November 9, 2011

CHARLES DANIELS
Pharmacist-in-Chief
0657

Subject: **Pharmacy Business Operations**
Audit & Management Advisory Services Project 2010-14

The final audit report for Pharmacy Business Operations, Project 2010-14 is attached. We would like to thank Pharmacy personnel for their cooperation and assistance during the audit.

Because we were able to reach agreement regarding corrective actions to be taken in response to the audit recommendations, a formal response to the report is not requested.

The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the corrective actions. At that time, we may need to perform additional audit procedures to validate that actions have been taken prior to closing the audit findings.

UC wide policy requires that all draft audit reports, both printed and electronic, be destroyed after the final report is issued. Because draft reports can contain sensitive information, please either return these documents to AMAS personnel, or shred them.

Stephanie Burke
Assistant Vice Chancellor
Audit & Management Advisory Services

Attachment

cc: M. Baggett
       D. Brenner
       L. Donaldson
       G. Hagney
       R. Hollyfield
       T. Jackiewicz
       J. Lamott
       G. Matthews
       T. Perez
       R. Simonian
       S. Vacca

AUDIT & MANAGEMENT ADVISORY SERVICES

Pharmacy Business Operations
November 2011

Performed By:

Gabor Herman, Auditor
Terri Buchanan, Manager

Approved By:

Stephanie Burke, Assistant Vice Chancellor

Project Number: 2010-14

Pharmacy Business Operations
Audit & Management Advisory Services Project 2010-14

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Executive Summary

Audit & Management Advisory Services (AMAS) has completed a review of inpatient and outpatient Pharmacy business processes including inventory management reporting, and charge capture as part of the approved audit plan for Fiscal Year 2009-10.

The objective of this audit was to determine whether Pharmacy business process controls were adequate to provide reasonable assurance that Pharmacy inventory was well managed, inventory adjustments were adequately supported, and charges were captured.

We concluded that Pharmacy business process controls required improvement to provide reasonable assurance that inventory adjustments were adequately supported, and charges were captured. This was primarily due to the absence of standard, documented procedures for capturing and reporting product costs, revenue, and inventory adjustments. As a result, inventory data was at times incomplete, and impacted by timing differences.

As procedures and systems changed to comply with new regulations, and accountability for managing inventory moved from the Main Pharmacy to each location, several changes were implemented without central management review to ensure that they were consistently applied across all Pharmacies.

We noted that documentation and management oversight was inadequate to assure that all charges were reported, that inventory transfers were recorded and that pricing errors were identified. In addition, efforts to monitor and update the cost of filled prescriptions were inconsistent. Drug wastes were inconsistently monitored, and opportunities to charge for them were not pursued. Outpatient Pharmacy revenue and cost reporting was not synchronized, and charges and costs were incomplete. The Hillcrest Infusion Center and Hillcrest Inpatient Pharmacy operating and inventory costs were combined, which did not facilitate the financial management of each location. In addition, drug costs for compounded products were not allocated to the Pharmacies that dispensed and billed for the products.

Opportunities for process improvements are discussed in greater detail in the remainder of this report.

I.   Background

Audit & Management Advisory Services (AMAS) has completed a review of inpatient and outpatient Pharmacy business processes including inventory management, reporting, and charge capture, as part of the approved audit plan for Fiscal Year 2009-10.   This report summarizes the results of our review.

The UCSD Health System (UCSDHS) pharmacies provide services to the UCSD Medical Centers at Hillcrest (Hillcrest) and La Jolla (Thornton) and associated outpatient clinics. Pharmacy Administration has organized operations so that drug inventories from 14[1] unique locations are available to meet the pharmacological needs of inpatient, outpatient, and research departments. The schedule below provides a list of 12 Pharmacy locations which were reviewed, and their respective inventory balances at October 31, 2010.

<div align="center">UCSDMC Pharmacies</div>

	Pharmacy	Common Reference	Inventory at 10/31/10
1	Compounding	CIVA	$0
2	Hemophilia Treatment Center	HTC	198,278
3	Hillcrest Inpatient/Infusion Center	Main/Hillcrest I.C.	2,279,376
4	Hillcrest Outpatient	Outpatient	337,525
5	Home Care	Home Care	64,425
6	Internal Medicine Group	IMG	68,820
7	La Jolla Inpatient	Thornton Inpatient	1,679,202
8	Perlman/Mail Order	Thornton Outpatient/Mail Order	302,852
9	Moores Cancer Center (MCC) Infusion	MCC IC	913,321
10	Moores Center Center (MCC) Outpatient	MCC Outpatient	404,258
11	Medical Offices South	Ambulatory Care Center (ACC)	366,584
12	Medical Group	Med Group	85,690
	Total Inventory - All Locations		$6,700,331

Drug Inventory

The UCSDHS contracts with Cardinal Health (Cardinal) as its primary vendor to supply wholesale pharmaceuticals. Prices paid are determined based on either a Novation contract or a 340B pricing structure. This arrangement requires that each Pharmacy maintain segregated inventory identical in every respect except cost.

The Novation[2] contract is a purchase agreement in which UCSDHS participates as a member or the University Health System Consortium[3] (UHC). Under this contract, members receive

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[1] The Investigational Drug Service (IDS) pharmacies at Hillcrest and Thornton were excluded from the scope of this review. Drugs inventories maintained at those locations are received from commercial research sponsors and managed on behalf of UCSD Principal Investigators.

[2] Novation is healthcare supply contracting company that provides services to VHA Inc. and University HealthSystem Consortium (UHC) member organizations.

[3] The University HealthSystem Consortium, with headquarters in Oak Brook, Ill., is an alliance of more than 100 academic medical centers and 200 of their affiliated hospitals representing approximately 90 percent of the nation's nonprofit academic medical centers.

discounts from drug wholesalers such as Cardinal. In general, Inpatient Pharmacies purchase pharmaceuticals using the Novation discounts.

