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Evaluating Hospital Pharmacy Inventory Management and Revenue Cycle Processes

White Paper Guidance for Healthcare Internal Auditors

Introduction

Pharmacy inventory management is a complex but critical process within the healthcare delivery system. Without adequate pharmacy inventory management practices, hospitals run the risk of not being able to provide patients with the most appropriate medication when it is most needed. Additionally, pharmacies' dispensing patterns and drug selection choices may have a direct effect on the affordability of care. Utilizing drugs that are non-contracted or not on the formulary may be more costly to the patient or may result in a lower than expected reimbursement. In addition to patient safety and financial considerations, stringent regulatory requirements pertaining to drug traceability, inventory reporting and inventory management elevate the importance of maintaining effective control over drug inventories in today's ever-expanding healthcare compliance environment.

Pharmacies can control a number of factors within the pharmacy inventory management and pharmacy revenue cycles that can support better outcomes for patients and enhance the bottom line for facilities. This whitepaper provides perspectives on leading practices and internal controls pertaining to: procurement, charge description master maintenance, tracking systems, traceability, storage, disposal and segregation of duties. These control mechanisms can provide a basis for consistent quality, better financial performance and improved regulatory compliance when implemented appropriately and adhered to during day-to-day operations.

Drug procurement

Drug costs make up an increasing percentage of healthcare expenses. Proper management of drug procurement is essential for addressing cost and promoting patient safety and quality care. To ensure pharmacy procurement activities are operating appropriately, management should develop formal procurement procedures to be followed throughout the organization. These procedures should be reviewed regularly and updated as necessary to reflect changes in regulations and operations. They should be designed to promote safety and efficacy for drug purchases, and should include cost containment techniques, such as:

- Defining the process for formulary inclusion;
- Utilizing a limited drug list or the formulary defining each drug to be purchased;
- Practicing competitive bidding to secure optimal drug pricing;
- Participating in the 340B Drug Pricing Program when eligible;
- Taking advantage of greater purchasing power by teaming with industry partners in group purchasing (Note: certain restrictions may apply for 340B Program participants) ;
- Limiting the use of local contracts negotiated outside of the group purchasing organizations; and
- Defining criteria for selecting drug product manufacturers and suppliers.

For ordering controlled substances, hospital pharmacies in the US must register with and abide by the requirements of the US Drug Enforcement Administration (DEA). The DEA categorizes controlled substances into five schedules. Schedule II includes controlled substances that are currently used for medical treatment and are considered to have a high potential for abuse, such as oxycodone, hydrocodone, hydromorphine, fentanyl, etc. Hospital pharmacies must order schedule I and II controlled substances on an official paper DEA 222 order form or electronically using DEA's Controlled Substances Ordering System The form must be executed or digitally signed by a DEA registrant.

Data analytics and benchmarking can be used by hospital pharmacy management to evaluate medication costs relative to industry standards and to identify drugs that cost the pharmacy more than the expected reimbursement received for their use. Data analytics can also be used to identify drugs with a missing or invalid National Drug Code (NDC). The National Drug Code Directory is available online at the U.S. Food and Drug Administration's (FDA) website. Incorrect NDC data can cause inaccurate billing and may negatively impact patient safety. Some facilities use software to automate the NDC update process in order to keep NDC data current and reduce errors. This automation can be particularly beneficial during drug shortages when suppliers and products may change frequently.

In addition to cost management techniques and strong controls around drug procurement, hospital pharmacy management must properly monitor the processing and payment of drug vendor invoices to ensure that products ordered were correctly received and invoiced. Sufficient supporting documentation should be maintained for pharmacy purchases evidencing drugs received match the type and quantity reflected on the vendor invoice. Data analytics can also be used to compare the price on the vendor invoices to the negotiated or contracted drug purchase price. Finally, for eligible participants, the 340B program may present significant savings opportunities; however, participation is contingent upon a hospital adhering to strict regulatory standards. Participating hospitals should therefore consider implementing strong internal controls including, but not limited to, a formalized compliance program.

