have a leadership role on the CSDPP committee.
- A diversion response team should be established to respond immediately to suspected incidents, with stakeholder notifications tiered and based on the stage and findings of the investigation.

Human resources management

It is important that healthcare organizations approach CS diversion prevention with the same diligence they would apply to any potential compromise to patient safety and create a culture of awareness that supports an effective organizationwide CSDPP. A comprehensive human resources approach to support the CSDPP should at a minimum include (1) a written employee and provider substance abuse policy, (2) an HCW education and awareness program, (3) a supervisor training program, (4) an employee and provider assistance program, (5) peer support and systems (e.g., pharmacist recovery networks), (6) requirements for drug testing, including a for-cause policy for drug testing, (7) return-to-work policies for HCWs,[21] and (8) sanctions for performance and diversion violations. Pharmacists should participate in or contribute to the development of substance abuse prevention and assistance programs within healthcare organizations.[22]

First and foremost, organizations must implement policies to protect patients from potential harm related to substance abuse and diversion and have a process to remove an HCW suspected of being impaired from delivering patient care and to prevent further access to CS either pending investigation or after a confirmed diversion or policy breach. Organization policies should ensure compliance with federal and state laws regarding referral to local law enforcement and applicable licensing boards. The organization's senior leadership should determine the repercussions or sanctions for violations and for confirmed thefts or diversion and should ensure that those repercussions or sanctions are consistently applied across all disciplines. HCW sanctions should not vary depending on whether the HCW is supporting his or her own addiction (or that of an associate) or there has been theft of CS for sale and financial gain. The organization's substance abuse policy should address circumstances in which an HCW is discovered to be diverting to support an addiction. Such diversion should be addressed as theft and referred to local law enforcement and applicable licensing boards. The substance abuse policy should also address actions to take when a person separates from the employer during the course of an investigation, including when the organization should inform local authorities and notify the relevant licensing board.

There are signs that signal possible CS diversion, and all HCWs need to understand their role in recognizing diversion. The organization's senior leadership should communicate the expectation that HCWs speak up when they become aware of or suspect an issue related to CS diversion and should ensure that HCWs will be protected from retaliation if they report a suspected issue related to CS diversion. The organization should therefore establish and communicate ways for HCWs to speak up anonymously (i.e., hotline, paper, or electronic submission). The organization should treat such information as confidential and take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information.

All HCWs should receive initial orientation and annual education in diversion prevention and substance abuse and diversion awareness (signs and behavior patterns and symptoms of impairment) and reporting options. Education on medication diversion and CS policies and procedures should be required before granting an HCW authorization to access CS. The organization should emphasize the importance of reporting the signs of a potentially impaired HCW or suspected CS diversion and the potential impact on patient care, including ramifications for failure to report. Employees should be made aware that random compliance checks will occur and that employees will be held accountable for complete compliance with policies, laws, and record-keeping requirements. Managers should also receive training about signs, symptoms, and behavior alerts; what to do when they suspect an HCW is impaired; managing an HCW in recovery; and their responsibilities should they become aware of a known or suspected diversion.

The organization should establish a process to support recovery for HCWs who are diverting CS for an active substance abuse problem (i.e., an employee assistance program process, which may include mandatory program referral, reporting to the relevant state board program, and a contract for the HCW's return to work). Drug testing for cause should be permitted, and, as required for investigations or by licensing boards or other employment contracts, organizations should implement reliable testing and validation for drug screening. The organization should have policies to address the assessment of an HCW's ability to return to patient care when there has been a for-cause investigation. Furthermore, the organization should have a policy that addresses how to handle situations when there may be an additional impact on patient care, such as an infection control risk, and should address requirements for further testing (e.g., human immunodeficiency virus, hepatitis C).

If provider services are contracted, contracts should ensure that all contracted workers receive employee education regarding CS and that the contracted company will immediately notify the organization if there is disciplinary action against an HCW or if an HCW is removed because of an impairment issue.

Organizations will need to establish policies and procedures to manage situations in which diversion results in an HCW overdose or death in the workplace. These situations will require all of the investigation and discovery aspects of any suspected diversion but will also require that determinations be made regarding which authorities need to be immediately contacted, whether evidence will

need to be quarantined, and whether and how the chain of custody will be documented. See Appendix B for additional guidance.

Automation and technology

Automated technology, including automated dispensing and prepackaging devices, and diversion monitoring software have been developed to assist with the management of CS, including inventory control; documentation of removal, administration, and waste; billing; and auditing.[23] The level of automation may depend on the risk assessed by the organization for various areas. For example, areas commonly considered to be high risk include the main pharmacy CS vault, anesthesia and procedural areas, emergency departments, surgery centers, and remote locations. When available, automated solutions that support adequate control, surveillance, and auditing processes should be implemented. Despite their perceived ease of implementation an d use, automated dispensing and surveillance technologies still require diligence in the development of meaningful and readily retrievable reports, investigation of trends and variances, and review of the impact of changes in the automation technology. Pharmacists and other stakeholders in the organization should engage only vendors who will work collaboratively to develop adequate implementation testing, HCW training, and maintenance and upgrade plans for their technology solutions. Key elements of automation and technology to support a CSDPP include the following (See Appendix B for additional guidance.):

- An interdisciplinary team that includes pharmacy representation participates in the selection and implementation of all medication-related automated systems (e.g., surveillance software) and technology (e.g., automated dispensing devices, syringe and infusion pumps, security devices) to ensure they support diversion control, surveillance, and auditing of CS and meet legal, regulatory, and functionality requirements. Pharmacy has an integral role in the selection and implementation process. Any changes or upgrades to existing technology are reviewed by key stakeholders, including pharmacy, to assess the impact on systems of control, surveillance, and auditing, and the changes are tested and vetted to ensure that implementation meets legal, regulatory, and functionality requirements. A report of this assessment and any gaps identified with the new system/upgrade and a plan for remedy are documented in a formal report and reviewed by the CSDPP committee before implementation.
- CS management automation and technology vendors collaborate with healthcare organizations to provide adequate solutions that support control, surveillance, and auditing functions that address the entire chain of custody, up to and including administration to the patient, and have the ability to track waste, identify discrepancies, and pull data from technology systems into actionable reports, including, but not limited to, trending of information that supports diversion surveillance.
- Records generated from technology solutions are readily retrievable and contain information required to conduct investigations and fulfill investigator requests. Reporting capability is tested to ensure that data within reports are complete, accurate, and integrated into actionable reports that are readily retrievable.
- Systems are utilized in high-risk areas with high-volume CS (e.g., surgery or anesthesia areas, central pharmacy).
- Integrated systems are utilized in high-risk areas (e.g., auditing software, automated dispensing devices).
- All HCWs are adequately trained regarding their roles and responsibilities in the use of automation and technology, including surveillance capabilities, and their competency is assessed. Competency is assessed when an HCW assumes a new position, annually, or when there is a relevant change to existing technology.
- A pharmacist is designated to oversee automated dispensing devices, including selection, maintenance, and inventory management, and to ensure that procedures are in place to limit access to CS in automated dispensing devices by minimizing the number of authorized individuals with access, as well as the ability to immediately add or rescind access privileges.
- Policies and procedures that address access, security, and documentation are established in the event of automation downtime or system failure.

Monitoring and surveillance

The organization, through its CSDPP committee, should define, review, and audit relevant data that could indicate potential CS diversion and ensure that trends and variances are acted on in a timely manner and that corrective action plans are implemented (Figure 3). All variances should signal an opportunity for improvement. CS monitoring and surveillance rely on the availability and use of data and information, including timely access to actionable reports that support an effective surveillance and detection system. Furthermore, the CSDPP should assess the comprehensiveness and level of documentation and response to suspected diversion events and compliance with established policies and procedures. Automated systems and diversion monitoring software are recommended to support efficient surveillance, particularly for high-risk or high-volume locations.

The CSDPP committee, with input from the designated diversion officer, designated pharmacist representative, and pharmacy compliance team (if applicable), should oversee the organization's monitoring and surveillance efforts, including identifying required and routine compliance reviews, determining surveillance metrics for trend reports, assigning responsibility for and frequency of review, providing facility oversight, and conducting established audits of facility-based diversion monitoring and documen-

tation of suspected diversion events. The organization, through the CSDPP committee, should establish surveillance requirements, including the definition of monitoring and surveillance measures, thresholds of variance that require action, reporting frequency, and surveillance procedures. The organization, through the CSDPP committee, should ensure that all elements are implemented, conducted in a timely manner, investigated, and reported as required. All systems of control should be regularly audited for compliance on a scheduled basis. The CSDPP committee should provide facility oversight to ensure that established audits for facility-based diversion monitoring are conducted and documented. The use of diversion monitoring software to support surveillance activities is recommended.

Surveillance. Surveillance processes should be interdisciplinary and touch all aspects of the CS management system, from purchasing, inventory management, administration, waste and disposal, and documentation through expired-product management. CS auditing should be performed on a regularly scheduled basis, as determined by processes in a particular area, such as anesthesia, patient care units, special procedure areas, ambulatory care areas, and the pharmacy, focusing on identified risk points (Figure 1) and previous events. Self-audits should be conducted within areas as well as regularly scheduled audits by individuals external to the area being audited. The organization should periodically audit compliance with all diversion controls, including human resources requirements for individuals authorized to handle CS (i.e., completion of required background checks, documentation of training and competency requirements for authorized HCWs, compliance with licensure board reporting, testing for fitness for duty, random drug-testing requirements, and compliance with rehabilitation program requirements). Important examples of recommended surveillance practices include the following (See Appendix B for additional guidance.):

Figure 3. Monitoring and surveillance cycle.