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes, and qualified disproportionate share hospitals. Under section 340B, the federal government seeks to indirectly support hospitals that treat significant populations of indigent patients. Participation yields significant savings on pharmaceuticals. UCSDHS qualifies to make Section 340B purchases as a Disproportionate Share Hospital (DSH). In general, Outpatient Pharmacies purchase pharmaceuticals using the 340B pricing program.

The majority of Pharmacy locations have separate Novation and 340B accounts with Cardinal which results in separate drug deliveries to multiple locations. A flowchart that tracks the inventory flow from suppliers and between Pharmacy locations is provided in **Attachment A**.

Although Cardinal is the wholesale vendor, it is not the exclusive source of Pharmacy stock. If Cardinal does not stock the required drugs, or is unable to fill an order because the drugs are out-of-stock, Pharmacy may purchase them directly from the manufacturers. When required dosages are not available, drugs may be purchased using a specific Cardinal account, and delivered to a repackaging vendor.

Pharmaceutical acquisition requires specialized knowledge and is time intensive. As a result, purchasing duties are primarily handled by a team of four Pharmacy buyers. In addition to purchasing, buyers are responsible for calculating drug prices and entering new or updated prices in various Pharmacy systems.

Pharmacy also participates in the Cardinal Assist Program (Cardinal ASSIST®). Cardinal Assist drug orders arrive directly from Cardinal daily, and are delivered to specific Pyxis® MedStations®, otherwise known as Automatic Dispensing Machines (ADMs). Each ADM that is included in Cardinal ASSIST is connected to the Cardinal network, which enables the distributor to poll each unit to obtain the order for the following day. The orders arrive in ADM specific totes, and each drug is packaged in a patient ready dose labeled with the National Drug Code (NDC) lot number and expiration date in a bar code format. The barcode labeling automates the restocking process.

Pharmacy Systems

Five applications/systems are used to process prescriptions, charge patient accounts and to run cost reports. The systems include:

- CMS[4]   (Recharge)
- CPR+[5]   (Home Infusion Pharmacy) System

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[4] The Clinical Management System is a UCSDMC developed system used to recharge clinics and research areas for pharmaceuticals.
[5] Complete Patient Records (CPR+) is a product of Definitive Homecare Solutions, Ltd.

- Epic[6] Beacon (Oncology)
- Epic Willow (Inpatient Pharmacies)
- PCSI[7] (Outpatient Pharmacies)

The table below identifies the systems that are utilized by Pharmacy location:

UCSD Pharmacies and Systems

Pharmacy	EPIC	PCSI	Recharge	CPR+	Manual
Compounding				X	X
Hemophilia Treatment Center				X	X
Hillcrest Infusion Center	Beacon				X
Hillcrest Inpatient	Willow		X		X
Hillcrest Outpatient		X			X
Home Care				X	X
Internal Medicine Group		X			X
La Jolla Inpatient	Willow		X		X
Perlman/Mail Order		X			X
Moores Cancer Center Infusion	Beacon		X		X
Moores Cancer Center Outpatient		X			X
Medical Offices South		X			X
Medical Group		X			X

Willow is the Epic Inpatient Pharmacy module. Orders from Epic flow directly into Willow for verification and dispensing. Pharmacists have direct access to EMR during the order verification process. In addition, Pharmacists can monitor medication treatment and improve medical outcomes, improving patient safety, minimizing adverse effects and helping control costs.

Beacon is the Epic Oncology module that provides physicians with the functionality to enter a drug treatment plan for cancer patients. Because Epic modules are fully integrated, Beacon shares drug and price databases with the Epic Willow module. Pharmacists utilize Beacon to prepare drugs for scheduled patients. Although the drugs may be customized for each patient before they arrive for their scheduled appointment, associated charges are not generated until the patient is medically cleared to receive the treatment. Beacon data used in Moores Cancer Center (MCC) Pharmacy inventory calculations is included in Cost of Sales Reports.

PCSI is the system used to process Outpatient Pharmacy prescriptions, and to facilitate insurance claim adjudication. Outpatient Pharmacy management would consider utilizing the PCSI inventory management module; however, since the software was converted to the Windows version the inventory module has not been functional.

Pharmacy utilizes the UCSDHS Clinical Management System (CMS) recharge functionality to allocate the cost of drugs transferred to internal customers such as outpatient clinics and research

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[6] Epic is the electronic medical record system implemented by the UCSD Health System and several other UC campuses.
[7] The RX/3000 system is a product of Pharmacy Computer Systems, Inc. (PCSI).

departments. On a monthly basis, a charge is created for each cost center that received drug orders the previous month. Recharge entries interface with the Medical Center general ledger system to transfer costs.

CPR+ software facilitates the management and logistics required to deliver drug therapies in patients' homes. The software is used to manage equipment used to process charges, and to chart medical records. Other critical functions include prescription order entry and management of inventory expiration dates. Compounding Pharmacy orders are also processed via CPR+.

Inventory Calculation Process

At one time, tracking inventory costs between Pharmacies was not considered critical, and therefore, the drug inventories for all Pharmacies were combined in the hospital financial statements. Inventory adjustments, based on physical counts, were proportionally spread across all Pharmacies. However, since Novation and 340B pricing regulations were implemented, inventories have been logically and physically separated. Individual accounts have been established for each Pharmacy location to report financial performance, inventories and resulting adjustments, which allows Pharmacy management to evaluate performance by location, and focus resources in problem areas.

Preparation of the monthly inventory calculation is a manual process. Pharmacy staff print various reports from their respective systems to determine the cost of all orders or prescriptions filled during the month. For each Pharmacy, the information is then compiled, along with new purchases and transfers, to determine ending inventory.