Considerations when conducting an internal audit:

- Is the formulary appropriate?
    - Select a sample of new drugs and obtain the applicable Pharmacy and Therapeutics Committee meeting minutes to ascertain approval for changes to the formulary.
    - Analyze the formulary against the NDC for completeness and accuracy.
    - Analyze drug costs compared to industry standards and expected reimbursement to identify high cost outliers.
- How are controlled substances ordered?
    - Test a sample of controlled substance orders and request the manual DEA 222 form or electronic documentation. Test system access to procure controlled substances to ensure it is limited to licensed pharmacists.
- Are appropriate approvals in place prior to invoice payment?
    - Select a sample of drug payments and obtain the associated receipt and invoice support. Verify invoice pricing is aligned to contractual terms. Verify that all transactions were appropriately approved and payment aligns to goods received and ordered.
- For 340B Program participants:
    - Analyze internal controls documented within program policies and operational procedures as well as accuracy of program registration documentation.
    - Test of sample of 340B pharmacy claims to assess whether the product was dispensed to an eligible patient and that the drug was not purchased under a group purchasing contract. For Medicaid Claims, assess whether claims were appropriately billed.

Drug receipt and storage

Drugs received and stored in a pharmacy can be placed into inventory through a number of avenues. When drugs are received, before placing them into inventory, pharmacy personnel should perform appropriate receipt procedures, such as reconciling drugs received to drugs ordered, to ensure that discrepancies between quantity and drug type do not exist. Once the drugs received have been verified, they should be physically maintained in secure storage areas or active dispensing areas of the pharmacy. Drug storage can include the use of automated dispensing devices where drugs are directly scanned and input into the pharmacy management system according to the type of substance, allowing for automatic tracking and inventory counts. Controlled substances require additional storage security to prevent any unauthorized access and must be received by authorized personnel with a DEA Form 222 (purchaser's copy) completed and acknowledged by the pharmacist. For storage, pharmacies can utilize narcotic vaults - that remain locked and restrict access within the pharmacy or automated dispensing machines - which require controlled substances to be individually placed into secured bins. Both forms of storage should be restricted through badge access or biometric readers.

In instances where drugs are placed and maintained on pharmacy shelves, a typical procedure and leading practice used is called "stock rotation". Newly purchased drugs with later expiration dates should be placed behind drugs that are already in inventory. This practice may help ensure that expired drugs are not dispensed.

Temperature can be an important factor in maintaining and storing drugs to ensure their quality and integrity. Many drugs (e.g., chemotherapy drugs) require storage in climate controlled environments such as a refrigerator with specific temperature ranges. Reading and understanding drug labels are critical in determining the storage conditions required. Rather than solely relying on wholesaler shipment labels that are placed on packaging, which may not always be consistent or accurate, pharmacies should be looking at the specific individual drug labels to understand if any special storage and temperature requirements exist.[1] Monitoring the temperature of the drug storage area is a critical function to maintain drug integrity.

There may be times when drug deliveries are placed on a hospital's loading dock rather than directly at the pharmacy. In these instances, individuals need to be aware of the temperature control requirements for certain drugs – that way they can accelerate the process of transporting the drugs from the delivery location to the pharmacy. In addition, if drugs need to be transported to other locations from the pharmacy, monitoring and maintenance of a controlled temperature environment must be ensured. Ideally, these types of drugs should be delivered to the pharmacy which can provide adequate temperature and physical security controls.

[1] Philip E. Johnson, *Case Law: When Temperatures Rise, Pharmacists Get Burned* http://www.pharmacypracticenews.com/ViewArticle.aspx?d_id=51&a_id=3432

Considerations when conducting an internal audit:

- Are drugs secured and stored appropriately within the pharmacy?
    - Conduct a physical walkthrough and observe areas within the pharmacy; take note of any loose/unsecured drugs and assess the storage environment. Ensure controlled substances are restricted to appropriate personnel and not accessible to support staff (such as maintenance).
- What monitoring is conducted over drug storage within the pharmacy?
    - Understand processes for monitoring temperature of drug storage areas. Test a selection of temperature controlled drugs to assess whether storage conditions are adequate to prevent spoilage and maintain efficacy.

