Breakdown of the ASHP Guidelines on Preventing Diversion of Controlled Substances

The American Society of Hospital Pharmacists (ASHP) have published a comprehensive set of guidelines aimed at preventing the diversion of controlled substances (CS). The guidelines provide a detailed outline of all the steps that should be taken at the different levels of management to enact a robust policy that will significantly reduce diversion.

In this whitepaper, we will provide a breakdown of the key messages of the ASHP guidelines to give you a head start when it comes to implementing your own Controlled Substance Diversion Prevention Program (CSDPP).

Reasons for enacting a stringent CSDPP

LEGAL

When drug diversion is detected by federal agencies, the penalties for individuals and healthcare facilities can be severe. The DEA has made it clear that ignorance is not an excuse and diversion will not be tolerated. To this end, well documented CSDPPs will help to show that your healthcare facility is taking all reasonable precautions to eliminate diversion.

WELLBEING

Diversion causes suffering for your patients and staff. Patient safety concerns include the wrong medication, lower dose or no dose of analgesics the patient needs and risk of infection from contamination. Staff who are diverting drugs are often suffering from addiction. Allowing this to occur breeds a toxic environment leading to low morale, staff turnover and illness.

IMPROVED QUALITY

CSDPP include lots of institutional habits which are primarily designed to eliminate diversion, but also have several positive knock-on effects. The main tenets of a CSDPP are accountability throughout the organization as well as enacting procedures, often with the help of automation, that will streamline day-to-day operations while making things safer and more efficient. When they are properly adopted, these habits can have a transformative effect on the workplace making everything easier and more efficient to run.

PREVENTING THE INEVITABLE

However, perhaps the most compelling reason is that, if you don't act to stop it, drug diversion is inevitable if it is not already happening. Research shows that around 10–15% of healthcare workers abuse alcohol or drugs during their career which is about the same as the general population. With a lax or no CSDPP in place and with easy access to controlled substances, drug diversion becomes inevitable if actions are not taken to prevent it.

The principles of an effective CSDPP

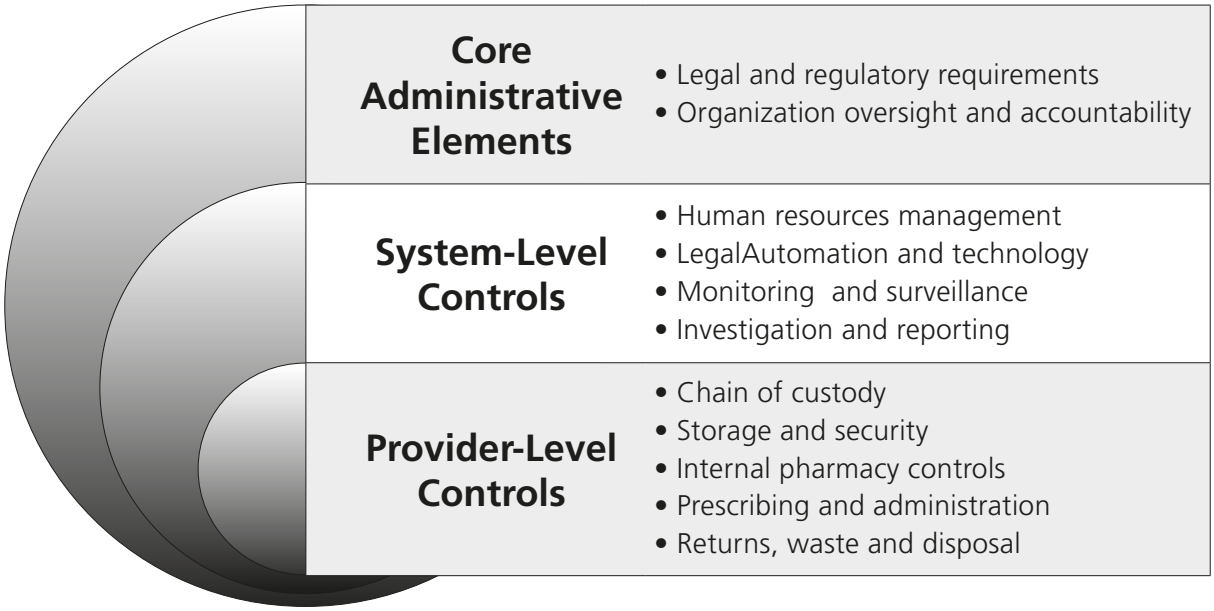
The ASHP guidelines go into detail of many different principles that should be included in an effective policy. We will summarize those later in this whitepaper. However, at the top level, there are only two principles that matter and will dictate the entirety of your CSDPP.