Drug inventory is calculated using the formula below.

January	February
Beginning Inventory	Beginning Inventory
+ Purchases	+ Purchases
- Cost of filled orders	- Cost of filled orders
+/- Transfers	+/- Transfers
= Ending Inventory	= Ending Inventory

Because each drug has definitive shelf life, inventory is used on a First In – First Out (FIFO) basis. The inventory pricing model is Last In – First Out, which effectively passes on the latest drug prices to patients.

II.   Audit Objective, Scope, and Procedures

The objective of this audit was to determine whether Pharmacy business process controls were adequate to provide reasonable assurance that Pharmacy inventory was well managed, inventory adjustments were adequately supported, and charges were captured.

We performed the following audit procedures to meet the project objective:

- Reviewed University of California (UC) Business and Finance Bulletin 49 (BUS 49): *Policy for Cash and Cash Equivalents Received*;
- Interviewed the Pharmacy Director and other key Pharmacy personnel to obtain information about Pharmacy inventory management processes and report preparation;
- Discussed Pharmacy inventory and sales reports with the Medical Center Director of Budget & Financial Forecasting and Finance staff;
- Evaluated drug order access controls;
- Reviewed Pharmacy ordering and inventory receiving processes;
- Evaluated the Pharmacy drug transfer process;
- Evaluated Pharmacy processes for reporting monthly prescriptions costs to Finance (**Attachment B**);
- Observed the Pharmacy physical inventory process;
- Reviewed the process for implementing and monitoring drug price updates in various systems;
- Reviewed and tested the accuracy of Outpatient Pharmacy Filled Prescription Cost Reports and associated charges reported to Finance;
- Evaluated the process for monitoring the accuracy of drug costs in Pharmacy systems;
- Researched Pharmacy waste issues with UC campuses, UHC, and a Pharmacy audit expert;
- Verified drug costs with Cardinal.com;
- Traced three months of Outpatient Pharmacy charges for completeness testing and validated "no-bill" payer charges;
- Reviewed the Finance inventory adjustment process;
- Analyzed the Compounding Pharmacy drug cost allocation methodology;
- Evaluated the waste tracking and reporting process at the MCC Infusion Center;
- Analyzed three months of Outpatient Pharmacy cost of sales records; and,
- Reviewed the procedure for UCSD Pharmacies and non-UCSD Pharmacies to lend/borrow drugs.

During the course of fieldwork, the Inpatient Pharmacy implemented the Epic Willow Inpatient Pharmacy system. Because the Siemens system was being phased out, and Pharmacy staff was being trained to use Epic Willow, we did not evaluate the processes and controls associated with either of these systems during this review.

III.   Conclusion

We concluded that Pharmacy business process controls required improvement to provide reasonable assurance that inventory adjustments were adequately supported, and charges were captured. This was primarily due to the absence of standard, documented procedures for capturing and reporting product costs, revenue, and inventory adjustments. As a result, inventory data was at times incomplete, and impacted by timing differences.

As procedures and systems changed to comply with new regulations, and accountability for managing inventory moved from the Main Pharmacy to each location, several changes were implemented without central management review to ensure that they were consistently applied

across all Pharmacies. For example, both Infusion Centers track waste. One location maintains an electronic log that is available online, and includes data that is traceable to the monthly inventory calculation. The other location uses a paper log that requires manual tabulation, and the information maintained is not readily traceable to inventory reports.

We noted that documentation and management oversight was inadequate to assure that all charges were reported, that inventory transfers were recorded and that pricing errors were identified. In addition, efforts to monitor and update the cost of filled prescriptions were inconsistent. Drug wastes were inconsistently monitored, and opportunities to charge for them were not pursued. Outpatient Pharmacy revenue and cost reporting was not synchronized, and charges and costs were incomplete. The Hillcrest Infusion Center and Hillcrest Inpatient Pharmacy operating and inventory costs were combined, which did not facilitate the financial management of each location. In addition, drug costs for compounded products were not allocated to the Pharmacies that dispensed and billed for the products.

Opportunities for process improvements are discussed in greater detail in the remainder of this report.

IV.   Observations and Management Corrective Actions

A.   Pharmacy Inventory Management Coordination and Oversight

Pharmacy is likely the most complex organization in the UCSDHS. Pharmacy personnel operate in a highly regulated environment, requiring that Pharmacy business system controls satisfy federal and state drug security standards, and assist Health System units with accurate drug charge capture. Considering this, Pharmacy inventory process controls need improvement to ensure compliance with regulatory and charge capture requirements in both the inpatient and outpatient environments.

1. Inventory Management

Pharmacy inventory management and financial reporting practices were not coordinated across all locations. Physical inventory and other key business processes were not documented.

As noted above, Pharmacy utilized several computer systems to process physician drug orders and/or fill prescriptions. However, inventory data was not maintained in any of those systems for the purpose of financial reporting. Inventory balances were derived from several data sets, obtained using system data queries, and manual data compilations. Additions to inventory were based on purchases entered into the general ledger. Deductions from inventory were based on the cost of filled orders and/or prescriptions system data queries. Transfer data obtained from copies of manual transfer forms could result in an increase or decrease in the inventory balance. Several factors affected the accuracy of monthly inventory cost calculations, which included:

- Completeness – Pharmacy may receive stock into inventory prior to month end, but not report those items to Finance if the related invoice was not paid. As a result, a portion of that drug shipment may have been sold, and included in the cost of prescriptions filled, while the associated cost was excluded.

- Transfers –Transfers that are not appropriately recognized by the transferring Pharmacy as issued, and by the receiving Pharmacy as received, will impact the accuracy of inventory data in individual Pharmacy locations.