- The healthcare organization assigns a pharmacist, with adequate support staff and dedicated time for surveillance monitoring, who is accountable for optimizing the implementation and functionality of automated dispensing devices and diversion monitoring software reporting capabilities. Other disciplines (e.g., nursing, quality assurance, anesthesia providers) are actively involved in surveillance monitoring and audits and assist with evaluation of trends and incident investigation.
- Processes for procurement surveillance are followed by all areas (e.g., research areas) that purchase CS under their own DEA license. For all purchases, authorization (e.g., power of attorney) is verified. The healthcare organization reviews purchase history through regularly scheduled audits to identify diversion through variations or changes in volume or pattern. CS purchase invoices are compared with CS orders and receipt into the pharmacy's perpetual inventory. Because the invoice–receipt pair may be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. A process is in place to identify unusual peaks in quantity or frequency of CS purchased and to conduct periodic reviews of the quantity of CS removals from the main inventory to patient care areas compared with actual documentation and/or patient care charges.
- Verification of a perpetual inventory should be conducted on a regular basis with the frequency consistent with the controls to limit the time frame for discovery. It is important to identify inventory discrepancies in a timely manner so the reason for the discrepancy can be more easily investigated. CS managed through automated dispensing device counts are verified (by blind count) each time a CS drawer is accessed. A complete inventory for CS in automated dispensing devices is conducted weekly, and CS storage areas outside automated dispensing devices are inventoried at each shift change by two authorized HCWs. CS inventory in the pharmacy narcotic

vault is counted at least monthly. A biennial physical inventory of all CS is completed and documented per DEA requirements (or per state requirements, whichever is the more strict interpretation). Movement of CS throughout the organization is traced, and all transactions are reconciled (e.g., reports match narcotic vault transactions with receipt into the automated dispensing device and/or paper inventory record with nurse signature of receipt).

- Prescribing practices and prescribing trends are evaluated, and significant variation from peers should be reviewed.
- Automated dispensing device reports are reviewed at least monthly by pharmacy and patient care managers as defined by the organization, and the results of the review are documented. Reports compare automated dispensing device activity with medication administration records. Patient response to medication (i.e., pain management) is also evaluated against medication administration records, documentation of response, and patient interview. The medication record is reviewed for the amount and quantity administered and compared with what other HCWs administer on subsequent shifts (when there is no change in patient condition).
- Nursing management integrates routine auditing and surveillance activities into core daily, weekly, or monthly responsibilities, including staff education regarding signs of diversion, symptoms of substance abuse, and diversion-reporting procedures; review of nursing removal, return, and wasting records; development, implementation, and monitoring of procedures for witnessing CS-related transactions; and investigation and reporting of suspected diversion in accordance with organization procedures.
- Nursing management conducts random patient interviews to verify that patients received pain medication and that the medication adequately controlled pain and also compares responses to nursing patient assessment notes and medication administration records. Inconsistencies found on patient interview may point to diversion at the time of administration. When possible, medication administration is integrated with clinical assessment in the electronic medication record. Incidents in which pain response is not as expected and all nurses are experiencing similar lack of medication efficacy are reported to the pharmacy for further investigation of product integrity; there are case reports of prepackaged CS containing the wrong medication, and these circumstances could signal a medication error.
- A process is in place to resolve CS discrepancies and specify the time in which discrepancies must be resolved. It is recommended that CS discrepancies be reported to the supervisor in charge and resolved as soon as possible upon discovery, preferably no later than the end of the work shift, and that discrepancies deemed to be resolved are reviewed by the supervisor to ensure the legitimacy of the resolution. Discrepancies that cannot be resolved ("unresolvable discrepancies") are reported immediately to pharmacy and are jointly reviewed by pharmacy and patient care leadership, with resolution within 24–72 hours.
- Pharmacy is immediately notified of and supports the reconciliation investigation when an unresolvable discrepancy is discovered, and a pharmacist is responsible for overseeing the investigation of the discrepancy, even when a technician assists with these duties.
- A trend of poor documentation practices by HCWs is reviewed for possible diversion. Provider transactions are reviewed for poor documentation patterns (e.g., failure to document, corrections in the pharmacy CS vault or automated dispensing machines), and trends of users and cosigners are tracked.
- Pharmacy reconciles CS in high-risk areas, such as surgery and anesthesia areas, by comparing the amount dispensed with the amount documented on the CS administration record and the amount documented as wasted.
- The organization identifies specific high-risk CS medications that are randomly assayed, and procedures include random testing of waste from all high-risk or high-volume areas (e.g., pharmacy sterile products preparation, surgery and anesthesia areas), as permitted by and in accordance with state and federal rules and regulations.

High-risk areas. The organization should identify high-risk areas (e.g., surgery, anesthesia, and sterile compounding areas, emergency departments) and include an assessment of risk for diversion (e.g., known diversion points), ease of detection (e.g., high-volume locations, level of oversight and controls, state of awareness of patients), and probability of harm (e.g., potential to impact the quality of care). Automation and technology should be utilized in high-risk areas to facilitate security controls and surveillance. High-risk areas should be defined by the organization but include areas where the same provider is prescribing, obtaining, preparing, and administering the medication, such as surgery centers, operating rooms, and procedural and anesthesia areas. High-risk areas are also locations where high volumes of CS are ordered, prescribed, stored, and dispensed within the same location. The main pharmacy is considered a high-risk area.

Anesthesia and operating rooms are high-risk areas for which organizations should consider additional policies and procedures. Documentation of doses administered in the health record should be routinely reconciled with documentation of doses dispensed, waste, and return quantities as well as prescribed doses. The pharmacist should be responsible for all drugs and CS dispensed and distributed in the setting. Pharmacy technicians, under the supervision of the pharmacist, could be assigned most of the responsibility for these daily activities as permitted by state and federal law. If there is a satellite pharmacy, minimal drug stock should be kept

in each surgical suite, and additional drug inventory should be maintained within a pharmacy location to the extent possible.

Satellite pharmacies supporting surgery and procedural areas should be staffed whenever the areas providing surgery and administering anesthesia are normally staffed. If the satellite pharmacy is not open 24 hours a day, it may be necessary to establish an after-hours drug supply. The pharmacy and anesthesiology departments should collaborate to decide the drugs and quantities required for this supply, including an assessment of the smallest appropriate dose and packaging, and the accountability system to be used. Supply levels should be checked, reconciled, and replenished daily. Dedicated pharmacy resources within the perioperative area allow for more active and timely monitoring of CS utilization and identification of possible diversion. Systems to track drugs used, adjust par levels as needed, and monitor drug expiration dates should be devised. The ASHP Guidelines on Surgery and Anesthesiology Pharmaceutical Services provide specific guidance on best practices unique to CS management for these patient care areas and services.[24]

Investigation and reporting of suspected diversion

It is imperative that there is a detailed and thorough approach to investigating and reporting suspected diversion. Incomplete investigations and follow-up can have serious patient care, legal, and compliance implications. Any unresolvable discrepancy should be considered a possible diversion and escalated to an investigation, with notifications to occur as defined in the organization's CSDPP. Processes should be in place to prompt an immediate investigation, the appropriate internal and external communications, and the completion of required reporting. Although the supervisor in the area where diversion is suspected will assist in conducting the investigation, those external to the area should be involved to ensure that biases do not influence the investigation. The pharmacy director or his or her designee and diversion officer (if different) should be notified immediately of any suspected diversion within the organization and participate in all active investigations. Investigation and reporting procedures should include the following (See Appendix B for additional guidance.):

- Guidance is provided with regard to the review process, including who will coordinate the investigation, appropriate team members, leadership and organization legal counsel notification, documentation of the investigation, and coordination of internal and external reporting.
- Investigations are conducted as thoroughly and completely as possible; at a minimum, reporting occurs when it is determined that the discrepancy is unresolved or that there has been a known theft or diversion. As the investigation proceeds, there is an escalation and broadening of notifications specified in the policies and procedures defined by the CSDPP.
- If the organization becomes aware of an arrest of an HCW for illicit use of CS, the organization immediately conducts an investigation of the HCW's transactions to assess whether diversion has occurred. The organization assesses whether to suspend, transfer, or terminate the employee or take other action (e.g., remove access to CS) or impose other sanctions against the HCW. The organization immediately removes access privileges to CS if diversion is suspected until the investigation is completed and a determination of diversion or other risks to patient care is made.
- The organization establishes guidelines for engaging external entities, such as DEA, licensure boards, laboratories (for testing), and local law enforcement. Guidance is provided with regard to review processes to determine who is required to be notified, when to notify, who is responsible for contacting the agency, and other circumstances for the notification. The organization fulfills reporting requirements for diversion or other unaccountable loss of CS in accordance with laws and regulations.
- 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.

Quality improvement. For significant diversions, a quality-improvement review should be initiated by the CSDPP committee, including a root cause analysis and recommendations to prevent future occurrences. Representatives from the area where there is a suspected diversion should be engaged in the investigation and refinement of prevention strategies. Furthermore, the CSDPP should coordinate a proactive diversion risk review, such as by conducting a failure mode and effects analysis, of processes, particularly when new drug products and dosage forms are approved, new technology or technology upgrades are being implemented, and new drug delivery systems are implemented. Results of the risk review should be used to make system improvements as part of the organization's performance-improvement activities.

Communications. The organization should have a clearly defined, full-disclosure policy and process to communicate to patients and families that are affected by CS diversion. The organization should also have guidelines for engaging the media and managing external public relations. Policy and processes should specify when to notify the media, what internal communications are required, and who is responsible for contacting the media

representative and approving media communications.

Chain of custody

Effective diversion control systems depend on implementing retrievable evidence that the chain of custody is maintained at all times and at all points when the transfer of CS occurs between individuals, whether within or external to the pharmacy (i.e., courier transport to other facilities, use of pneumatic tube systems, transfer to emergency medical service providers, or transfer from contract pharmacy services). Chain-of-custody controls depend on the ability to reliably audit the trail of transfer. The organization should establish and enforce a policy stating that employees with access to CS may not delegate their access to another employee in a way that will alter the audit trail for the chain of custody (e.g., not sharing electronic medical record, automated dispensing device, or pharmacy door passcodes; not providing key access and entry to unauthorized HCWs). The delivery of CS to a storage location without witness and receipt confirmation by another authorized HCW may not meet the intent of the chain of custody requirement. In addition, controls should be built in when transfer is made via transport mechanisms (e.g., a pneumatic tube system) to ensure that the CS is received and verified as received by an identifiable, authorized individual.

Measures should be in place to ensure the integrity and security of CS and the safety of personnel transporting CS to offsite locations. Secure, lockable, and tamper-evident delivery containers (i.e., carts, trays, or boxes) should be used to deliver CS. Packaging should not make apparent the contents (e.g., an opaque container). When used, locking mechanisms should be tamper-resistant and traceable (e.g., plastic tie locks with unique numerical identifier). The chain of custody should also apply to laboratory services (internal or external) used to analyze syringes or other products as part of an investigation or random assay process.