1. **Accountability**
2. **Effective processes**

The only way to guarantee success with your CSDPP is to have both accountability and effective processes. Accountability means that people are responsible for your policy all the way through the organizational hierarchy. These key individuals need to know and accept the responsibility and be held accountable for the CSDPP. It is also important that the rest of the organization knows who these people are.

Effective processes mean that engaging in drug diversion prevention does not interfere with the day-to-day running of your healthcare facility and yet, make diversion more difficult and reporting easier. If possible, effective processes will enhance patient care by improving quality and accuracy of medicine administration. Often the answer to effective processes is automation which is something that we are very familiar with at Codonics.

The core of the ASHP Guidelines



At the core, the ASHP guidelines have three levels. The aim is to build layers of protection against drug diversion that span across the entire organization. Importantly, the guidelines also address how to engage with controlled substances as they enter and leave your facility which are often weak points when it comes to dug diversion. The three layers are **Core Administrative Elements, System-Level Controls and Provider-Level Controls**.

Core Administrative Elements

The core administrative elements can be broken down by what the law states as well as how and who is responsible for making sure the letter of the law is followed within your facility.

LEGAL AND REGULATORY REQUIREMENTS

Refer to all current legal and regulatory requirements when establishing policies and procedures for your CSDPP. Where necessary, CSDPPs should include state level licensing board requirements as well as Joint Commission and CMS compliance standards.

ORGANIZATION OVERSIGHT AND ACCOUNTABILITY

In a healthcare facility the key person for a CSDPP is the pharmacy executive as they are responsible for the medication-use system. However, the guidelines are clear in stating that the responsibility cannot rest with one person. There needs to be a collaborative and cross-disciplinary approach when designing and implementing a CSDPP. The guidelines recommend establishing a committee with relevant stakeholders throughout the organization. The committee members should represent the entire organization and the responsibility of each member should be clearly defined and agreed upon. The goals for the committee should also be explicitly stated and shared by the members. The committee will take overarching responsibility for the entire CSDPP including inter-departmental collaborations and providing essential training to healthcare workers.

System Level Controls

System level controls are to ensure that the correct systems and procedures are in place to implement an effective CSDPP. Many people from across the organization will be engaged with the system level controls, even if they are not directly responsible for handling of controlled substances. It is important that everyone involved in system level controls are aware of their responsibilities and the impor-

tance of their role, even if it is not directly related to the handling or processing of controlled substances.

HUMAN RESOURCE MANAGEMENT

The health care workers in an organization are the key to an effective CSDPP. The ASHP guidelines recommend a comprehensive human resources approach to support the CSDPP that 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 healthcare workers.**
8. **Sanctions for performance and diversion violations.**

This is an extensive list and shows how important human resource management is to a CSDPP. The diverse nature of this list also highlights the need for proper allocation of tasks and responsibilities. Even though this all comes under human resource management, each one of the steps could easily be a project for a different person.

AUTOMATION AND TECHNOLOGY

The ASHP guidelines explain how technology allowing automation of certain parts of the CSDPP are now prevalent and can really assist in the management of controlled substances in any organization. Automation can be especially useful in high-risk areas where many individuals have access to controlled substances, such as in anaesthesia or the emergency department. The choice of what automation to introduce and where should be decided by an interdisciplinary committee who can evaluate the usefulness of the automation as well as whether the use of the technology will fulfil the legal and reporting obligations of the organization.

MONITORING AND SURVEILLANCE

The guidelines place a lot of emphasis on monitoring and surveillance. Without effective surveillance, a CSDPP will simply not work. So, what are the keys to effective surveillance?