- Errors – Price and quantity system updates require Pharmacy staff to manually enter data, compile information and prepare reports. Input errors could impact the accuracy of the calculated inventory balance.

Because Pharmacy processes are decentralized, and data is compiled from several sources, it is important that financial inventory reconciliation and analysis processes be documented. However, because many of the procedures for compiling data and performing other tasks that affected inventory value have been in place for a number of years, staff continue to complete them based on training from prior staff, without documented guidelines.

Pharmacy conducted a semi-annual physical inventory count in all locations, which required nine days to complete. Although Pharmacy management had prepared draft instructions to outline steps required to plan and staff physical inventory efforts, these instructions were never finalized.

The development of written inventory management procedures would help management reassess and improve processes as needed. Procedures would also provide guidance for new staff, and assist current staff with performing tasks in accordance with management expectations.

Management Corrective Actions:

1. Pharmacy Managers have documented the inventory management and charge capture processes and guidelines. The inventory management guidelines, which include a master procedure checklist, will be used for the October 1, 2011 physical inventory count.

   Pharmacy management will also:

2. Require that steps for acquiring inventory adjustment files are appropriate for each location and that the computer system is documented. The data will indicate the total of drug purchases, and the number of prescriptions filled to ensure that the inventory count for each Pharmacy may be adjusted to reflect end of period numbers.

3. Develop instructions for assigning a value to outstanding transfers between Pharmacies.

4. Identify best practices for managing and reporting inventory transactions, and implement process changes as needed. Standard processes will be implemented in all locations.

2. Inter-Pharmacy Outpatient and Inpatient Drug Transfers

Drug transfers between Pharmacies were not consistently reported to Pharmacy Administration.

Drugs may be transferred between Pharmacy locations, as long as 340B and Novation stock remain separate after transfer. A transfer document was prepared to document each transaction. One copy of the document was retained at the lending Pharmacy, and a copy was forwarded to Pharmacy Administration and the borrowing Pharmacy along with the drug. The transfer process required the Pharmacy to replace borrowed stock with the same drug. However, this was not always possible, particularly in cases when the borrowing Pharmacy was not able to purchase the drug because it was not included on its formulary.

The transfer process allowed Pharmacies to quickly acquire the drugs needed. However, it did not provide adequate documentation of the transfer, or assist with ensuring that borrowed inventory was returned. AMAS reviewed a judgmental sample of transfer documents and observed the following deficiencies in the form(s) used to document the process:

- Three separate forms were used in various locations to document transfers;
- Fields were not available to identify whether the inventory being transferred was from 340B or Novation stock; or to identify a permanent transfer, which would require an immediate inventory adjustment; and,
- Forms were not numbered to facilitate the monitoring of transfer activity.

We also noted that the drug cost was not entered on the form in many cases.

Because the drug inventory for each location was separately reported, drug transfers potentially affect inventory values. The current manual process for tracking transfers and compiling transfer data for financial reporting purposes provided some level of documentation to support transfers, but was incomplete.

When the co-located Hillcrest Inpatient and Outpatient Pharmacies were established, inventory segregation by Pharmacy or 340B/Novation pricing was not required. However, compliance with the 340B regulations has increased the risk of comingled inventories. Transfer logs were used in this location to document inventory transfers. However, AMAS observed Pharmacy staff moving drugs from one Pharmacy to the other without logging the transfer.

Management Corrective Actions:

Pharmacy management will:

1. Develop one transfer form and distribute to all pharmacies via iShare.

2. Require that all drug transfers be authorized by a Pharmacist, documented and reported.

3. Define "nominal value" as a materiality standard to provide guidance for transfers with a value to small to be reported and will ensure that the standard chosen is compliant with Board of Pharmacy regulations.

4. Require employee identification on manual transfer forms, and will state on the form how copies are to be distributed.

5. Require that Pharmacy Fiscal Closing Procedures state that transfer documents must be used to support the Inventory Transfer line item on the inventory reconciliation.

B.   Prescription Drug Charge Capture

1. PCSI Price Updates

The process for monitoring and changing drug prices in PCSI, the Outpatient Pharmacy system, was inconsistent and not completed on a regular basis.

AMAS was advised by Outpatient Pharmacy personnel that drug prices have sometimes not been updated for as long as six months.   Although not observed by AMAS, Pharmacists reported that drug pricing errors have occurred in the past that resulted in Outpatient Pharmacy losses that exceeded $100K.

A standard written procedure for monitoring and adjusting drug prices had not been implemented. The procedures being followed during audit fieldwork were time consuming, and the actions taken were not documented or reported to Pharmacy management.

The Outpatient Pharmacy Buyer was responsible for updating drug prices. The process we observed required the Buyer to log into each Pharmacy's individual Cardinal account, and identify the last price charged for each drug. The price per dosage unit was then calculated and verified in the system. The Buyer also updated the prices of drugs that changed based on periodic special promotion prices. However, approximately 15 personnel in addition to the Buyer had the system access required to make price changes, making the manual PCSI price update process subject to human error.

Because outdated drug prices affect the accuracy of Pharmacy revenue and negatively impact the operating margin of each Outpatient Pharmacy, drug prices should be monitored regularly by someone not involved in drug purchasing. Routine analysis of a random sample of drug prices would serve as a cost effective control to verify price accuracy.

Management Corrective Actions:

Pharmacy management will:

1. Document procedures for price updates and routine monitoring in all Pharmacy systems.

2. Limit the number of staff with access to input Pharmacy system price updates to one staff member and one back-up per system.

3. Identify a Pharmacy staff member other than the Pharmacy Buyer to periodically monitor the accuracy of drug prices in all Pharmacy systems.

2. Accounting for Drug Waste

The allowance for drug waste included in the Medical Center cost accounting system was not based on actual data, and had not been adjusted in several years. Although Medicare has established criteria for charging for drug waste, Pharmacy management has not implemented that process.