If CS are provided to emergency medical services (e.g., ambulance services), the organization should ensure that procedures are in place that comply with local and state requirements and ensure that the chain of custody is maintained and the disposition of CS is documented and retrievable. See Appendix B for additional guidance.

Storage and security

Storage and security of CS require a coordinated approach that includes facility controls (e.g., camera surveillance), physical access controls (e.g., locks or biometric access technology), and frequent inventory checks and surveillance to allow discrepancies to be discovered in a timely manner. Key elements of CS storage and security include the following (See Appendix B for additional guidance.):

- CS are stored in a locked and secured location (e.g., automated dispensing devices, safe, locked cabinet/drawer) at all times unless in the direct physical control of an authorized individual. When implementing or assessing facility and physical access controls, the security and safety of HCWs are taken into consideration.
- Storing CS in transportable lock boxes or "fanny packs" is avoided. If used, such lock boxes follow the same requirements for storage, security, and chain-of-custody controls as other inventory. Transportable lock boxes are not considered secure and are stored in a locked area accessible only to authorized personnel when not in use or otherwise unattended.
- Lock-out times for electronic locks on carts (e.g., medication or anesthesia carts) containing CS are limited to the narrowest window of time that is appropriate for the particular setting.
- There is a defined process to ensure that only authorized individuals have access to CS. Access to CS storage areas is minimized and limited to authorized personnel. There is a complete assessment of all HCWs with access privileges to ensure that only those permitted to access have access (i.e., currently employed, temporary employees, or licensed independent practitioners with privileges), and removal of access privileges occurs immediately upon separation.
- There are policies and procedures regarding CS access, including restrictions through assignment, key controls, and the use of passwords. For automated dispensing devices, biometric identification with a user ID is preferred over passwords. CS cabinets and carts that are not automated dispensing devices are secured with an electronic lock that requires a user-specific biometric identification, code, or badge swipe. Access is recorded and retrievable for surveillance.
- Where traditional key lock security and manual inventory systems are used, there is a procedure to track keys, secure keys after hours, replace lost keys, and change locks. Any HCW authorized to have access to or prescribe CS will be able to provide an appropriate photo identification upon request.
- The physical plant should provide for monitoring of secure locations (e.g., video surveillance and recording), particularly in high-volume storage areas at risk for theft and diversion, such as the main pharmacy vault, inventory storage location, and packaging areas.
- Camera surveillance should be considered (1) in locations where there is high risk for diversion, (2) in locations where electronic or biometric access is not available, (3) in remote locations, and (4) to assist with an active diversion investigation.
- Automated dispensing device technology should be utilized in high-volume CS areas, including the pharmacy, anesthesia and surgery locations, high-volume clinics, and outpatient procedure areas.
- When delivering CS to an automated dispensing device, restocking an automated dispensing device, or pulling returns from the return bin, there

should be a witness or other verification process (as previously described in the Monitoring and Surveillance section).

- Controls are in place to monitor pharmacy inventories for discrepancies. Within pharmacy areas with automated dispensing device vault management, CS are manually inventoried by two rotating, licensed, or otherwise authorized pharmacy personnel (e.g., pharmacy technicians) monthly. For high-volume or high-risk areas, more frequent verification audits are considered to prevent or minimize inventory count discrepancies and minimize the time window for discovery of the discrepancy. At least one of those conducting the inventory is a licensed pharmacist. For pharmacies without automated dispensing device vault management, a physical inventory is conducted at least once per month but preferably weekly. The inventory count includes expired or otherwise unusable CS awaiting disposal or transfer to a reverse distributor.
- CS counts managed by automated dispensing devices or done manually are verified by a blind count each time a CS drawer, pocket, cabinet, or refrigerator is accessed, except when unit-of-use dispensing technology is deployed.
- Inventory verification is conducted for CS managed by automated dispensing devices by two authorized HCWs if a blind count has not been performed within one week. CS not managed by automated dispensing devices are manually inventoried by two authorized HCWs at the beginning and end of every shift when the area is open for services.
- Patient-specific CS infusions are contained in a secured lock box utilizing no-port tubing unless under constant surveillance. Keys and access to these controls are limited and tracked as with any keys and lock boxes.
- Documents used to procure or prescribe CS (e.g., DEA Form 222, blank prescriptions) are secured and monitored with the same diligence as CS to prevent theft or loss.

CS brought into the hospital by patients

Procedures are established that address special circumstances to ensure controls are in place to secure CS and prevent diversion of CS brought into the organization by patients. Patients should be encouraged to return their own medications to home via a family member or agent when possible. CS should only be accepted when they are to be administered to the patient pursuant to a medication order. These medications should be inventoried and secured as with other CS in the patient care area and returned to the patient at discharge. Documentation of the patient's home medication, quantity inventoried, and signatures of two verifying HCWs should be recorded in the medical record upon receipt and at patient discharge. The patient or patient's representative should sign that he or she has received the medication and its quantity. CS that cannot be returned to home and are not to be administered to the patient are to be inventoried and removed from patient care areas with appropriate chain-of-custody documentation and stored securely per organization policies, which include procedures for returning CS to the patient or authorized persons and management and final disposition of CS if not returned to the patient or authorized persons. The organization should, in collaboration with local and state authorities, consider providing a public receptacle for disposal of CS by patients. When patients bring illicit substances into the organization, procedures should address notification of the local authorities as required by law.[19,20]

Internal pharmacy controls

Internal pharmacy controls include controls related to procurement, preparation, and dispensing of CS. These processes typically apply only to pharmacy locations. Diversion can occur at various points within these processes, and it is important to apply key principles to effectively minimize opportunities for diversion. Key principles include limiting the number of people authorized to order CS, creating separation of duties and rotation of HCWs through various responsibilities within the process, and observing for variation in processes. It is recommended that these processes be audited by external (to the pharmacy) review at least biannually. Examples of recommended procurement, preparation, and dispensing controls follow; see Appendix B for additional guidance.

Procurement controls

- All CS are procured from the pharmacy. If other departments or individuals are authorized to procure CS, there are checks and balances established to ensure the same policies and procedures are consistently followed throughout the organization.
- There are purchasing safeguards in place that prohibit ordering of CS by those not authorized by the organization. CS may only be ordered by authorized individuals (DEA registrant and those with power of attorney granted).
- An electronic CS ordering system (CSOS) is utilized, eliminating or minimizing use of paper DEA Form 222s.
- When paper DEA Form 222s are used, those forms are locked in a secure location, recorded on a perpetual inventory log, and accessible only to those authorized to procure CS. CSOS order files are backed up to an organization-based system to ensure that archived files are readily retrievable by designated personnel.
- Separation of duties exists between the ordering and receipt of CS. Two authorized individuals count and check in CS received and confirm that the order, invoice, and product-received documentation match. At least one of the receivers is licensed. The process is overseen by a licensed pharmacist.
- There is a process to investigate and remedy discrepancies when CS are received in the pharmacy from the wholesaler or other distributor.
- There are processes to track, reconcile, and audit CS products where prepara-

tion is outsourced to and received from a third party.
- Procedures exist that ensure the chain of custody is maintained for interorganization transfer or transport of CS (e.g., from a central distribution hub).
- Procedures define the controls and documentation required where CS are transferred between pharmacies.
- All CS procurement paperwork is reviewed for completion and filed according to applicable laws and regulations. Procedures are in place for patient care areas of the organization that are considered under common control that support the pharmacist-in-charge to provide oversight and authority to ensure proper procurement controls are being utilized.

Preparation and dispensing controls
- A perpetual inventory is maintained, and a blind-count process is used when adding or removing CS from a pharmacy inventory location.
- Access to inventory is limited, with controls to identify who accessed the inventory, when the inventory was accessed, and what changes were made to the inventory; access provides a readily accessible audit trail.
- To minimize diversion through drug product alteration or tampering, drug products are inspected for alteration or tampering, and any potential discrepancy is investigated for possible diversion.
- To minimize diversion during repackaging, CS are purchased and dispensed in unit dose packaging whenever possible. Diversion controls are in place when CS are repackaged, and repackaged products are routinely inspected to ensure product integrity.
- Delivery and restocking of CS in patient care and procedural areas require an auditable verification of delivery and receipt.
- Returns from the patient care and procedural areas (e.g., emptying a return bin) have an auditable verification of return. Returns are inspected for integrity.

Prescribing and administration

CS may only be ordered by licensed authorized prescribers with DEA authorization. When possible and as permitted by law, CS orders are generated and transmitted by electronic systems with controlled access, except in emergency situations or when impractical. When written prescriptions are used, there are controls in place to track and secure these prescriptions and paper used to print prescriptions (see the Storage and Security section). Order sets and guidelines that include CS should be evaluated and supported by clinical evidence. Guidelines, restrictions, and diversion controls should not delay patient treatment or compromise patient comfort. Key elements of prescribing and administration diversion controls include the following (See Appendix B for additional guidance.):

- A valid order from an authorized prescriber exists for all CS administered, and the number of CS allowed via automated dispensing device override status is minimized.
- There is a process to identify and verify authorized prescribers within either an electronic or a manual ordering system. There is also a process to identify and verify authorized prescribers and prescriptions written by medical residents or other providers who are authorized to prescribe CS under the organization's DEA registration (e.g., use of a suffix).
- Pharmacists clarify orders for which the prescriber or order is questionable with regard to prescriber identity or other legitimacy of the prescription or order.
- Active prescriptions and orders for CS are reevaluated regularly, and CS orders are reordered per the organization's policies when a patient transfers to a different level of care. The medical staff, in coordination and consultation with pharmacy, determines and establishes an automatic stop-order system for CS when there is not a specific time or number of doses prescribed. CS are retrieved from the storage location and administered to patients by a licensed provider within his or her scope of practice, and such administration is documented in the medical record. When administration is scheduled "as needed," the administration can be correlated to the patient assessment (e.g., pain scale).
- Access to medications for a particular patient is suspended immediately at discharge.
- CS are retrieved from inventory by the authorized HCW responsible for administering the medication as close to the time of administration as possible. Procedures for exceptions in emergency situations or settings are defined, and these exceptions are reviewed for appropriateness. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.
- CS packaging (e.g., vials, prefilled syringe systems, unit dose packages of oral dosage forms) is inspected for integrity when being inventoried, before dispensing, and upon administration.
- Generally, outside of pharmacy compounding areas and in patient care areas, CS are not drawn up into syringes in advance, and sequential dosing is avoided, recognizing that these processes may be necessary in some procedural areas. Specifically, single-dose syringes and vials are not used to deliver multiple doses. The syringes prepared in these procedural areas are labeled as required by approved procedures and kept under the direct control of the person preparing the syringes until administration. When sequential doses are required from a single syringe (e.g., during procedures), there is a method in place to track the doses ordered versus those administered.
- Policies and procedures address the documentation of CS issued but unused, and there is a process to return the unused CS to inventory. Returns should be placed in a one-way, secure return bin and not sent back to the automated dispensing device. These products should not be restocked until inspected for tampering.

