

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT SERVICES**

**Medical Center
Pyxis Systems & Operations
Audit Services Project #11-046**

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**Medical Center
Pyxis Systems & Operations
Audit Services Project #11-046**

MANAGEMENT SUMMARY

As a planned review for fiscal year 2010-2011, Audit Services conducted a limited review of management of inpatient pharmaceuticals dispensed through Pyxis MedStations System.

The purpose of the review was to assess system and process controls of inpatient pharmaceuticals dispensed through Pyxis MedStations System to assure effectiveness of inventory management, accuracy and completeness of charges, oversight of Pyxis overrides, and access authorization to Pyxis. The review focused on two inpatient units: Labor & Delivery and Intensive Cardiac Care at the Moffitt / Long Hospital.

The results of the review showed oversight of controlled medications are operating well and there is timely clearance of charge rejection edits. Pharmaceutical Services may benefit from evaluating new reporting system for opportunities to reduce the high volume of paper-based printing and ensure effective analysis to exceptions and/or trends. Additionally, process improvements are needed for assuring that outdate medications are removed from the Pyxis devices and that inappropriate overrides are mitigated and well documented to achieve better compliance with policy and reduce risk to patient safety.

Detailed information can be found in the body of this report.

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I. BACKGROUND

As a planned review for fiscal year 2010 – 2011, Audit Services conducted a limited review on management of inpatient pharmaceuticals dispensed through the Pyxis MedStations System (Pyxis).

Pyxis is an automated medication storage and distribution device that provides information for medication management that is readily accessible and meets patient needs in a timely manner. The system can also improve resource management by linking to the supply ordering and distribution system and eases the billing of pharmaceuticals by posting charges and credits to the patient account when medication is dispensed from or returned to the device.

Pyxis typically stores routine, emergency medications, narcotics and keys to pumps and elevators. Pharmaceutical Services is currently transitioning the storage of 24 hours routine medication on rings to the Pyxis. There are approximately 2,871 users for a total of 116 Pyxis devices located at Mount Zion and Moffitt/ Long hospitals. At the time of the review, the total value of medications in the Pyxis was approximately \$611,401.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess the controls operating over the management of pharmaceuticals dispensed through the Pyxis devices and focused specifically on assessing the:

- Effectiveness of the inventory management controls;
- Controls for ensuring the accuracy and completeness of charges;
- Effectiveness of the procedures for review and oversight of Pyxis system overrides; and
- System controls for assuring that only authorized personnel have access to the medication units.

In conducting the review the following procedures were performed:

- Pharmaceutical Services management and staff were interviewed to obtain an understanding of existing policies, practices, and processes relating to use of Pyxis for dispensing of medication.
- Pharmaceutical Services policies and procedures surrounding the use of Pyxis for medication administration and management were reviewed.
- Refill transactions for a three month period ending March 2011 were reviewed to determine the frequency of refills to assure that the PAR levels established were appropriate and adjustments were made to meet usage requirements.

- Nursing managers in the two Units sampled were interviewed to determine if there were patterns and causes for medication shortages.
- Two months of Daily Inventory log of narcotics were reviewed to verify whether inventory discrepancies were reviewed and resolved in accordance with established policy and procedures.
- In conjunction with a Pharmacy Technician, checks were performed to verify the removal of expired medications for two MedStations.
- Automated Dispense Machines (ADM) reports for five consecutive days were evaluated for timeliness of clearing rejected transactions.
- A sample of 15 Stock Return transactions was tested to verify proper credit posting to patient accounts.
- Overrides reports were reviewed and discussed with Pharmaceutical Services Manager to assess the effectiveness of the process for review and follow-up of overrides.
- A sample of ten overrides was performed to verify the appropriateness of the override including documentation in the incident report system where applicable.
- Employees with clinical titles that had separated within the three months ending April 2011 were reviewed to verify timely access removal.
- The most recent 90 days Inactivity Report was reviewed to assure that there was monitoring and removal of inactive accounts.
- A sample of ten users pertaining to five user groups were reviewed to determine whether they were granted appropriate access levels based on the roles performed.
- Password controls for the Pyxis system were reviewed to determine compliance with the Unified UCSF Enterprise Password Standard policy.