A separate "Waste and Spoilage" expense account was created for each Pharmacy location on the annual Medical Center flexible budget. The budget allocation for drug waste and spoilage varied, based on the prescription volume and drug formulary at each location. The budgeted waste and spoilage amounts were arbitrarily set and have not reviewed for a number of years.

The process of filling prescriptions generated waste that resulted from the difference between the drug dosage ordered by the physician and the drug quantity in the original package. To be effective, some cancer drugs must be used within a matter of hours. In order to recognize the total cost of filling drug orders and patient prescriptions, the MCC IC Pharmacy began tracking drug waste daily in January 2010. AMAS' review of waste tracking documents revealed that approximately $40K of drug waste was recognized each month. In comparison, the annual flexible budget for MCC IC allows drug waste and spoilage of only $100.

Medicare guidelines allow drug waste to be billed under certain circumstances, using the JW modifier.[8] The Center for Medicare and Medicaid Services (CMS) transmittal

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[8] CMS Manual System, Publication 100-04: Medicare Claims Processing; Transmittal 1962: *Discarded Drugs & Biologicals* (dated April 10, 2010, effective 7-30-10).

states: *"when a physician, hospital, other provider or supplier must discard the remains of a single use vial or other single use package after administering a dose/quality of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label."* Although charging for drug waste may not be practical in all patient care locations, drug costs for a single infusion treatment in the MCC IC may exceed $10,000. Therefore, a charge capture process for drug waste should be further evaluated.

Management Corrective Actions:

1   Selected Pharmacies have begun tracking drug waste on a daily basis to support an adjustment to the budgeted waste allowance.

Pharmacy management will:

2   Consider implementing the MCC IC method of tracking and reporting drug waste at other patient care locations, if practical.

3   Work with Revenue Cycle Administration to implement a charge process for billing Medicare patients for wasted drugs using the JW modifier as appropriate.

C.   **Outpatient Pharmacy Financial Reports**

1. Timing Differences – Revenue and Expense Reporting

A consistent cut-off date for generating monthly revenue and expense reports for all Outpatient Pharmacy was not established. As a result, various prescription charge and cost reports were compiled at different intervals.

The Outpatient Pharmacies compiled internal financial data that was provided to Finance to assist with preparing the Medical Center monthly financial reports. The PCSI system provided updated sales data on a daily basis, as prescription sales were completed. Therefore, it was critical that additional financial reports (such as prepared charge reports, reports listing the value of filled prescriptions, and associated costs reports) be compiled on the same date to ensure that the data was comparable.

The Outpatient Pharmacies generated a report that included filled prescription charges on either the 4th or 5th of the following month. In comparison, the filled prescriptions sales reports were generated between the 11th and the 14th of the following month. The charge and cost data was compiled by different Pharmacy staff, for different locations. The approximate seven to ten day difference in the reporting process introduces a variance such that charges (amounts billed for prescriptions) are under

reported or costs are over reported. ***Attachment B*** provides an overview of the current report preparation process.

Pharmacy management stated that because charges were not generated until prescription sales were completed, the compilation of the Filled Prescription Report was delayed to allow patients additional time to purchase prescriptions that were filled before the end of the prior month. Customers had 14 days to purchase prescriptions before the drugs were returned to stock.

Matching charges (sales) with costs of sales (cost) is a basic accounting principle. A consistent cut-off date for compiling financial information affecting inventory would ensure that comparable revenue and expense data is obtained.

> ### Management Corrective Action:
>
> Pharmacy management will establish one month end closing date for all Outpatient Pharmacy financial reports to ensure that drug charges and expenses are from the same accounting period.

2. **Completeness of Inventory Adjustment Data**

   Cost data used to adjust the Pharmacy inventory balance on the Medical Center financial statements was not complete.

   AMAS reviewed the July 2010 Outpatient Pharmacy Filled Prescription Report (Report) to evaluate content and data completeness. The report included detailed information about individual prescriptions dispensed, including the drug cost and the amount charged to the customer. We noted that the Report included a number of entries that referenced the prescription charge, but the cost field was left blank.

   To determine the potential impact created by missing data, we obtained the December 2010 and January 2011 Reports and extracted the line items without cost data for focused review.   The results of our analysis are summarized in the schedule below.

UCSDMC Outpatient Pharmacy
Filled Prescriptions Without Costs for Sampled Months in 2010

	Pharmacy	January Rx Count	Charges	July Rx Count	Charges	December Rx Count	Charges
1	Hillcrest Outpatient	1	$0	11	$902	6	$737
2	Internal Medicine Group	1	94	2	31	0	0
3	Mail Order	6	666	1	74	1	215
4	Moores Cancer Center Outpatient	7	31,595	17	105,558	14	100,244
5	Medical Offices South	1	192	7	658	4	663
6	Medicine Group	12	1,708	7	980	7	1,190
7	Perlman	0	0	7	512	0	0
	Total	28	$34,255	52	$108,715	32	$103,048

The table identifies that each of the seven Outpatient Pharmacies reported sales with no related costs, but the MCC Outpatient Pharmacy realized the highest dollar impact.

While analyzing the data we also observed that the cost data for drop shipped drugs appeared to be eliminated during the PCSI system drug price update process. As a result, for the affected transactions, sales were correctly recorded in the period they occurred. However, the cost of items removed from inventory was understated, increasing the inventory value included on the financial statements. Although the inventory value was adjusted when the semi-annual physical inventory counts were performed, interim balances were incorrect.