Returns, waste, and disposal

To minimize waste, CS are stocked

in as ready-to-use form as possible (e.g., avoiding the use of multidose vials) and in the lowest commercially available units for doses frequently prescribed for patients. Waste may include products expiring, products prepared for administration but not administered to the patient (e.g., when a physician discontinues or a patient refuses administration), and drug product remaining after a partial dose is removed from its packaged unit. Waste may also include overfill in vials and drug product remaining in transdermal delivery systems. The organization's waste-handling practices should maintain chain of custody to minimize the risk for CS diversion. CS should be wasted immediately or as close to the time of administration as possible.

The wasting of all CS requires an independent witness and documentation; at least one, but preferably both, of the witnesses should be licensed. Procedures should define what constitutes complete and timely documentation of waste. An individual witnessing CS wasting should verify the product label, that the volume or amount being wasted matches the documentation, that the drug product being wasted physically matches the drug product in the documentation, and that the wasting occurs per policy for safe disposal and in a manner that makes the CS irretrievable. The entire process of drawing up and wasting from a vial should be witnessed so the individual verifying can be certain that the actual CS is being wasted and not a substituted or adulterated product. Approved methods for returns, wastes, and disposal of CS are defined in federal, state, county, and municipal laws and regulations. Key elements of returning, wasting, and disposing of CS include (See Appendix B for additional guidance.):

- All issued but unused CS that may be potentially reusable are returned to the pharmacy or to a designated, secure return location. All returns to the pharmacy and when using a reverse distributor require that the chain of custody be maintained and that witness of transfer is documented.
- In patient care areas where waste is documented through the automated dispensing device, the waste is documented in the same device from which the medication was removed.
- In patient care areas, unless selected for random assay (see the Monitoring and Surveillance section), unusable CS products, including patient-specific partially used preparations, are immediately wasted and witnessed by authorized individuals per specific organization procedures. Procedures ensuring that the chain of custody is maintained are established when waste is transferred to the pharmacy for conducting random assays.
- Partially used preparations or containers are not returned to the pharmacy for disposal, except for purposes of random assay. The act of wasting and the documentation of CS waste are completed by the same HCW who accesses and administers the medication, when feasible. Examples of cases in which this may not be feasible include wasting a CS infusion, patient-controlled analgesia cartridge, or multiday patch. Within the pharmacy, CS waste from compounded sterile preparations is wasted with a cosignature and randomly assayed at least quarterly.
- CS overfill is considered an unusable product and is wasted and documented according to established procedures.
- For defined high-risk areas (e.g., surgical, anesthesia, procedural, high volume) and/or specific high-risk CS medications (e.g., fentanyl), waste is witnessed and reconciled with an authorized HCW. Approved methods for wasting CS are defined in policies and procedures and comply with universal precautions and organization waste disposal requirements.
- Waste containers with any unusable CS product are secured to prevent tampering or made otherwise nonretreivable.
- Expired CS are clearly identified as such and stored in a separate secured location from other medications, and inventory is monitored until return via a reverse distributor or destruction and disposal in accordance with legal requirements. Before final transfer to a reverse distributor, DEA Form 222 is audited against amounts transferred. Expired or otherwise unusable CS are not retained or stored in the pharmacy for long periods of time, and the frequency of returns ensures that inventory is not allowed to accumulate. Returns or destruction occurs at least quarterly.

Special considerations

Although it is not possible to predict all scenarios, and procedures need to be customized for unique circumstances and settings, these guidelines present core principles applicable to all settings. Examples of areas with special considerations include both high- and low-volume areas, such as ambulatory care surgery centers, organization-owned physician practices, emergency medical services, research areas, off-campus clinics, long-term care facilities, home infusion services, and retail pharmacies.

Over 30% of hospitals and health systems operate retail pharmacies.[25] It is important to also understand and address controls unique to these operations. Organizations should include their retail pharmacies within the scope of their CSDPP oversight and proactively seek to improve controls, due to the high risk of diversion. Retail pharmacies within health systems pose a significant risk to the organization's CS supply chain because of potential theft and the possibility of receiving fraudulent prescriptions. Retail pharmacies should be aware that they are at risk for both internal and external theft and diversion. Schedule III, IV, and V CS are often stocked in bulk containers on shelves with limited physical access controls. To prevent external theft, these bulk CS containers should be stored with

non-CS inventory, where permitted by law.

Security measures, such as camera surveillance throughout the pharmacy, are imperative to deter and monitor for suspected theft and provide an avenue for discrepancies to be resolved in a timely manner. Badge reader or biometric access should be required for access to all Schedule II CS storage areas. These systems provide a physical access control, limit access to appropriate personnel, and create a perpetual log of employees who have accessed the storage cabinet. Schedule II CS requiring refrigeration should be stored among other refrigerated medications.

Inventory adjustments to CS medications pose a significant internal diversion risk. Depending on who within the pharmacy has security access to perform CS inventory adjustments, retail pharmacies should consider having auditing systems in place to track and validate inventory adjustments performed by staff. In addition, routine reports should be run to compare CS purchases with utilization to identify discrepancies in inventory and dispensing trends. In addition to CS inventory adjustments, CS prescriptions in will call and canceled prescriptions are significant internal diversion risks. Retail pharmacies should develop policies and procedures for an accounting of will-call and canceled prescriptions and consider developing several reports from their prescription management software to identify any CS medications that have not been picked up from will call within a specific period of time (e.g., 10 days) or have been canceled and returned to stock. Furthermore, organizations should consider interfacing their point-of-sale system with their prescription management software and develop a report to reconcile processed prescriptions with prescriptions in will call and sold.

Fraudulent prescriptions also pose a significant risk for diversion in the CS supply chain. Retail pharmacies should utilize a variety of diversion prevention and monitoring tools when reviewing CS prescriptions, including internal pharmacy documentation and dispensing records, third-party utilization reviews, and prescription drug monitoring programs, if applicable. Retail pharmacies should attempt to receive electronic CS prescriptions when possible. If hard-copy prescriptions are accepted, retail pharmacies should develop a system to document which employee received the CS prescription at prescription intake and validate that it was not introduced into the pharmacy dispensing system for fraudulent purposes. The same system should be utilized to document which employee processed the CS prescription. Finally, the CS prescriptions should be filed sequentially, and retail pharmacies should consider developing a system to audit hard-copy prescriptions for documentation of chain of custody from employee to patient, such as signature of receipt.

Personnel should keep a complete and accurate written or electronic perpetual inventory record for the receipt (CSOS and DEA Form 222) and disposition of all Schedule II medications, filed in sequential order. The perpetual inventory should be updated each time a Schedule II CS medication is received and should be verified by two employees, one of whom needs to be a licensed provider. Furthermore, the same sign-off process in the perpetual inventory log should occur with each fill of a Schedule II CS, when possible. Retail pharmacies should utilize labels from the prescription management software to record the quantity filled in the perpetual inventory log. Retail pharmacies should also consider implementing a system for partial fills of Schedule II CS, as they pose a significant risk for diversion. Schedule II CS medications should be audited each month to ensure correct counts and that the perpetual log has been signed off by two employees. All records, including but not limited to prescriptions, DEA Form 222s, CSOS receiving documents, perpetual inventory logs, and discrepancy reports, should be kept for a specified time as determined by the state board of pharmacy. When discrepancies are identified, they should be evaluated by a third party, such as CSDPP or internal auditing personnel.

Other areas providing CS prescriptions or drugs directly to patients (e.g., emergency departments, emergency medical services, discharge prescriptions, home infusion) should ensure the chain of custody from preparation to delivery or administration to the patient and wasting, if applicable, including procedures that validate that the chain of custody has been maintained.

Conclusion

Healthcare organizations should develop a framework for integrating CS diversion prevention strategies into a comprehensive CSDPP. With engaged interprofessional leadership and collaboration, organizations can foster a culture of organizational and individual awareness and accountability for CS diversion prevention and response.

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Additional information

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Appendix A—Definitions of terms related to diversion prevention

All terms used in these guidelines have the definition set forth in Title 21 United States Code Controlled Substances Act (CSA) (Section 102 of the Act [21 USC 802]) or part 1300 of Title 21 Code of Federal Regulations, except where noted.

Administer: Defined in the CSA [CSA §102(2); 21 USC 802(2)] (2), the term refers to the direct application of a controlled substance to the body of a patient or research subject by (a) an individual practitioner (or, in his presence, by his

authorized agent), or (b) the patient or research subject at the direction and in the presence of the individual practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

Audit trail: Defined in the DEA regulations [21 CFR 1300.03] but not in the CSA, the term refers to a record showing who has accessed an information technology application and what operations the user performed during a given period.

Automated dispensing system: Defined in DEA regulations [21 CFR 1304.02(g)] but not in the CSA, the term refers to a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications and which collects, controls, and maintains all transaction information.

Biometric: Defined in DEA regulations [21 CFR 1300.03] but not in the CSA, the term refers to authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both distinctive to the individual and measurable.

Blind count: A physical inventory taken by personnel who perform a hands-on count of inventory without access to the quantities currently shown on electronic or other inventory systems. Blind counts are used to assess the integrity of the automated inventory systems. (Source: www.businessdictionary.com/definition/blind-count.html)

Deliver: Defined in the CSA [CSA §102(10); 21 USC 802(10)], the term refers to the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

Dispense: Defined in the CSA [CSA §102(10); 21 USC 802(10)] but not in DEA regulations, the term means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, an individual practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery. Additionally, the term *dispenser*, as defined in the CSA [CSA §102(10); 21 USC 802(10)] and DEA regulations [21 CFR 1304.02(c)], means an individual practitioner, institutional individual practitioner, pharmacy, or pharmacist who dispenses a controlled substance.