Drug tracking and inventory management

Many organizations utilize pharmacy management systems as a means of ensuring appropriate accountability over pharmaceuticals and ensuring the traceability of inventory from purchase through administration to the patient or disposal. Effective and transparent tracking systems that allow pharmacies to accurately record inventory components, such as medication expiration dates and physical quantities, also have the potential to reduce adverse patient outcomes. In a national survey performed by the Institute for Safe Medication Practices, 20% of practitioners surveyed reported that adverse patient outcomes occurred because of a lack of inventory management and monitoring of supply levels.[2] Pharmacy management systems, which provide real-time inventory quantities, can assist in maintaining the balance between stocking appropriate quantities to satisfy patient requirements and minimizing excess inventory.

The “real-time” tracking ability offered through these systems includes recommending items and quantities to be ordered based on par levels set by the pharmacy in the system, providing limits on excessive orders, and electronically placing orders after a manual authorization. When setting the par levels for the automated ordering, it is important to set appropriate levels to maximize the ordering process and minimize excessive supplies.

An additional benefit of tracking systems is more effective management for adding, updating, and removing inventory as well as the ability to restrict certain functions to responsible personnel (e.g., dispensing certain types of drugs restricted to certain pharmacists). There are also enhanced reporting capabilities that serve as a benefit, not only for inventory ordering and replenishment, but also for regulatory compliance tracking and monitoring. These tracking systems are often capable of flagging discrepancies, such as potential concerns, safety risks, and compliance risks, based on predefined rule sets.

Not only do inventory controls need to be considered in pharmacy management systems but logical security is paramount to ensuring the effective operation of those controls. Systems should be restricted through a user name and password or biometric login. Roles within the system should be designed on the rule of least privilege and take into consideration both process and regulatory requirements in restricting access. System administrators for any pharmacy system should be limited to a few individuals with an operational / critical need to access the drugs. Finally, access management controls should be in place to

[2] Lindsay O’Brien, *Improving Supply Chain Efficiencies in the Safety Net: An Inventory Management Pilot Program for Free and Charitable Clinics,* http://www.safetynetcenter.org/sites/default/files/images/Vecna%20Cares%20Overview%203%2015.pdf

ensure changes to a job function or employment termination are reflected with timely and appropriate changes in user access to pharmacy systems.

Considerations when conducting an internal audit:

- What drug tracking system is utilized and how?
    - Assess the current drug tracking method and determine if par levels are used and are appropriate.
    - Assess the process for managing and monitoring par levels.
- Are discrepancy reports reviewed and investigated on a consistent basis?
    - Select a sample of discrepancy reports to analyze. Test whether the discrepancies were acceptable and whether they were reviewed, investigated and resolved.
- Who has access to the drug systems and is the access authorized?
    - Test system access by reviewing all current users to determine if their access is appropriate based on job roles and responsibilities. Perform a review of terminated and transferred employees to determine if access to the inventory systems was modified appropriately and in a timely manner.

Drug traceability and accountability

Proper drug traceability and accountability must be an essential component of a pharmacy's operations to maintain adequate control over inventory, adhere to federal and state regulatory requirements, and minimize medication errors to ensure patient safety and quality standards are met. Proper medication management requires pharmacies to maintain complete and accurate records of drugs purchased, received, stored, distributed, dispensed, and disposed, in the event of drug recalls or adverse events. Using a bar coding system to record each instance a drug is received, dispensed, recalled, or sent for destruction is an effective method to ensure accuracy and accountability.

The Drug Supply Chain Security Act (DSCSA) of 2013 established plans to build an electronic national traceability system for prescription drugs that are distributed in the United States. The goal is both to safeguard the nation's pharmaceutical supply as well as to protect consumers from counterfeit or compromised drugs. This law has requirements applicable to manufacturers, distributors, and dispensers.

One of the provisions in the DSCSA requires drug dispensers to pass, capture, and maintain three types of information related to drug transactions or changes in ownership of medication: (1) transaction information including drug name, strength, dosage form, NDC, container size, shipment date, and name and address of sender and recipient; (2) transaction history including a list of all prior transactions; and (3), a transaction statement from the prior owner stating that they have complied with the requirements of the DSCSA.