We also noted a second miscalculation of cost data that occurred in the MCC Infusion Center (IC) Pharmacy. When Pharmacy management reviewed the July 2010 Epic Cost of Sales Report, they noticed that the Epic cost data was significantly understated for a number of drugs. Management corrected cost data in the system when the problem was discovered. However, an adjustment was not submitted to Finance to correct the cost data provided for the previous month. As a result, the cost of IC Pharmacy filled prescriptions for June 2010 was understated by $24,443.

Because it would not be feasible to maintain a perpetual inventory, continual monitoring of suspect or missing data, and the use of system price dictionaries are critical to ensure that the inventory balance reported in the Medical Center financial statements is as accurate as possible. Collaboration with Finance personnel to request assistance when data anomalies or inaccurate data is noted will assist Pharmacy with ensuring that appropriate inventory adjustments are submitted.

Management Corrective Actions:

Pharmacy management will:

1. Require that the Filled Prescription Report data be reviewed to ensure that product costs are recorded for all prescriptions.

2. Manually verify that drop ship product costs are reinserted in Pharmacy system price lists.

3. Report all price adjustments that affect the cost of sales calculation to Finance.

4. Document standard cost of sales error correction procedures.

3. Unrecorded Charges

The Outpatient Pharmacies did not record charges for all prescriptions dispensed.

We noted that Outpatient Pharmacies reported the drug cost, but did not record the charges for prescriptions filled for patients approved for a charity care write-off.

In addition patient prescription charges were suspended pending an approved Medi-Cal[9] Treatment Authorization Request (TAR) and were not reported to Finance. Pharmacy management indicated that because TAR approvals typically take several months to process, payment was considered uncertain and it appeared reasonable to exclude those charges from revenue.

All prescription charges should be reported in the month dispensed at retail rates, and include the associated cost to ensure that all revenue is captured, and all dispensed products are recorded at cost in the inventory calculations.

> **Management Corrective Action:**
>
> Pharmacy management will report all drug charges to Finance, regardless of payer classification.

D.   Cardinal Assist Program Oversight

Oversight of Cardinal Assist Program invoices was sporadic; and the cost effectiveness of the program in general had not been documented.

The Hillcrest and Thornton Inpatient Pharmacies implemented the Cardinal Assist Program (Cardinal Assist) to reduce drug logistics costs. Thornton has been participating in the Program for over three years, and Hillcrest implemented it in fall 2010. The purpose of the Program is to reduce Pharmacist effort required to prepare individual doses and verify drug shipments. Drugs purchased through this Program arrive pre-packaged by dose, in a specific tote for each Pyxis automated dispensing machine (ADM). Drugs received are then verified by a Pharmacy Technician while being loaded into ADMs. As a result, Pharmacists' do not need to spend time receiving drug shipments and then preparing patient ready doses for the Cardinal Assist locations. In October 2010, the Hillcrest Inpatient Pharmacy Cardinal Assist inventory was valued at $15.3K (1%) of the total Pharmacy inventory of $1.664M.

Each Pharmacy using Cardinal Assist is charged a subscription fee of $1,500 per month. The Thornton Pharmacy is charged an additional $1,500 per month for early morning delivery. In addition, there are "Line" and "Dose" service fees on each invoice. Line fees

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[9] Medi-Cal is the common title for the State of California Medicaid program.

are charged for listing the drug on the invoice. Dose fees are charged for repackaging, but are not charged on Manufacture Unit of Sale (MUS) items.

Each drug ordered from the Cardinal Assist formulary was billed to Pharmacy when 10% of a container was delivered. At that point, the drug became part of Pharmacy's inventory, but it continued to be stored at Cardinal until additional orders were filled. Therefore, Pharmacy staff managed off-site inventory by tracking drugs that were purchased but not yet delivered.

In addition, drugs on the Cardinal Assist formulary, and/or already purchased by Inpatient Pharmacy were not guaranteed for delivery. In January 2011, staff was following up on a list of 27 drugs, valued at $1,614, that were purchased by Hillcrest Inpatient Pharmacy and held in Cardinal Assist inventory, but were not available for delivery. When Cardinal Assist failed to deliver purchased drugs, Pharmacists filled ADMs orders with drugs from the Inpatient Pharmacy stock, which negated a portion of the efficiency realized. At Hillcrest, one Pharmacy administrator spent approximately one hour each day on Cardinal Assist issues.

Cardinal Assist has, at times, substituted the drug ordered with an alternative drug without informing Pharmacy of the substitution, or bar-coding the substituted drugs for easy identification during the ADM stocking process. Drug substitutions not identified by Pharmacy staff may put patients at risk.

The pre-payment invoice review process was complicated by the large number of invoices generated each week, and the need to reconcile inventory receipts to charges, and to validate the purchased inventory remaining in off-site Cardinal facilities. Due to staff resource constraints, the invoice review process was only completed one or two times a year. As a result, weekly invoices were typically approved for payment without being traced to daily shipment documents. In addition, because drugs stored at Cardinal Assist were not on-site when physical inventories were counted, Pharmacy staff input the list of drugs purchased but not delivered into Cardinal.com and obtained a current value for that inventory, which was then reported to Finance along with the on-site physical inventory count.

Considering the complexity of Cardinal Assist management processes, a cost benefit analysis should be performed to provide assurance to Pharmacy management that the Program results in an overall savings.

Management Corrective Action:

Pharmacy management is in the process of transitioning to a new electronic drug delivery system that will help to reduce dispensing errors. In the interim, oversight of Cardinal Assist expenditures will be increased by reconciling invoices more frequently.

E.   Inpatient Pharmacy Operations

1. Combined Financial Reporting

The Hillcrest Infusion Center and Hillcrest Inpatient Pharmacy operating and inventory costs were combined.

Pharmacy operated two infusion centers (IC), one at the MCC and another at Hillcrest. For inventory purposes the IC at MCC is a stand-alone Pharmacy. Hillcrest IC financial data has been combined with the Hillcrest Inpatient Pharmacy.