Distribute: Defined in the CSA [CSA §102(10); 21 USC 802(10)] but not in DEA regulations, the term means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term *distributor* means a person who so delivers a controlled substance or a listed chemical.

Diversion: The term includes any unaccountable loss, theft, use for unintended purposes, or tampering of a drug. For purposes of these guidelines, *drug diversion* is a medical and legal concept involving the transfer of any legally prescribed drug from the individual for whom it was prescribed to another person for any illicit use, including any deviation that removes a prescription drug from its intended path from the manufacturer to the intended patient.

Healthcare worker: Refers to an employee, individual practitioner, or contracted worker who provides services within an organization and who has access to controlled substances.

Individual practitioner: Defined in the CSA [CSA §102(20); 21 USC 802(20)] but not in DEA regulations, the term refers to a physician, dentist, veterinarian, scientific investigator, pharmacy, organization, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practitioner practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Long-term care facility: Defined in DEA regulations [21 CFR 1306.02(e)] but not in the CSA, the term refers to a nursing home or a retirement care, mental care, or other facility or institution that provides extended healthcare to resident patients.

Password: Defined in DEA regulations [21 CFR 1300.03] but not in the CSA, the term refers to a secret code, typically a character string (letters, numbers, and other symbols), that a person memorizes and uses to authenticate his identity.

Pharmacist: Defined in DEA regulations [21 CFR 1304.02(g)] but not in the CSA, the term refers to any individual licensed by a state to dispense controlled substances and also includes any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by that state.

Prescription: Defined in DEA regulations [21 CFR 1300.01(b)] but not in the CSA, the term refers to an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily retrievable: Defined in DEA regulations [21 CFR 1304.02(h)] but not in the CSA, the term means that certain records are kept by automatic data-processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Reverse distributor: Defined in DEA regulations [21 CFR 1306.02(e)] but not in the CSA. The term *reverse distribute* means to acquire controlled substances from another registrant or law enforcement agent for the purpose of (a) return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf or (b) destruction. A *reverse distributor* is a person registered with the DEA as a reverse distributor.

Significant loss. A significant diversion is any unaccountable loss of a controlled substance. Some states and local authorities may have specific requirements for what is considered significant. In its 1971 regulation, 21 CFR 1301.74(c), DEA provided the following list of factors to consider when making determinations about whether losses are significant:

- The actual quantity of controlled substances lost in relation to the type of business,
- The specific controlled substances lost,
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances,
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses, and, if known,
- Whether the specific controlled substances are likely candidates for diversion, and
- Local trends and other indicators of the diversion potential of the missing controlled substance.

Appendix B—Controlled substances diversion prevention program self-assessment guide[a,b]

Organization Oversight and Accountability

- ☐ The organization establishes a controlled substances (CS) diversion prevention program (CSDPP).
- ☐ The organization establishes an interdisciplinary CSDPP committee to provide leadership and direction for

developing policies and procedures for overseeing the CSDPP. A pharmacy representative has a leadership role on the CSDPP committee, and there is a designated diversion officer who coordinates activities of the CSDPP.

- ☐ The diversion officer should have a license and a college degree in pharmacy or nursing, with at least 5 years of healthcare experience; ideally, the diversion officer would be a licensed pharmacist with 10 years or more of experience as a staff or managerial pharmacist and an advanced management degree (e.g., M.H.A. or M.B.A.). The diversion officer should have a thorough understanding of medication management systems and technologies (e.g., automated dispensing devices, medication carts, repackaging systems); CS surveillance and management systems and techniques; federal and state regulatory compliance requirements; and auditing techniques. The diversion officer should be familiar with operations of the pharmacy department (e.g., ordering, receiving, storage, distribution, administration, returns, wasting) as well as other pertinent areas (perioperative, anesthesia, procedure, clinic, research, and retail pharmacy areas). The diversion officer should be able to lead the complex investigatory processes of an interdisciplinary team, which will require strong analytical and communication skills, attention to detail, organization, ability to work independently and collaboratively, and a commitment to healthcare ethics and confidentiality. The diversion officer should have formal training in the processes of conducting a drug diversion investigation and, if performing interviews or interrogation, in those techniques as well. The diversion officer should have the ability to work with local, state, and federal law enforcement organizations during criminal investigations, as well as with state licensing agencies and national accrediting organizations. The diversion officer should have the ability to work with the organization's human resources department and hospital leadership to develop strong policies to protect employees and mitigate employee diversion risks. Familiarity with the causes, symptoms, recognition, and treatment of drug addiction and human behavioral assessment is desirable, as is a passion for patient safety and protecting the organization from diversion. Diversion officers should be familiar with national, state, and local drug abuse and diversion trends. They should be involved with national, state, and local organizations and efforts to help raise awareness of drug diversion, and attend local, state, and national diversion meetings (e.g., National Association of Drug Diversion Investigators conferences).
- ☐ The CSDPP committee
  - ○ Includes representatives from, but not limited to, the following departments: medical, anesthesia, pharmacy, nursing, security, human resources, compliance, risk management, administration, legal, communications, information technology, and employee health;
  - ○ Establishes a charter that includes membership composition, roles, responsibilities, reporting structure, and meeting frequency; and
  - ○ Is proactive in its prevention efforts and actively addresses prevention control, diversion detection, incident investigation, and reporting procedures (e.g., minutes that document monitoring trend reports, quality-improvement efforts and outcomes of those efforts, compliance with existing procedures, and reviews of internal and external audits and action plans).
- ☐ The functions of the CSDPP committee are integrated with existing compliance management programs, and the committee reports at least quarterly directly to the senior leadership of the organization.
- ☐ A diversion response team that can rapidly and effectively respond to suspected incidents is established, with notifications tiered based on the stage of investigation.
- ☐ The diversion response team members conduct diversion risk rounds.[c] Diversion risk rounds involve observation of areas where controlled medications are received, stored, or utilized, as well as interaction with staff and patients in these locations. The objectives are to assess security, monitor compliance with regulations and institutional policy, and initiate process improvement where warranted.
- ☐ Established policies and procedures reflect federal and state regulatory requirements.
- ☐ Policies and procedures build in closed-loop chain of custody with individual accountability that is readily auditable.
- ☐ CS diversion incidents are collated, reviewed, and analyzed to identify further opportunities for improvement in existing systems.
- ☐ Surveillance data are trended and shared with the CSDPP committee to review on at least a quarterly basis. Trended information is acted upon, corrective actions are implemented, and resolution of the identified issue is verified.
- ☐ The CSDPP conducts failure mode and effects analysis to identify potential points of risk and develop prevention strategies.
- ☐ The CSDPP ensures that policies and procedure reflect a segregation of duties where there is overlapping processes for diversion risk.
- ☐ The organization identifies high-risk areas where CS diversion could occur and implements specialized controls and more focused surveillance for these areas when warranted.
- ☐ Drug Enforcement Administration (DEA) licenses are current, and power-of-attorney designees are reevaluated at least annually.
- ☐ The organization collaborates and cooperates with key external stakeholders, including local DEA officials, local law enforcement, wholesalers, technology vendors, state licensure boards, and contract pharmacy services.

Human Resources Management (Staff Education, Expectations, Culture, Support)

- ☐ The organization implements a process to remove a healthcare worker (HCW) suspected of being impaired from delivering patient care and to prevent further access to CS either pending investigation or after a confirmed diversion or policy breach.
- ☐ The organization has a clearly defined full disclosure policy and process to communicate to patients and families that are affected by CS prevention diversion.
- ☐ The organization conducts pre-employment background checks for HCWs who have access to CS in the course of their job responsibilities.
- ☐ When HCWs with access to CS are suspended, terminated, or otherwise separated, the pharmacy and designated system administrator are notified immediately so access to CS can be removed promptly, within a time frame defined by the organization.
- ☐ Known diverters who are licensed or registered are reported to the appropriate licensing or registration board as required by state law.
- ☐ A comprehensive human resources and occupational health approach to support the CSDPP at a minimum consists of (a) a written employee and provider substance abuse policy; (b)

an HCW education and awareness program; (c) a supervisor training program; (d) an employee and provider assistance program; (e) peer support and systems (e.g., pharmacist recovery network); (f) requirements for drug testing, including a for-cause policy for drug testing; (g) return-to-work policies for HCWs; and (h) sanctions for performance and diversion violations.

- ☐ The CSDPP ensures that training of all staff with access to CS is mandatory and occurs annually or when there is a significant change in policies or procedures.
- ☐ Pharmacists participate in or contribute to the development of substance abuse prevention and assistance programs within the organization.
- ☐ The organization's senior leadership emphasizes the importance of reporting signs of a potentially impaired HCW or suspected CS diversion and its potential impact on patient care, including ramifications for failure to report; communicates the expectation that staff speak up when they become aware of or suspect an issue related to CS diversion; and ensures and communicates that staff will be protected from retaliation if they report a suspected CS diversion or impaired HCW.
- ☐ The organization establishes and communicates ways for staff to speak up anonymously (e.g., telephone hotline, paper or electronic submission).
- ☐ All HCWs receive annual education in diversion prevention and substance abuse and diversion awareness (signs and behavior patterns and symptoms of impairment) and reporting; and managers receive training in signs, symptoms, and behavior alerts, what to do when they suspect an HCW may be impaired, and managing HCWs in recovery.
- ☐ The organization establishes a process to support recovery and peer assistance programs for those who have diverted for an active substance abuse problem.
- ☐ Drug testing for cause is permitted, and, as required by licensing boards or other employment contracts, organizations implement reliable testing and validation for drug screening.
- ☐ The organization establishes behavioral standards and norms among all employees that discourage the abuse of CS.
- ☐ An ongoing CS diversion education program is in place to promote the safe handling of CS and awareness of medication diversion. Education on medication diversion and CS policies and procedures is required before authorizing HCW access to CS.
- ☐ The organization develops and enforces sanctions for CSDPP policy and procedure violations.
- ☐ If provider services are contracted, contracts provide that all contracted workers receive education regarding CS and that the contracted company notify the organization immediately if there is disciplinary action against an employee or if an employee is removed because of an impairment issue.