Key requirements of the DSCSA[3] - Manufacturers, wholesaler drug distributors, re-packagers, reverse distributors, and many hospital pharmacies (dispensers) must:

[3]Food & Drug Administration,*DSCSA,* http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct

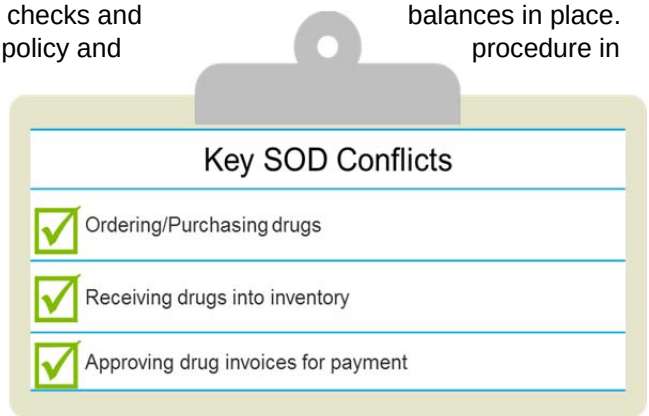
- **Product tracing**: Provide information about a drug including who handled it each time it is sold in the U.S. market.
- **Product verification**: Establish methods, systems and processes, to verify the Unique Device Identification or UDI on certain prescription drug packages.
- **Detection and response**: Quarantine and promptly investigate any drug that has been found to be potentially counterfeit, unapproved, or dangerous.
- **Notification**: Establish methods, systems and processes, to report any illegitimate drugs to the FDA and other stakeholders.

Considerations when conducting an internal audit:

- Does the pharmacy have the necessary protocols in place in the event of a recall?
  - Request all policies and procedures to determine if drug recall protocols are formalized and documented. This includes review of distributor refunding process.
  - Review patient safety and tracking processes to ensure appropriate and timely notification.
  - If recall occurred in the audit period, perform sample selection testing of the process.
- How has the pharmacy addressed the new DSCA requirements?
  - Review relevant meeting minutes, policies and procedures related to DSCA requirements. Test the adequacy of records maintained against the DSCA requirements to ensure completeness.

Segregation of duties

Illegal diversion of drugs is a major issue for pharmacy operations. This risk can be greatly mitigated by the appropriate segregation of duties (SOD) within the drug procurement process. As with the procurement of any asset, a single employee with complete control over the procurement process may be in a position where committing and concealing medication errors or fraud is possible. The individual responsible for ordering and purchasing drugs should not be the same as the person receiving and stocking a pharmacy's inventory. This should be true for all drugs, especially controlled substances. The potential for drug diversion increases when the responsibility for purchasing and receiving is owned by just one person, without the necessary oversight or checks and balances in place. Therefore, pharmacies must have a drug diversion policy and procedure in place, which includes documentation of duty segregation.



In smaller hospitals, where pharmacies may not have enough staff to separate all responsibilities, management review of exception reporting is especially important. Additional reviews should be performed and documented on inventory transactions by a different pharmacist, technician, or pharmacy director to ensure there are no discrepancies in pharmaceutical inventory.

Particularly with the purchase of controlled substances, supporting documentation and additional reviews should be maintained due to their high-risk nature. Pharmacies should have formal documented processes to review purchasing and receiving activities that occur on a daily basis. This may include a review of invoices, documented notes of what was or was not received, and a physical review of the quantities present in the delivery. Dual signatures on these documents provide the evidence and support that the review was completed.

With the use of automated inventory management and dispensing devices (often referred to as "Carousels"), controls and tools for monitoring the pharmacy's procurement process are automatic rather than manual. Carousels can be connected to the pharmacy's drug ordering system. This allows the Carousel to track which drugs have been ordered so when the drugs are placed into inventory, the quantities will either automatically match or show a discrepancy that needs to be investigated and resolved. By understanding a pharmacy's staffing, division of responsibilities, and utilization of automatic/system controls, the appropriate SOD can be maintained and the risks of theft or loss can be reduced.

