

# TRUST BUT VERIFY HOSPITAL COMPLIANCE PROGRAM

WHITEPAPER



**H**ealthcare professionals providing medical care while impaired is a significant problem for hospitals and the organizations that own and operate them. Recently, there has been a significant rise in the rates of theft and diversion of controlled drugs attributed to hospital employees. It is critical for hospitals to have easy access to medications to remain operational, without them they would not be able to function. However, the regulations enforced by the DEA mandate that hospitals secure and safeguard these drugs to detect and prevent theft and diversion. Typically as medications flow through a hospital from the pharmacy until administered, dispensed and or wasted, they are handled by employees with different responsibilities and often little if any oversight. The Pharma Compliance Group has developed the **“Trust but Verify Hospital Compliance Program”** to assist hospitals recognize and reconcile drug theft and or loss before a significant problem develops. The misuse, abuse and subsequent addiction to prescription drugs is well documented and healthcare professionals are not immune to what has been referred to as the prescription drug epidemic. To the contrary, recent studies have shown that healthcare related workers have high rates of prescription drug addiction. As a result of this trend hospitals are struggling with increasing instances of theft, diversion and addiction by their employees. The ramifications are alarming and have far reaching consequences, none more important than the safety and wellbeing of patients.

The compliance staff responsible for securing controlled substance medications have a daunting task; ensure optimal patient care while securing and safeguarding medications to prevent theft and loss. Diversion is often difficult to detect because of the many access-points embedded in the hospital distribution system. Recently, there have been a number of well publicized cases involving hospitals where drug thefts remained undetected for an extended period of time and when discovered the diversion had become so egregious that the DEA determined the hospital did not have effective controls in place to prevent it. Some hospitals

that have experienced similar issues have been subject to significant fines and in some instances adverse actions against their DEA registrations.

The hospital environment is complex and involves many healthcare professionals with a myriad of roles and responsibilities. The inherent complexities demand comprehensive policies that incorporate all facets of the movement of prescription drugs through the facility. Developing and implementing Standard Operating Procedures (SOP’s), is a critical component of a compliance program and must incorporate all aspects of controlled substance utilization. When ordered from the drug distributor and subsequently received at the pharmacy until administered, dispensed, disposed or wasted there are opportunities for employee theft and diversion to occur.

In most hospitals, the Pharmacist in Charge is responsible for ensuring adherence to policies and procedures that mandate drug control and access. For a compliance program to be effective there must be an expectation and willingness of all employees to participate and therefore “buy in” to a program of policies and procedures that are strictly followed by all who are entrusted with handling controlled medications. The employees should also receive training that includes recognizing the warning signs or behaviors associated with prescription drug abuse or addiction. When an addiction issue is suspected they should immediately report their suspicions to a superior.

When hospitals develop and implement policies and compliance programs, specific criteria should be followed to ensure drug security and accountability. The hospital compliance program should contain checks and balances that the Pharma Compliance Group refers to as a **“Trust but verify Hospital Compliance Program”**. The following are critical components and must be included in a hospital compliance program:

#### **Prevention/Detection**

There are several methods a hospital, or any DEA registered entity involved with controlled substances, can undertake to prevent diversion before the opportunity manifests. For example:

- Pre-employment background inquiries on potential employees as well as post-employment checks every three to five years is critical in ensuring that only law abiding employees are hired and retained.
- Training and educating employees that includes identifying behaviors and habits of someone who is misusing and or stealing prescription medications.

- Providing employees with information regarding trends and drugs that are most likely to be stolen and abused and encouraging an employee to report activity that is cause for concern.
- Hospital employees should expect that there will be random audits and compliance checks to determine that the drugs on hand are consistent with the pharmacy inventory and any shortage or overage should be reconciled immediately.
- Discipline and accountability for violations.
- Drug testing

### **Oversight/Supervision**

Ensuring policies and protocols are followed is critical to preventing diversion:

- Continuous accountability
- The pharmacy and nursing managers must be diligent, they should review recordkeeping and perform random counts and audits. If records are incomplete drugs cannot be audited to verify accountability. The CFR and DEA mandate that accurate records are kept and all controlled substances are reconciled.
- Managers must hold employees responsible for reconciling drugs removed and returned to inventory especially when utilizing an ADM
- Division of duties amongst staff specifically pertaining to activities requiring two employees
- Independent audits
- Internal auditing is critical to tracking the movement of these drugs through the hospital.
- Auditing processes and functions are readily available from internal and commercially available software programs to manual reports that the pharmacy or nurse supervisors can generate to reconcile the inventory.
- The compliance program must ensure that all departments and divisions are continuously monitoring the inventory.
- Any discrepancies or anomalies must be reconciled. If those responsible for reviewing and monitoring the records and documents need to determine what is ordered and received from the wholesale drug distributor is consistent with the pharmacy records.

### **Investigation**

The hospital should have a compliance program with specific policies that mandate how thefts and or diversion are investigated. A designated group of stakeholders in the hospital will execute an investigative action plan that should include the following:

- Notify appropriate law enforcement and or regulatory agency
- A significant theft or loss must be reported to the DEA on a Form 106 within twenty four hours of it being discovered. It can be amended when the total loss has been determined.
- A designated hospital management level employee should be designated to be the Point of Contact (POC) for requests for information from the DEA and or other law enforcement and regulatory agencies.
- Reconciling the inventory of controlled substances is critical to determine how much was stolen and how long the diversion has been taking place.
- Reviewing CCTV tapes in the pharmacy and in areas where Automated Dispensing Machines (ADM) are located will assist in investigating the theft and loss.
- Review records of employees accessing an ADM is critical when investigating a theft or loss by an employee.
- Review order records from the wholesale drug distributor and compare them against the hospital pharmacy ordering system to determine inconsistencies.
- Review pharmacy and nursing work schedules to determine patterns or trends consistent with the thefts or diversion.
- Interview employees in the unit(s) or areas where diversion has occurred.

### **Administrative/Human Resource Issues**

When an employee is found to have stolen from his or her employer it is imperative that the appropriate stakeholders have a pre-determined plan to handle the issues concerning the employee or employees responsible.

- Human Resources should be part of the compliance team that handles the sensitive employee issues

- Employee should be drug tested immediately
- Law enforcement should be notified as soon as the diversion is detected
- Employee termination if appropriate
- Media issues – dealing with damage to the reputational image
- Amending false billing
- Lessons learned

The ramifications to a hospital and the healthcare systems that own and operate them when an employee or employees steal and divert can be severe. There are so many negative consequences depending on the scope and scale of the diversion that it will almost always require a complete review and subsequent overhaul of policies and procedures regarding how hospitals handle and safeguard controlled substances. Being proactive and developing and implementing policies and procedures that encapsulate the organizational needs while mandating the secure movement of prescription drugs from the time they are ordered until dispensed, administered and or wasted will assist in preventing theft and diversion.

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The second PCG Hospital Compliance E book in this series will discuss changing employee behaviors in the hospital environment to maintain compliance with the regulations enforced by the DEA.

The logo for The PHARMA Compliance Group. The word "The" is in a small, white, serif font. "PHARMA" is in a large, white, serif font. "Compliance" is in a white, sans-serif font. "Group" is in a white, serif font. A stylized white "X" symbol is positioned between "Compliance" and "Group". A registered trademark symbol (®) is located to the upper right of "Group". The logo is set against a background of a blue, abstract, geometric pattern of lines and shapes, resembling a digital or architectural structure.

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