Automation and Technology

- ☐ An interdisciplinary team that includes pharmacy representation participates in the selection and implementation of all medication-related automated systems (e.g., surveillance software) and technology (e.g., automated dispensing devices, syringe and infusion pumps, security devices) to ensure they support CS diversion control, surveillance, and auditing and meet legal, regulatory, and functionality requirements.
- ☐ Pharmacy representatives have an integral role in the selection and implementation of all medication-related automated systems and technology.
- ☐ The organization works proactively with vendors to ensure there is adequate training and implementation testing before installing or upgrading new technology equipment or software.
- ☐ Changes in or upgrades to existing technology are reviewed by key stakeholders, including pharmacy representatives, to assess potential impacts on systems of CS control, surveillance, and auditing, and changes or upgrades are tested and vetted to ensure implementation meets legal, regulatory, and functionality requirements.
- ☐ Records generated from technology solutions are readily retrievable and contain information required to conduct investigations and fulfill investigator requests.
- ☐ Reporting capability is tested to ensure that records with complete and actionable information are readily retrievable.
- ☐ Staff is adequately trained regarding their roles and responsibilities in the use of automation and technology, and competency is assessed when an HCW is on boarded to a new position or responsibilities, annually, or when there is a relevant change to existing technology.
- ☐ Systems are implemented for areas with high-volume use of CS (e.g., surgery or anesthesia areas, central pharmacy).
- ☐ Access to CS in automated dispensing devices is limited to authorized individuals, and there is a process in place to immediately add or rescind access privileges (e.g., suspected diverters can be removed immediately, other users [e.g., terminated HCWs] removed within 24 hours, and temporary HCWs added as necessary).
- ☐ Administrative privileges that allow staff to add or delete automated dispensing device users are limited to as few individuals as possible.
- ☐ Policies and procedures specify that automated dispensing device overrides should be limited only to clearly defined situations. The amount of CS available for dispensing via automated dispensing device override functionality is minimized, and the process is directed by a comprehensive policy and review process that includes ensuring use is clinically appropriate, a valid order exists, and there is appropriate documentation in the medical record.
- ☐ The pharmacy department is the party responsible for authorizing access to CS and for adding and removing users to automated dispensing devices. If this authority is delegated to informatics or security personnel, the pharmacy department should still maintain responsibility to oversee the process and ensure that established procedures are followed.
- ☐ Controls are in place to limit lock-out access times, and this access discontinued as soon as possible when patients are transferred or discharged.
- ☐ Automated dispensing device or electronic vault downtime procedures are defined to maintain control, documentation, and accountability of CS.
- ☐ Automated dispensing device admission, transfer, and discharge patient profile information is managed in a timely manner.

Monitoring and Surveillance

- ☐ The CSDPP committee identifies surveillance metrics, responsibility for conducting reviews, and frequency of reviews.
- ☐ The organization, through the CSDPP committee, establishes surveillance requirements, including defining monitoring and surveillance measures, thresholds of variance that require action, reporting frequency, and surveillance procedures, and ensures that all elements are implemented, conducted in a timely manner, investigated, and reported as required.
- ☐ The CSDPP committee provides facility oversight to ensure that established audits for facility-based

diversion monitoring are conducted and documented.
- ☐ There is a process defining the escalation of discrepancies that cannot be resolved ("unresolvable discrepancies") or CS policy and procedure violations that include the director of pharmacy or designated pharmacy manager and other hospital leadership, including the chief executive officer, as appropriate.
- ☐ Surveillance processes are interdisciplinary and touch all aspects of the CS management system, from purchasing to waste and disposal.
- ☐ Self-audits are conducted within areas as well as regularly scheduled audits by individuals external to the area being audited.
- ☐ The organization periodically audits human resources requirements for individuals authorized to handle CS, including
  - Completion of required background checks,
  - Documentation of training and competency requirements for authorized staff,
  - Compliance with random drug testing requirements, and
  - Compliance with licensure board reporting and rehabilitation program requirements.
- ☐ Drug purchase history is monitored through regularly scheduled audits to identify diversion through variations or changes in volume or pattern.
  - CS purchase invoices are compared to CS purchase orders and receipt into the pharmacy's perpetual inventory.
  - Invoices are reconciled to statements or wholesale purchase history reports to detect missing invoices.
  - A process is in place to identify unusual peaks in quantity or frequency of CS purchases (e.g., quarterly review of purchases over the prior 12–24 months).
  - Wholesaler is able to flag unusual peaks in quantity or frequency of CS purchased.
- ☐ A perpetual inventory of all CS is maintained and verified on a regular basis, consistent with the control system used (e.g., inventory managed with automated dispensing devices with closed compartments and unit-of-use access limitations versus manual inventory).
  - CS counts from automated dispensing devices are verified (blind count) each time a CS drawer is accessed, and a complete inventory for CS in automated dispensing devices is conducted weekly by two authorized HCWs.
  - Deliveries, replenishment, and stocking of CS in patient care areas will be done by authorized pharmacy personnel and require an auditable verification of delivery and receipt.
  - CS inventory in the pharmacy narcotic vault is counted at least monthly.
  - Outside pharmacy areas, CS storage areas in which CS are not managed through automated dispensing devices are inventoried at each shift change by two authorized HCWs.
  - A biennial physical inventory of all CS is completed and documented per DEA requirements (or per state requirements, whichever is the stricter interpretation).
- ☐ Automated dispensing device reports are routinely monitored to ensure overrides occur only as permitted by policies and procedures.
- ☐ Automated dispensing device override reports are reviewed daily to ensure an order exists during the time the medication was accessed from the automated dispensing device, and corresponding documentation is in the medication administration record (MAR).
- ☐ Reports match narcotic vault transactions with receipt into automated dispensing device and/or paper inventory record with signature of receipt.
- ☐ Diversion monitoring software is implemented to support surveillance activities.
- ☐ A person is dedicated to surveillance monitoring and is accountable for optimizing implementation and functionality of diversion monitoring software. Other disciplines (e.g., nursing quality, anesthesia providers) are actively involved in surveillance audits and assist with evaluation of trends and incident investigation.
- ☐ Reports that monitor CS use in patient care areas are reviewed at least monthly by pharmacy and patient care managers as defined by the organization. The organization has a process to generate CS trend data and reports:
  - Tracking and trending of patient care usage.
  - Reports compare automated dispensing device activity with the prescriber order and MAR.
  - The MAR is reviewed for amount and quantity administered compared to what other caregivers administer on subsequent shifts (without patient change in condition).
  - Automated dispensing device CS activity is compared to peers with similar staffing responsibilities and appointments.
  - Transaction activity (e.g., inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns, waste) is compared with peers.
  - Transactions are reviewed after a patient is discharged or transferred to another unit.
- ☐ Prescribing practices are reviewed for unusual trends or patterns, such as variance in prescribing compared to peers.
- ☐ Patient response to medication (e.g., pain management) is also evaluated against medication administration, documentation of response, and patient interview.
- ☐ Nursing management conducts random patient interviews to verify that patients received pain medication and that the medication adequately controlled pain and also compares responses to nursing patient assessment notes and MAR.
- ☐ Nursing management integrates routine auditing and surveillance activities into core daily, weekly, or monthly responsibilities, including staff education regarding signs of diversion, symptoms of substance abuse, and diversion reporting procedures; review of nursing removal, return, and wasting records; development, implementation, and monitoring of procedures for witnessing CS-related transactions; and investigation and reporting of suspected diversion in accordance with organization procedures.
- ☐ CS storage inventory transactions are routinely compared with the MAR (e.g., anesthesia record, sedation record, electronic MAR) to ensure appropriate documentation of administration and waste.
- ☐ Anesthesia CS audits are performed on a regularly scheduled basis, as determined by the process for managing CS for anesthesia, identified risk points, and previous events.
- ☐ CS discrepancies are reported to the supervisor in charge, who reviews and attempts to resolves the discrepancy no later than the end of the work shift. Discrepancies that cannot be resolved (unresolvable discrepancies) are reported immediately to the pharmacy department and are jointly reviewed by pharmacy and patient care leadership, with resolution within 24 hours.
- ☐ The supervising or other designated pharmacist is notified of unresolvable discrepancies in automated dispens-

ing devices and supports the reconciliation investigation; a pharmacist has responsibility for investigating the discrepancy, even when a pharmacy technician assists with these duties.
- ☐ A trend of poor documentation practices by an HCW is reviewed by his or her immediate supervisor (e.g., nursing or pharmacy manager, department chair) for possible diversion.
- ☐ There is a procedure for random testing of waste from all high-risk, high-volume areas, including areas for pharmacy sterile products preparation, anesthesia administration, and surgery.
- ☐ CS dispensed in high-risk settings (e.g., for operating room cases or procedures) are reconciled by pharmacy against what CS were documented as administered or wasted.