Considerations when conducting an internal audit:

- Are all pharmacy duties appropriately segregated?
    - Assess current staffing roles and determine if they are separated among the staff as needed. Ask questions regarding specific situations such as: when a pharmacy staff goes on vacation or sick leave, who performs their responsibility? Are there additional reviews and oversight in place over current roles that are performed by the same person? Is segregation systematically enforced?
    - Test a selection of higher risk SOD conflicts to determine whether users or roles have been granted excessive transactional rights and could subvert SOD.
- Are the risks associated with drug diversion minimized?
    - Test a sample of controlled substances orders and request the associated invoice/receipt. Determine if the documentation was reviewed and signed. Make sure that the same person who received the drug delivery and inventory was different than who placed it. Ensure that the signers understand the importance of their role in the process.

Pharmacy revenue cycle

The pharmacy revenue cycle typically includes the following areas: pharmacy purchasing data, dispensing transactions, charge description master (CDM), pharmacy charges, and patient billing.[4] The amount of inventory a pharmacy carries may have a significant financial impact given that a drug resting in inventory has minimal payment/reimbursement value until it is dispensed. Some drugs, such as oncology drugs, are extremely expensive and have limited shelf life. Mismanagement and discarding of expired medications has a potentially costly impact.

An inventory tracking system that interfaces appropriately with the billing system facilitates an effective pharmacy revenue cycle and revenue integrity program. Reconciling the two systems will assist with identifying charge capture and inventory issues. Both of these areas may present areas of risk to pharmacies. For example, situations where inventory quantities can be accounted for but charges are

[4] Deloitte, *Documentation, coding, charging and billing for medications,* http://www.ahia.org/assets/Uploads/pdfUpload/WhitePapers/DocumentationCodingChargingAndBillingForMedicationsWhitePaper09172014.pdf

missing in the billing system may be indicative of a charge capture issue. Similarly, an instance where a claim generated for drugs that were allegedly dispensed but are showing up as unaccounted inventory may be a sign of drug diversion. Systems that allow for reconciliation have the potential to reduce charge capture and billing errors, prevent unaccounted inventories, and identify potential regulatory compliance issues.

The Charge Description Master (CDM) is essentially a list of devices, medications, services, supplies, and other items that may be charged to a patient during an encounter. Specific to medications, the CDM typically includes details such as drug description, dose, and billing unit. This data in the CDM must align with the drug information that is maintained within the pharmacy management system in order to capture all potential drug charges generated from the pharmacy. Given the significant role the CDM plays in charge capture and billing, maintaining a current drug list is essential. According to the American Health Information Management Association (AHIMA), an inaccurate CDM may cause the following negative effects: overpayment or overcharging, underpayment or undercharging, claims rejections, fines, and penalties[5]. Incorrect payments and charges may cause inaccurate revenue and financial estimates, and also impact financial analysis and budget planning.

Management of the CDM can be an onerous process but the benefits are far reaching. Facilities should develop standard policies and procedures for addressing CDM maintenance, structure, and charge capture. To coordinate this process, a hospital can appoint a CDM coordinator to facilitate CDM maintenance between various departments, including pharmacies. Changes to the CDM should utilize standard descriptions to minimize the use of non-specific Healthcare Common Procedure Coding System (HCPCS) codes.

Updates to pharmacy pricing are also critical and should be performed routinely. An organization's pricing methodology can be very complex and depends on factors such as cost, market data and payment when making pricing decisions. It is important to understand how the organization's pricing strategy relates to its hospital costs and ensure drug mark ups are not out of line.

A quality assurance process should be performed prior to implementing updates in the production environment to validate the accuracy of such changes. Periodic audits of a sample of drug items should also be performed and a review of the entire CDM should be performed annually.

Considerations when conducting an internal audit:

- How are drugs added to the CDM and are they added timely?
    - Test a sample of new drugs to see if they were also added to the CDM
- How are pricing updates determined and made? Are they reflected in the CDM?
    - Assess how often pricing updates are made to the CDM (should be on a periodic basis) and understand where the pricing information originates from.
    - Ensure adequate internal controls and documentation exists to support the organization's pricing strategy.