Although IC operations were similar in both locations, the current arrangement precluded the comparison of one IC to the other. Because drug expenses for Hillcrest Inpatient and Hillcrest IC were comingled, we could not determine whether Hillcrest IC inventory was effectively managed. If Hillcrest IC were established as a separate cost center, operations could be monitored and compared to the MCC IC.

> **Management Corrective Action:**
>
> Pharmacy Management will work with Medical Center Finance to establish the Hillcrest IC as a standalone cost center.

2. Cost Allocation Process

The Hillcrest Inpatient Pharmacy purchased drugs for the Compounding Pharmacy (CIVA), but did not allocate CIVA product costs to Hillcrest Medical Center and Thornton Hospital.

The Central IV Admixture[10] service (CIVA) is the UCSDHS Compounding Pharmacy. CIVA is co-located with Home Care Pharmacy and provides drug compounding services for the UCSDHS hospitals and clinics.

CIVA purchased certain drugs and supplies from a separate Cardinal account, which were delivered directly to CIVA facilities. However, the majority of CIVA drugs were purchased by the Inpatient Pharmacy and transferred to CIVA. Prior to June 2010, CIVA product costs were not allocated between Hillcrest and Thornton Medical Centers.

During audit fieldwork, Pharmacy Administration began allocating CIVA product costs to the hospitals. However, we reviewed the allocations made for the period June through November 2010 and noted that allocations were calculated based on a general

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[10] The word intravenous simply means "within a vein". The drug added to an IV solution is called additive and the completed preparation is called IV admixture.

percentage of activity with no supporting data. The procedure was not documented, and had not been approved by Pharmacy management.

To ensure that product costs are appropriately allocated to the location that will generate the associated charges when the product is dispensed, the allocation process should be standardized, and included as part of the monthly financial closing process.

Management Corrective Actions:

Pharmacy management will:

1. Develop and document a standard CIVA cost allocation methodology based on the products provided to each hospital. The methodology will be reviewed annually to determine if factors on which it is based are relevant.

2. Require that the CIVA cost allocation be completed as part of the monthly financial reporting package and reviewed by Pharmacy management.

F. **Outpatient Pharmacy Separation of Duties and Cash Controls**

Deposits were processed by the same staff member responsible for managing Outpatient Pharmacy charges. Checks were not processed in compliance with cashiering practices (BUS 49).

Check payments were processed for deposit by a Pharmacy staff member who was also responsible for completing follow up with payers on pending accounts receivable balances. The same staff member picked up checks received in Hillcrest Pharmacy Administration and transported them, without an escort to another Pharmacy office to prepare the deposit.

This practice does not comply with BUS 49 segregation of duties and security requirements.

Management Corrective Actions:

Pharmacy management will:

1. Require that two staff members complete cash counts and process deposits.

2. Require that staff call for a Security escort when transporting cash from Pharmacy Administration to the Outpatient Pharmacy business office.

G. **Password Sharing**

Cardinal.com and other business application passwords were shared at various Pharmacy locations.

AMAS reviewed Cardinal.com access profiles and found that 19 users had access rights to place drug orders. Four of those users have separated from the University, but had not been removed from the system. Management stated that one additional staff member had access rights to completed drug orders, but that individual did not have an access profile on Cardinal.com

A common profile and password in Cardinal.com was actively shared by an unknown number of individuals in order to allow a Pharmacy Buyer to review pending orders. We also observed that a common password to a statistical application used in the recharge process was shared by staff in Pharmacy Administration.

Password sharing is against policy and it negates controls. Orders may be placed by unauthorized personnel with unintended consequences. For example, the Thornton Inpatient Pharmacy had one leukemia drug in its inventory worth approximately $70,000 will likely expire in 2013 before it is used. Pharmacy management could not determine who placed this order to determine the cause.

Access controls are fundamental to ensuring user identification and accountability all systems. Shared passwords can result in unauthorized transactions.

Management Corrective Actions:

Pharmacy management will:

1. Work with Cardinal.com users and re-set the passwords for all users with the exception of Pharmacy Administration staff.

2. Remind all staff that MCP prohibits password sharing, and encourage staff to periodically change their passwords.

3. Include a step in the staff separation process to notify UCSDHS and Cardinal.com system administrators to remove system access.

4. Establish separate passwords for all critical systems to be sure that key personnel and their alternates have their own individual access rights.

5. Work with Cardinal to remove dedicated Pharmacy terminals if they are not in use, or to change the default passwords on those terminals.

H.   **Freezer Alarm Monitoring**

The contractor responsible for monitoring refrigerator alarms failed to timely notify Pharmacy management when the MCC Pharmacy refrigeration unit failed.

The safeguarding of Pharmacy drug inventories is essential. Because storing drugs at appropriate temperatures is imperative[11], alarms are installed on refrigeration units and monitored 24 hours per day and seven days per week by a contractor to ensure that appropriate temperatures are maintained.

During a site visit to the MCC Pharmacy, AMAS was advised that during the prior evening, a leak had occurred on the floor above the Pharmacy, which shorted out a refrigeration unit. The refrigeration unit alarmed; however, the contractor failed to timely notify Medical Center Facilities Management and Pharmacy personnel. As a result, Pharmacy was concerned that drugs had spoiled.

Pharmacy had established a Standard Operating Procedure (SOP) that included specific refrigeration unit monitoring procedures and instructions on the steps to take if alarms were activated and temperature limits were exceeded. Staff had received training on the procedures. However, a periodic test of the entire process was not performed. AMAS understand that alarm testing was not performed periodically at any of the Pharmacy locations.

A periodic full cycle test would uncover any deficiencies and give management confidence that backup systems will work as intended.