Investigation and Reporting of Suspected Diversion

- ☐ The organization creates and implements a standard process to investigate discrepancies that are not resolved (unresolvable discrepancies) or other discovered or suspected diversions.
- ☐ Any unresolvable discrepancy is considered a possible diversion and escalated to investigation, and notifications occur as defined by the CSDPP.
- ☐ A process is in place to report and respond to suspected diversions and prompt an immediate investigation:
  - ○ A 24 hours-per-day/7 days-per-week medication diversion pager or phone number is available to report (anonymously, if desired) suspected medication diversion.
  - ○ An interdisciplinary drug diversion response team is in place to provide consultation, direction, and oversight for suspected diversion incidents.
  - ○ Designated team members external to the area under investigation are also involved to ensure the impartiality of the investigation of incident.
  - ○ A standardized process exists for interviewing suspected CS diverters.
  - ○ Guidelines are in place for the handling of suspected impaired HCWs and drug testing, including guidance when for-cause testing may be initiated.
- ☐ A defined process is in place for the internal and external reporting of medication diversion incidents.
- ☐ The pharmacy director or his or her designee and diversion officer (if different) are notified immediately of any suspected diversion within the organization, participate in all active investigations regarding CS diversion, and are informed of the outcomes of all investigations.
- ☐ There are guidelines for determining whether a CS loss is considered significant, which include factors such as
  - ○ Quantity of CS lost in relation to the type of business.
  - ○ The specific type(s) of CS lost.
  - ○ Whether the loss can be associated to access by specific individuals or can be attributed to unique activities.
  - ○ A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses.
  - ○ Whether the specific CS are likely candidates for diversion.
  - ○ Local trends and other indicators of the diversion potential.
- ☐ There are guidelines for engaging others internal to the organization, such as the risk management, legal, and human resources departments, as well as leadership levels of medical staff and administration. Guidelines specify who will coordinate the investigation, including communications to appropriate team members, conducting the investigation, and coordinating internal and external reporting.
- ☐ If the organization becomes aware of an arrest of an HCW for illicit use of CS, the organization immediately conducts an investigation of the HCW's transactions to assess whether diversion has occurred. The organization assesses whether to suspend, transfer, terminate, or take other action (e.g., remove access to CS) or other sanctions against the HCW. The organization immediately removes access privileges to CS if diversion is suspected, until the investigation is complete and a determination of diversion or other risks to patient care is made.
- ☐ The organization establishes guidelines for engaging external entities, such as DEA, licensure boards, laboratories (for testing), and local law enforcement. Guidelines specify who is required to be notified, when notifications take place, who is responsible for contacting the agency/designated representative, and the time frame and circumstances for notification.
- ☐ The organization fulfills all reporting requirements for diversion or other unaccountable loss of CS in accordance with laws and regulations.
  - ○ Investigations are conducted as thoroughly and completely as possible; reporting occurs when it is determined that the discrepancy is unresolved or that there has been a known theft or diversion
  - ○ Organizational policy defines when a DEA Form 106 should be completed with discrepancies that remain ultimately unresolved. There are clear responsibilities for completion of a DEA Form 106 for a theft or significant loss, who is to be notified, and when.

Quality Improvement

- ☐ For significant diversions, a quality-improvement review is initiated, including a root cause analysis and recommendations to prevent future occurrences.
- ☐ Representative(s) from the area where there is a suspected diversion are engaged in the investigation and refinement of prevention strategies.
- ☐ Proactive, systemic analyses of CS processes are conducted, such as a failure mode and effects analysis, to identify risk points and take action to improve diversion prevention practices.

Communications

- ☐ There are guidelines for engaging the media and managing external public relations. Guidelines specify when to notify the media, what internal communications are required, and who is responsible for approving media communications and contacting the media representative.

Chain of Custody

- ☐ Authorized HCWs verify dispensing and receipt of CS. In areas without automated dispensing device storage, the HCW delivering and the HCW receiving CS both cosign documentation of receipt, and the CS is secured immediately.[d]
- ☐ When using an automated dispensing device for dispensing and storage of CS, transactions should be tracked and reconciled electronically.
- ☐ Sending CS via a pneumatic tube system is not recommended; if employed, delivery requires a secure transaction function (e.g., not a generic passcode when CS is received in a patient care area).
- ☐ Persons transporting CS (e.g., couriers) are trained and competent in relevant organizational policies and procedures.
- ☐ When using a courier for CS transport, procedures and documentation are in place to ensure receipt of CS at the final destination. CS delivery to areas with automated dispensing devices requires co-signature for delivery and return.

- ☐ Hand-offs during a patient procedure are avoided, but in the event a hand-off is required, there are procedures to document the chain of custody provider transfer of CS during a case (e.g., preparation of case trays, for break coverage or change of shift).
- ☐ Secure, lockable, and tamper-evident delivery containers (e.g., carts, trays, boxes) are used to deliver CS. Packaging does not make the contents apparent (e.g., opaque containers).
- ☐ When used, locking mechanism on transport containers should be traceable (e.g., plastic tie locks with a unique numerical identifier).
- ☐ There is a process to ensure that chain of custody is maintained when transferring CS to a laboratory service (internal or external) analyzing products as part of an investigation or random assay process.
- ☐ Dispensing a prescription for CS to patients from patient care areas, such as the emergency department, is not recommended; if such dispensing occurs, chain of custody is documented from the provider to the patient.
- ☐ The organization establishes a procedure for transfer of CS to emergency medical services that complies with federal, state, and local requirements.

Storage and Security (Facilities, Requirements, Inventory Management)

- ☐ CS are securely stored in a locked location (i.e., automated dispensing device, safe, locked cabinet/drawer, refrigerator) accessible only to authorized individuals at all times unless in the direct physical control of an authorized individual. CS not under the direct physical control of an authorized individual are in an area allowing direct observation at all times and where distractions are minimized.
  - ○ Environmental services and other support staff should not have access to central CS storage locations when unattended (e.g., after hours).
  - ○ When used, lock boxes are stored in a secure location when left unattended.
  - ○ Codes for electronic or keypad locks on cabinets or carts are not set at the manufacturer's default code and are protected with a strong code (e.g., not "1-2-3-4").
  - ○ Lock-out times for electronic locks on carts (e.g., medication carts, anesthesia carts) containing CS are limited to the narrowest window of time appropriate for the particular setting.
  - ○ There is a procedure to track keys, secure keys after hours, replace lost keys, and change locks, and there is evidence of compliance with those procedures.
  - ○ Storage areas, including medication rooms, have a window to allow visibility within the area. Backpacks, purses, and bags are not allowed in the pharmacy CS area. Surveillance is present in primary CS pharmacy storage and preparation areas (e.g., CS vault).
- ☐ Access to CS storage areas is minimized and limited to authorized staff.
  - ○ When key lock security is used, chain of custody is maintained for keys, and there is a process to secure keys after hours in locations not in continuous operation.
  - ○ There are policies and procedures regarding CS access, including restrictions through assignment, key controls, and use of passwords.
  - ○ At least every 6 months there is a complete assessment of all staff with access privileges to ensure that only those permitted access have access (e.g., authorized HCWs, temporary employees, independent practitioners with privileges).
  - ○ Removal of access occurs in real time as employees are terminated. For auditing purposes, staff termination reports (date and time) are reconciled against date and time of documented removal of access.
  - ○ Patient-specific CS infusions are contained in a secured, locked box utilizing no-port tubing unless under constant surveillance. Keys to these controls are limited and tracked as any keys or lock boxes are.
- ☐ Within pharmacy areas with automated dispensing device vault management, CS inventory verification counts are conducted by two rotating, licensed, or otherwise authorized pharmacy providers monthly. For pharmacies without automated dispensing device vault management, a physical inventory is conducted at least once per month, preferably weekly.
  - ○ Inventory count includes expired and otherwise unusable CS awaiting disposal or transfer to reverse distributor.
  - ○ CS counts done via automated dispensing devices and manual systems are verified by a blind count each time a CS location (e.g., drawer, pocket, refrigerator) is accessed.
- ☐ Automated dispensing device technology is utilized in areas with a high volume of CS use, including the pharmacy, anesthesia and surgery areas, high-volume clinics, and outpatient procedure areas.
- ☐ User identification and biometric authentication are used rather than passwords. When biometrics cannot be used, password security on automated dispensing devices follows institutional policy and standards and includes requirements for password complexity and frequent changes. For manual access to CS, signature and initial logs recording receipt and disposition are maintained as appropriate. Any HCW receiving, transferring, or dispensing CS will be able to provide photo identification upon request.
- ☐ Camera surveillance is considered for high-risk areas (e.g., receiving areas, central pharmacy vault location, approved waste receptacles), remote areas, areas where electronic or biometric access is not available, and when for-cause surveillance is required to support an investigation.
- ☐ Procedures are implemented to secure storage of DEA forms, and access to forms is limited to authorized individuals.
  - ○ There are procedures and documentation (e.g., a log book) for tracking the receipt and filling of DEA Form 222.
  - ○ Blank DEA Form 222s are listed consecutively on a log documenting the disposition of each form.
  - ○ The DEA Form 222 log is stored separately from unused DEA forms.
  - ○ DEA Form 222s are not presigned.
- ☐ Procedures are implemented to secure prescription pads and paper, and access is limited to authorized individuals.
  - ○ Prescription blanks and paper for printing prescriptions are dispensed per patient rather than the entire prescription pad.
  - ○ There is a method (e.g., numbering system) to allow for tracking of individual prescriptions.
- ☐ Procedures are established that ensure controls are in place to secure CS and prevent diversion in the rare cases in which CS is brought into the organization by patients.
  - ○ CS should only be accepted when they are to be administered to the patient pursuant to an authorized prescriber's order.
  - ○ Documentation of patient's CS, quantity inventoried, and signatures of two verifying HCWs

should be recorded in the medical record upon receipt and at discharge.
- Patient's own CS are secured and tracked via a perpetual inventory record, and any remaining CS is returned to the patient upon discharge.
- The patient or patient's representative signs that he or she has received the CS, noting the quantity.
- CS that cannot be returned to home and are not to be administered to the patient are to be inventoried and removed from patient care areas with appropriate chain of custody documentation and stored securely per organization policies, which include procedures for returning CS to the patient or authorized persons and management and final disposition of CS if not returned to patient or authorized persons.
- Organizations consider providing, in collaboration with local and state authorities, a public receptacle for disposal of CS by patients.
- If patients bring illicit substances into the organization, procedures address notification of the local DEA office and law enforcement, as required by law, and as advised by those authorities.

Internal Pharmacy Controls

Procurement controls

- ☐ All CS are procured from the pharmacy. If other departments or individuals are authorized to procure CS, there are checks and balances established to ensure the same policies and procedures are consistently followed throughout the organization.
- ☐ The number of people authorized to order CS is limited to individuals authorized and defined by policy.
- ☐ Electronic CS ordering system (CSOS) is used and CSOS order files are backed up to an organization-based system to ensure that archived files are readily retrievable by designated personnel.
- ☐ If DEA Form 222s are used, they are secured, and the DEA Form 222 accountability and control log includes
  - DEA order form number
  - Date the form was received from the DEA
  - Date the form was issued for use
  - The company the form was issued to
  - The initials (if the organization uses a signature/initial log) or signature of user
- ☐ Separation of duties exists between the ordering and receipt of CS.
  - Two authorized individuals count and sign (two signatures) for CS upon receipt (packing slip) and confirm that what is received matches what was ordered and invoiced (purchase order and invoice).
  - A pharmacist reconciles CS received against what is indicated on the delivery ticket or invoice and documents receipt as required; the documents will be signed or initialed. CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory. Since the invoice–receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. Staff should be cross-trained and rotated through functions related to procurement and prepackaging.
  - Automated vault technology is utilized in the central pharmacy main storage location.
  - If the HCW who provides the second count at check-in is not a pharmacy employee (e.g., at a small organization where only one pharmacy employee is available), the designated HCWs receive appropriate training.
  - CSOS orders are acknowledged as received within 7 days of placing the order.
  - CS inventory levels are routinely reviewed, and orders are based on usage to minimize excess stock.
- ☐ There are processes to track and reconcile CS products when preparation is outsourced to a third-party vendor.
- ☐ There are procedures for interorganization transfer and transport of CS, including distribution from or to a central distribution hub within an organization.
- ☐ There are procedures for transfer of CS between pharmacies.
- ☐ The organization establishes a policy that discrepancies in the procurement process will be documented and brought to the attention of the director of pharmacy or designated pharmacy manager.