1. **Surveillance should touch on every aspect of the controlled substance management system.**
2. **All deviations should be monitored and should be seen as an opportunity to improve the process.**
3. **Surveillance should be carried out at many different levels, from automated reports to in person interviews.**
4. **All systems of control should be regularly audited.**
5. **However – random monitoring checks should also be performed to reduce the possibility that diversion could occur because gaps have been found in the surveillance system.**
6. **Reviews of surveillance data should be conducted regularly.**
7. **High-risk areas should be monitored more closely.**

INVESTIGATION AND REPORTING

Investigations, according to the ASHP guidelines, should be swift and automatic. An investigation should be triggered automatically by any reported discrepancies or abnormalities with respect to standard procedures. Acting automatically removes the need for human decisions and allows the investigation process to run faster. Any discrepancies that cannot be resolved after a thorough investigation should be considered potential diversion events and should be reported to the correct authorities, including the DEA.

Provider-Level Controls

Provider level controls are designed to be implemented at the interface between the healthcare workers and controlled substances. Any direct contact between the organization and controlled substances should be covered in the CSDPP.

CHAIN OF CUSTODY

A reliable and retrievable chain of custody evidence chain is an essential part of a CSDPP. If this is not in place, then tracking down diversion events becomes very difficult. Likewise, if a good chain of custody protocol exists and is subsequently broken, this is grounds for investigation. Measures should be taken to make sure that chain of custody is accurately maintained in accordance with state and federal laws. Where necessary, tamper proof locked compartments should be used to store and transport controlled substances.

STORAGE AND SECURITY

Layers of security should be used to surround the use of controlled substance. Physical locks as wells a surveillance equipment like cameras should both be used to keep controlled substances securely stored. Processes should be in place for regularly checking the stored inventory for discrepancies that would trigger an investigation. With controlled substances locked away, access should then be clearly documented and controlled. Whenever possible, try to keep controlled substances behind a barrier that requires ID access and biometrics whenever possible. This increases the level of accountability on those with access.

INTERNAL PHARMACY CONTROLS

The pharmacy is the hub for all controlled substance procurement, preparation, dispensing and disposal. An effective CSDPP should apply a few key principles to minimize diversion from pharmacy personnel. When possible limit the number of authorized people who can order controlled substances. Create separation of duties within the procurement, preparation and the dispensing processes and rotate personnel through these responsibilities. An audit of the processes should be conducted by external pharmacy committee members biannually.

PRESCRIBING AND ADMINISTRATION

Controlled substances should only be ordered by licensed prescribers with authorization from the DEA. Whenever possible, the preferred method of receiving controlled substance orders is electronically as this makes record keeping and reporting more efficient. However, it is also clear from the ASHP guidelines that nothing in the CSDPP should delay patient treatment or compromise patient comfort. Therefore, controlled substance administration controls should include packaging inspections, when being inventoried or administered. Retrieval of controlled substances from ADM's or CS safe should occur as close to administration as possible.

RETURNS, WASTE AND DISPOSAL

Wasting of controlled substances has been identified as a key high risk area for diversion to occur. To minimize waste, stock controlled substances in ready to use forms and in the lowest unit amount when possible. Waste should be performed as soon as possible and documented in the same ADM it was retrieved from unless being returned to the pharmacy for random assay. A procedure is created for random screening of waste from all high risk, high use areas including pharmacy. WasteLog® is a cost effective screening device that can easily fit into your CSDPP.

Summary

The ASHP guidelines set out a detailed roadmap to implement a CSDPP. It is clear that following this roadmap, will not only prevent diversion of controlled substances, but will also protect your organization from serious consequences if diversion is detected through an audit or other means.

While adherence to such a thorough set of guidelines is easy to agree on in principle, the practicalities of implementing it could be challenging. However, what is clear from the guidelines is that for a successful and practical CSDPP a good team is required who all understand and accept the responsibilities place upon them. At the beginning, your role will be to recruit the right team and for a committee who represent your entire organization. From there, it will be easier to implement the various tasks that are required. There are a lot of tools on the market to assist with surveillance, storage, dispensing and waste screening like our WasteLog® device. Automation can save a lot of time as well as providing robust, cost effective solutions for high risk areas.

For additional information on how WasteLog® can easily be incorporated into your CSDPP, please contact us at info@codonics.com.

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