Management Corrective Action:

Pharmacy management will periodically test the new AwarePoint alarm notification process to ensure that the designated Pharmacy personnel receive notification.

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11 JCAHO, Standard MM.2.20 Medications are stored under necessary conditions to ensure stability.

Attachment A
UCSDMC Pharmacy Inventory Movement

Inventory Source	Pharmacy Acquisition	Inventory Movement	Pharmacy Order Fill	Dispense

Legend:
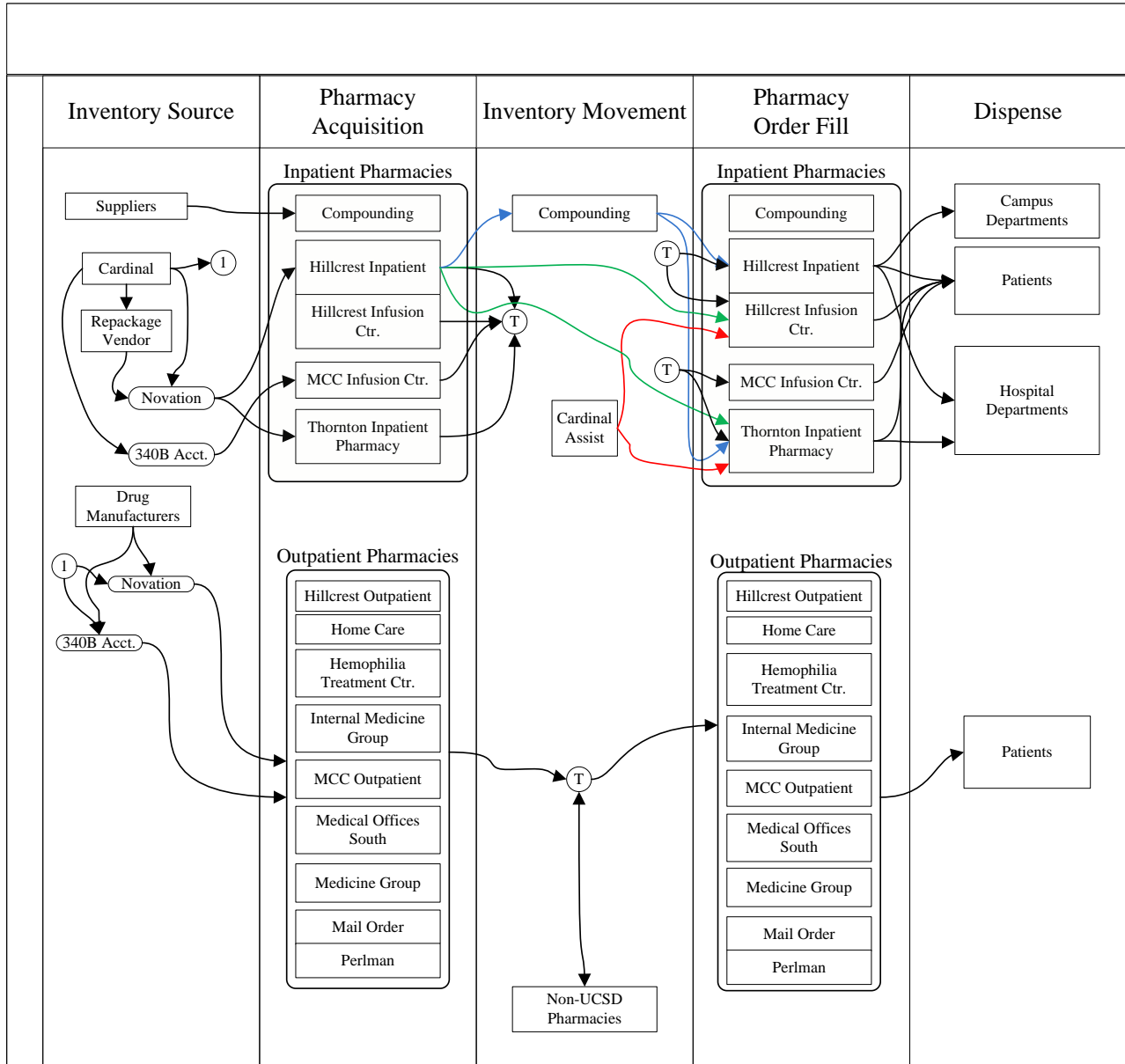
1 — On-page connector.

T — Transfers between pharmacies.

→ (blue) Compound pharmacy (CIVA) drug flows.

→ (red) Infusion Center (IC) drugs purchased by Hillcrest pharmacy as per regular resupply process.

→ (green) CardinalAssist drugs arrive daily per orders place by Pyxis machines.

→ (black) Pharmacy drug distribution routes.

Attachment B
UCSDMC Outpatient Pharmacy Reporting Process
Data Flow Schematic

Day	Process	Observation

Month One

1
2

Month One Prescription Processing - During the month, orders are received and prescriptons are processed.

25
26
27
28
- -

Subsequent Month

1 Budget Reports
2
3
4
5 Finance reports
6
7 Patients continue to pick up prescriptions filled in Month One. As they do, the reports listing the data below are constantly changing.
8
9
10
11
12
13 Cost of Sales Reports
14

See Report Finding
C.1 Timing Differences - Revenue and Expense Reporting

Month One Financial Report		
Prescription Component	Cost	Charge
∑Drop Ship Drugs	☒	✓
Prescription Types		
∑Cash Rx	✓	✓
∑Payer Rx	✓	✓
∑Charity Rx	✓	☒
∑Medicare Rx	✓	☒
∑Medical Rx	✓	☒
∑TAR needed Rx	✓	☒

See Report Finding
C.2 Completeness of Inventory Adjustment Data

See Report Finding
C.3 Unrecorded Charges

Key:
☒   Not included in reports
✓   Included in reports