Preparation and dispensing controls

- ☐ A perpetual inventory is maintained and a blind count process is used when adding or removing CS from a pharmacy inventory location.
- ☐ Access to CS inventory is limited, with controls to identify who accessed the inventory, when the inventory was accessed, and what changes were made to the inventory.
- ☐ Effective access controls are in place to ensure the integrity of the inventory and provide for accurate, timely surveillance.
- ☐ To minimize opportunities for CS diversion during repackaging, CS are purchased and dispensed in unit dose packaging whenever possible. There are diversion controls in place when CS are repackaged by pharmacy personnel, including separation of duties.
- ☐ Automated dispensing device technology is utilized in patient care areas for the distribution and accountability of CS.
- ☐ In patient care areas, automated dispensing device–managed CS counts are verified by a blind count each time a CS drawer/pocket/cabinet is accessed (unless unit-of-use dispensing technology is employed).
- ☐ In patient care areas, CS managed through automated dispensing devices are manually inventoried by two authorized HCWs if a blind count has not been performed within one week.
- ☐ In patient care areas, CS not managed through automated dispensing devices are manually inventoried by two authorized HCWs every shift.
- ☐ CS managed through automated dispensing devices are stored in a location with single pocket or unit of use access when possible.
- ☐ Barcode-scanning is utilized when replenishing automated dispensing devices.
- ☐ When dispensing, removal from the pharmacy inventory is matched to the refill transaction on the patient care unit to validate that CS reach their destination.
- ☐ CS returned from nursing units to the return bin of the automated dispensing device or to the pharmacy are matched to the CS received by the pharmacy and documented in the perpetual inventory or a return to active inventory transaction on the automated dispensing device.
- ☐ Returns from the patient care and procedural areas (e.g., emptying a return bin) have an auditable verification of return. Returns are inspected for integrity.

Prescribing and Administration

- ☐ A valid order from an authorized prescriber exists for all CS administered, and the number of CS allowed via automated dispensing device override status is minimized.

- ☐ There is a process to identify and verify authorized prescribers within either an electronic or manual ordering system. There is also a process to identify and verify authorized prescribers and prescriptions written by medical residents or other providers who are authorized to prescribe CS under the organization's DEA registration (e.g., use of a suffix).
- ☐ Pharmacists clarify any orders for which prescriber identity is uncertain or other factors create doubt about the legitimacy of the prescription or order.
- ☐ Oral orders for CS entered into the medical record are reviewed for appropriateness and accuracy by the ordering prescriber before cosigning orders.
- ☐ Prescriptions or orders for CS are reevaluated regularly (e.g., through use of automatic stop reminders, by discontinuing and reordering CS per organizational policy when patients transfer to a different level of care). Medical staff, in coordination and consultation with the pharmacy department, develops and implements an automatic stop-order system for CS when there is not a specific time or number of doses prescribed.
- ☐ Organization policy prohibits authorized prescribers prescribing for themselves or an immediate family member.
- ☐ The organization assesses lock-out times for automated dispensing devices and duration for temporary access, including appropriate number and units of automated dispensing devices for which each HCW is granted access.
- ☐ CS are retrieved from inventory as close to the time of administration as possible. CS retrieved for a patient is the package size equivalent to, or closest available to, the dose to be administered.
- ☐ When being administered to a patient, CS infusions are secured in locked infusion pumps.
- ☐ All CS drawn up into syringes, if not immediately administered, are labeled per organizational policy, and the initials of the HCW who drew up the drug are written on the label. Syringes are kept under the direct control of the person preparing the syringes until administration to the patient, and the initials on prepared syringes are verified immediately before administration to ensure that the syringe has not been switched. Generally, only single doses are drawn up into a syringe. When sequential doses are required from a single syringe, there is a method to track the dose ordered versus the dose administered.
- ☐ In areas in which CS are not managed through automated dispensing devices, CS administration records (CSARs) are accurate and include the following information:
  - Date and time administered
  - Medication name
  - Medication strength
  - Dosage form
  - Dose administered
  - Signature of the HCW who administered the dose
  - Amount wasted (if applicable), with cosignature
  - Proof of count verification per shift
  - Signature of HCW who transferred the balance forward when transcribing to another CSAR.

Returns, Waste, and Disposal

- ☐ CS are stocked in as ready-to-use form as possible (e.g., avoiding the use of multidose vials) and in the lowest commercially available units frequently prescribed to patients. Inventory is routinely evaluated for opportunities to reduce the need to waste.
- ☐ Procedures require that CS be wasted immediately or as close to the time of administration as possible; there is an established timeframe allowed per policy.
- ☐ The wasting of all CS requires an independent witness and documentation, except in situations in which waste is being returned to the pharmacy for assay and wasting.
- ☐ An individual witnessing CS wasting verifies that the volume and amount being wasted match the documentation and physically watches the medication being wasted per policy for safe disposal and in a manner that the CS is not retrievable.
- ☐ There is a procedure for wasting fentanyl transdermal patches according to Food and Drug Administration or state-specific guidelines in a manner that renders the fentanyl irretrievable or otherwise deactivated before disposal.[d]
- ☐ Pharmaceutical waste containers render CS unrecoverable, irretrievable, and unusable. Containers and their keys are secured, and a process for waste removal and disposal that ensures that chain of custody controls are maintained is implemented.[d]
- ☐ Potentially reusable products issued from automated dispensing devices are returned to a secure return bin or pocket and not to the original automated dispensing device pocket, and these returns are witnessed and have an auditable verification of return. Returns are inspected for integrity.
- ☐ Empty CS containers are discarded in limited-access waste containers that render the waste irretrievable, and waste procedures comply with organizational procedures for waste management.
- ☐ Expired or otherwise unusable CS are clearly identified as such and stored in a location separate from other medications. They are properly accounted for with a perpetual inventory list that is regularly verified, as is other CS inventory within the pharmacy, and the inventory is monitored until return via reverse distributor or destruction and disposal in accordance with legal requirements. The frequency of returns and destruction ensures that inventory is not allowed to accumulate, but returns and destruction are done at least quarterly.
- ☐ Documentation provided by the reverse distributor is verified and corresponds with the pharmacy perpetual inventory record of expired and unusable CS before the drugs leave the pharmacy.
- ☐ DEA registrant or his or her designee assists with all phases of transfer of CS to a reverse distributor or hazardous waste disposal company.
- ☐ Items returned via reverse distribution are reconciled with the reverse distribution log of CS.
- ☐ If the inventory quantities are double-counted separately by the reverse distributor, these recorded quantities should be reviewed and reconciled with the pharmacy inventory list before the medications leave the pharmacy.

Special Considerations for Retail Settings

- ☐ There are physical access controls, such as secured storage cabinets only accessible by badge or biometric access, to limit and track access by personnel.
- ☐ The organization has security measures in place (e.g., cameras) to monitor theft and provide an avenue for discrepancies to be resolved in a timely manner.
- ☐ The organization has systems in place for documentation and monitoring of CS inventory adjustments made by pharmacy employees, CS prescriptions cancelled and returned to stock, and CS prescriptions left at will call past 10 days from processing.

- ☐ The pharmacy's point-of-sale system is interfaced with prescription management software and has developed reports to identify discrepancies.
- ☐ The pharmacy has developed a report or auditing process to compare CS purchases with utilization to identify discrepancies and trends.
- ☐ The pharmacy has a system for accepting hard-copy CS prescriptions that provides documentation of employee chain of custody and files CS prescriptions sequentially.
- ☐ The pharmacy has a system in place to audit documentation of employee chain of custody.
- ☐ The pharmacy maintains a perpetual inventory of Schedule II CS that is maintained and audited at least monthly.
- ☐ The pharmacy utilizes labels from prescription management software in the perpetual inventory log to identify the quantity of Schedule II CS filled.
- ☐ The pharmacy has established procedures for managing and documenting partial fills of CS.

[a]This implementation guidance includes recommendations reprinted with permission from the following: Minnesota Hospital Association's Road Map to Controlled Substance Diversion Prevention 2.0 (www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/Road%20Map%20to%20Controlled%20Substance%20Diversion%20Prevention%202.0.pdf), the California Hospital Association Medication Safety Collaborative Committee's Reducing controlled substances diversion in hospitals (www.chpso.org/sites/main/files/file-attachments/controlled_substance_diversion.pdf), and Berge KH, Dillon KR, Sikkink KM et al. Diversion of drugs within health care facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. *Mayo Clin Proc.* 2012; 87:674-82.

[b]This implementation guidance does not include all legal requirements and is intended to enhance diversion prevention controls in the health-system setting and should complement policies and procedures required by state, federal, and local authorities as well as accreditation agencies.

[c]New K. Diversion risk rounds: a reality check on your drug-handling policies (2015). www.diversionspecialists.com/wp-content/uploads/Diversion-Risk-Rounds-A-Reality-Check-on-Your-Drug-Handling-Policies.pdf (accessed 2016 Oct 13).

[d]Acute Care ISMP Medication Safety Alert. Partially filled vials and syringes in sharps containers are a key source of drugs for diversion. www.ismp.org/newsletters/acutecare/showarticle.aspx?id=1132 (accessed 2016 Oct 13).

APPENDIX H:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O. Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	October 16, 2019
Principal Investigator:	Joseph Martin Bailon
Protocol Number:	1910068765
Protocol Title:	Feasibility of Adding Controlled Substance Waste Assay Testing into a Current Drug Prevention Program
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *determination of human research.pdf*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(l): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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