Wasted and expired drugs

[5] Judy A. Bielby, *The Care and Maintenance of Chargemasters (Updated)* http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_047258.hcsp?dDocName=bok1_047258

Drugs placed into inventory should regularly be reviewed for expiration dates to ensure they are not outdated. Additionally, pharmacies should perform daily physical reviews of expiration dates for drugs and obtain reports to identify expiring drugs and pull them (e.g., two days before expiration) from automated dispensing cabinets throughout the hospital. Expired drugs, received or currently in a pharmacy's inventory, should be removed immediately and separated from the rest of the pharmacy inventory to be handled appropriately. This helps to ensure that the expired drugs are not available to be erroneously dispensed to patients. Once they are removed from inventory, they should also be accounted for and appropriately taken out of the pharmacy inventory tracking system.

Expired drugs can be returned to the manufacturer, which may lead to a full or partial credit. Parameters for returning expired or unused medication are typically specific to each manufacturer with requirements pertaining to the completion of necessary paperwork, appropriate packaging and labeling instructions. Pharmacies often contract with a third party to outsource the return of these drugs and to obtain credits for returned drugs. However, compounded drugs (i.e., medications created from raw materials in the pharmacy) or drug packages that were partially used or repackaged on site at a pharmacy, are not typically accepted back by the manufacturer. In those instances, they must be properly accounted for and disposed of after expiration or lack of use.[6]

To destroy drugs (pharmaceutical waste, expired drugs, or unused drugs that cannot be redistributed), pharmacies must have a waste management program in place, which can be managed in-house or outsourced to companies specializing in pharmaceutical waste and disposal. Waste management and the different processes and requirements for destroying and disposing of pharmaceutical drugs are dependent on Federal and State regulations.[7] Based on quantity, type, level etc., drugs can be disposed of in different ways according to requirements by law and also leading practices. Internal auditors should understand the applicable requirements and determine if the pharmacy is equipped to handle the waste appropriately.[8]

Extra precautions must be instituted for controlled substances and non-regulated hazardous pharmaceutical waste (i.e., arsenic trioxide, a chemotherapy agent) destroyed on-site. The DEA requires that pharmacies implement appropriate security requirements for the employees responsible for the destruction of controlled substances on site; for example, requiring certain screenings and background checks prior to allowing the handling of controlled substances during destruction and disposal. Additionally, the DEA requires two approved employees witness the destruction, record the drug type and quantity, and sign destruction documentation.[9] The Environmental Protection Agency (EPA) has regulatory oversight over hazardous waste which includes pharmaceutical waste. Hazardous waste protocols must be adhered to when disposing of toxic chemicals. The current requirements may change, in 2015, the EPA has developed a proposal to develop standards for management and disposal of pharmaceutical hazardous waste generated by healthcare facilities which will address tracking issues and focus on a subset of pharmaceutical waste.

Considerations when conducting an internal audit:

- What is the pharmacy's process for identifying expired drugs?

[6] Thomas R. Brown, *Handbook of Institutional Pharmacy Practice*, Handbook of Institutional Pharmacy Practice
[7] American Society of Consultant Pharmacists, *Pharmaceutical Waste Practice Resource Center*, https://www.ascp.com/articles/pharmaceutical-waste-practice-resource-center
[8] EPA, *Unused Pharmaceuticals in the Health Care Industry: Interim Report*, http://water.epa.gov/scitech/swguidance/ppcp/upload/2010_1_11_ppcp_hcioutreach.pdf
[9] Drug Enforcement Administration, *Disposal of Controlled Substances*, http://www.deadiversion.usdoj.gov/fed_regs/rules/2012/fr1221_8.htm

    - Conduct a walkthrough of the pharmacy and scan inventory on the shelves. Check the inventory for expiration dates to determine that the labels are clear and that none of the medication that is available for dispensing has expired or is close to expiring.
- Does the pharmacy have a waste management program (in-house or outsourced)?
    - If in-house, obtain documentation of the waste management program. Test a selection of disposed pharmaceuticals to ascertain whether disposal complied with regulatory requirements (DEA/EPA).
    - If outsourced, understand the process for working with and monitoring the outsourced entity. Obtain and review a Service Organization Controls report from the disposal entity. Understand the regulatory compliance requirements that remain after the outsourcer performs their contractual obligations.
    - Assess whether protocols and corresponding documentation related to expired and/or wasted drugs comply with regulatory standards. Analyze whether protocols included provider/patient communication and/or follow-up where applicable.