The scope of this review encompassed activities and transactions transpiring during the period from January 2010 to May 2011 for two inpatient units: Labor & Delivery and Intensive Cardiac Care at the Moffitt / Long Hospital. Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of controls and compliance beyond those areas specifically reviewed. Fieldwork was completed in May 2011.

III. CONCLUSION

Based on the work performed, monitoring and oversight of controlled medications are operating well and there is timely clearance of charge rejection edits. Pyxis system access management controls are effective in ensuring deactivation of separated employees and inactive accounts; although current password configuration needs to be revised to conform to UCSF password standards.

Currently, many of the management information reports for monitoring and managing the operations are paper-based and voluminous, limiting the ability to perform effective analysis to identify exceptions and / or trends that may require remediation. Efficiencies and enhancements in the oversight of operations could be achieved through the use of more effective data analysis and reporting tools. Additionally, to achieve better compliance with policy and reduce patient safety risks, process improvements are needed for assuring that outdated medications are removed from the Pyxis devices. Lastly, inappropriate overrides should be documented with complete information for identification of root cause and development of action plans to mitigate recurrence.

Specific observations and management corrective actions are detailed below.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

A. Management Information Reporting Tools

Pyxis system has limited reporting capabilities for effective monitoring and oversight of medication management

An effective reporting tool is essential to managing business operations and assuring compliance. Reports should be available in a form that allows for data analysis and trending to promptly identify problems and for effective use of resources.

Currently, the department uses a reporting tool called Pyxis Consultant, which is no longer supported by the vendor, and has limited capabilities. Specifically, reports are generated mostly in pdf format, while Excel reports are limited to predefined queries. The system is slow in generating reports (pdf) or queries (Excel) and can fail when reporting information for more than one month. Additionally, since the system does not allow for electronic transfer of information, extensive amount of paper reports are printed and then discarded.

Specific areas identified where the lack of effective reporting tools has limited the ability to perform analysis for monitoring performance and compliance include:

- A report of users accessing Pyxis is only available in hard copy and thus limits the ability to perform more automated comparison with HR / payroll records to ensure separated employees no longer have access to Pyxis.
- Monthly Proactive Diversion reports are only available in printed copy limiting the ability to perform trending analysis on potential area of concern by nurse, unit or medication-.
- Information on the level and pattern of write-offs for expired medication and discrepancies in non-narcotic drugs is not reported. As a result, Pharmaceutical Services cannot track the amount of potential revenue loss.
- Refill reports do not provide a means for decision-making on inventory adjustments as it requires a manual review of the report to identify which drugs are refilled frequently. Adjustment to inventory PAR levels is made by technicians or nurses' request rather than supported by data analysis.

Pharmaceutical Services recognizes the poor reporting for Pyxis activity and is in the process of implementing a new reporting tool called Pandora. The tool supposedly is a more robust industry standard reporting tool for diversion tracking, inventory management and medication distribution.

Lack of effective reporting tools limits management's ability to identify significant issues and risks; monitor and measure performance level and to take timely remediation actions.

Management Corrective Actions

To address the current reporting deficiencies, Pharmaceutical Services recently implemented new reporting tools, Pandora and Pyxis Knowledge portal. By March 31, 2012, the department will determine the reports that will be required for data analysis, validate the accuracy of reports to be used, and train designated staff on how to use of the newly acquired reporting tools. Additionally, when implementing the new reporting tools, the department will review existing reporting practices and strive to reduce the need to print voluminous reports, if possible, to support UCSF sustainable practices.

B. Medication Management Compliance**1. *Departmental procedures for removal of outdated drugs were not consistently followed.***

The Centers for Medicare and Medicaid Services (CMS) Condition of Participation §482.25 and Joint Commission Standard on medication management (05.01.19) require that outdated, mislabeled or otherwise unusable drugs and biological must not be available for or administered to patients. According to Pharmaceutical Services Policy 126.020 "Pyxis Report Generation" a daily report of outdated medication is generated and technicians are required to remove the items identified on the report.

Inspection of two MedStations at the end of a technician's shift found that 2 of 33 medications inspected had expired but had not been removed and one had incorrect expiration date entered into the system.

Discussions with Pharmaceutical Services personnel confirmed that the above observation is consistent with the monthly quality assurance inspections performed by the department. It was asserted that all technicians may not be following departmental practice of using the "outdated medication" report or function on Pyxis, but instead only checking for expired items for the medications that they are refilling.

Inconsistencies in practices for the removal of expired medications increase the risk of patient safety and non-compliance with regulatory requirements.

Management Corrective Action

Effective September 30, 2011, management will develop a plan to assess and identify methods to assure expired medications are removed from Pyxis MedStations.

2. *When Pyxis overrides occur, sufficient information is not available to confirm that such action was necessary.*

Pharmaceutical Services Policy 126.50 "Pyxis Medication Access" defines appropriate overrides to be acceptable for a system downtime and emergent situations for selected medications approved as "overridables" by the Pharmacy & Therapeutics Committee. Pharmaceutical Services has an established monitoring process for the daily review of overrides. Inappropriate

overrides, such as no medication order present or selection of wrong patient profile, are logged into the Incident Reporting (IR) system and referred to the respective Unit's Nursing Manager for follow-up.

Review of the incident reports showed a cumulative total of 208 overrides for quarter ending March 31, 2011 that were attributable to no medication orders.¹ Further inquiries into whether a root cause analysis has been performed determined that information was not available to assess the need for Pyxis overrides. It was noted that:

- Nursing staff do not always follow procedures for submitting an after-the-fact order to support the verbal physician order.
- Responses to questions in the IR system to determine the reasons for not obtaining medication orders were not consistently completed by some Nursing Units, making it difficult to determine causes and develop mitigation plans.
- Current manual tracking of overrides reporting in the IR system does not have location information to determine pattern of common problem areas.

Additionally, there was lack of clarity on whether patient accounts were adjusted for when overrides are performed due to incorrect selection of patient profile.

Communications with Nursing Administration revealed that they were not aware that overrides were still an issue although information on overrides is included in the medication error report to the Medication Quality Subcommittee.

Non-conformance with policy and procedure increases the risk to patient safety as medication is administered without a medication order that has been reviewed by a Pharmacist. Also, incorrect billing may occur where the wrong patient profile is selected by Nursing staff. Failure to address trends recurrence is noncompliant with Medicare Conditions of Participation (COPs). Additionally, lack of adequate responses to questions prevents proper identification of errors and resolutions.

¹ Total population of true overrides for the same period of time was not available.

Management Corrective Actions

Effective September 30, 2011, Nursing Administration will work with Pharmacy Medication Safety to enhance quality of IR documentation to provide adequate responses to questions in order to determine accurate problem trends and develop resolutions.

C. System Access

Access controls do not meet University Enterprise Password standard.

The Unified UCSF Enterprise Password Standard requires that all University Electronic Information Resources must meet strong password criteria that include:

- minimum password length of 7 characters,
- password masks including upper/lower case alpha, numeric, special character and repeated characters and prohibited pattern components,
- lock outs after pre-determined failed logon.

Currently, the Pyxis system does not meet the UCSF password setting standard since employees only need to enter a four character password. It was found that Pyxis can be changed to enforce minimum password length but not the special characters or case sensitivity policy requirement.

Although the majority of employees accessing Pyxis use the biometric finger printing option, weak passwords may compromise access controls increasing the risk of unauthorized access.

Management Corrective Actions

- a) Effective August 30, 2011, Pharmaceutical Services will communicate the change in the minimum password characters requirements to all nursing unit and the effective date when passwords need to be changed.
- b) Pharmaceutical Services has requested that the Medical Center's Information Services approve an exception to the UCSF password standards specific to special characters requirement for the Pyxis system.

D. Departmental Goals & Objectives

Pharmaceutical Services has outdated departmental goals and objectives.

Pharmaceutical Services' website shows the departmental goals for FY 2005/2006. More current goals were not available when inquired with department management.

Updated departmental goals and objectives provide strategic direction for the department and sets expectations for staff for achieving specific performance targets.

Management Corrective Action

By September 30, 2011, the department will develop goals and objectives for Fiscal Year 2012 and shall communicate these to all staff.

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