Physical security

A pharmacy's location, as well as the location of the drugs it houses, should be restricted through physical access controls. With today's changing environment and tightening of security controls, entrances to pharmacies should now be restricted by either badge access readers or biometric readers. The use of lock and key alone is no longer sufficient. Individuals who are able to enter the pharmacy should be limited to only licensed professionals who require access, such as pharmacists, technicians, pharmacy buyers and the pharmacy director. Non-licensed individuals or non-employees, such as volunteers or students should only be allowed under the guidance and supervision of an authorized individual. Cameras and alarm systems should exist in order to monitor access in and out of the pharmacy on a continual basis.

Once inside the pharmacy, additional restrictions to specific drug areas (e.g., controlled substances) should be in place. Drugs should be secured and stored within automated drug cabinets and dispensing devices, which also require another level of security such as biometric reader access or username and password access. Periodic physical access reviews should be performed to ensure the number of personnel with access is limited and appropriate. Terminated employees who may have once had access to the pharmacy should be deactivated.

Drugs maintained outside the pharmacy should also be secured in similar ways. Automated Dispensing Machines should be placed in "low traffic" locations. Medication rooms should be restricted by badge reader access with automated dispensing machines restricted by biometric readers. Without sufficient physical access controls, unauthorized access to drugs can occur, which can lead to misuse, theft, and patient safety threats.

Considerations when conducting an internal audit:

- How is access to the pharmacy restricted?
    - Observe and perform walkthroughs around the perimeter of the pharmacy. Determine if access is restricted through badge readers, biometric readers, or keys.
- Are doors to the pharmacy locked or left open during the day?
    - Observe if outsiders are able to enter the pharmacy and take note of who is working in the pharmacy – is it restricted to only pharmacy personnel?

- How is physical access monitored and maintained?
    - Obtain a listing of all individuals with access to the pharmacy and determine if they are appropriate.

Drug shortages

Drug shortages may occur for a variety of reasons including: natural disasters, manufacturing problems, regulatory issues, raw material shortages, and voluntary recalls. Given the adverse effect on patient care and financial pressures drug shortages may create, an organization should have a prepared response in the event a drug shortage occurs. Once the shortage situation has been resolved, the organization should resume standard operating procurement procedures. A variety of steps may be taken to manage, prepare for, and respond to drug shortages as outlined in the exhibit below:

Considerations when conducting an internal audit:

- What is the process followed when a drug shortage occurs?
    - Obtain policy and procedure documentation. Review for adequacy to ensure it encapsulates a clear process for action, organizes decision making, and describes required communication.

- What types of monitoring activities are followed to ensure that purchasing drugs from alternative suppliers such as the “gray market” includes documented contract terms and drug pricing which prevent price gouging and significant price mark-ups:
    - Review a sample of drugs purchased from alternative suppliers resulting from drug shortages to see if contracts are in place and what pricing methodology was used.

Conclusion

Addressing pharmacy inventory management and the revenue cycle effectively can enable organizations to improve financial performance, adhere to regulatory requirements and reduce risks relating to patient safety. Effectively tracking inventory from the time of purchase to CDM maintenance and billing can increase revenues and decrease the likelihood of drug shortages. By restricting access to inventory, hospitals can reduce the risk of theft, ensure only appropriate personnel are able to perform inventory transactions and demonstrate compliance with regulatory standards. Cost management techniques in pharmacy purchasing along with tight inventory controls can result in financial improvements. The proper use of pharmaceuticals in achieving positive patient outcomes is essential. When coupled with proper inventory management, organizations can reduce the risk for regulatory non-compliance and derive further financial benefits from an integral hospital function.

As healthcare looks to meet the patient care challenges of value and cost-effectiveness, pharmacies will be called to higher levels of performance. Healthcare internal auditors can provide necessary assurance that pharmacy processes are efficient and effective, sensitive inventory is protected and safeguarded, and patient care objectives are met.

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