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Angela M. Darragh, CPA, CFE, CISA, Director

May 21, 2014

Mr. Don Burnette
Clark County Manager
500 South Grand Central Parkway, 6th Floor
Las Vegas, Nevada 89106

Dear Mr. Burnette:

Pursuant to Audit Department policy, we performed a follow-up audit of the Surgery Vendors audit dated August 28, 2012. We obtained supporting documentation and performed detail testing to assess the adequacy of the corrective actions taken. The procedures we performed were focused on determining whether appropriate corrective action was taken on findings included in the original audit report.

We selected the period of August through October 2013 and reviewed 25 records (25% of the population) for the following:

- Documentation of implants
- Accuracy of implant logs
- Verification that implant logs were scanned into the electronic medical record
- Ensured that a compliant billing process was in place and that charges placed on patient accounts were accurate

We also performed testing on 1,243 (100%) orthopedic and spine implant purchases from the same vendor for the testing period to determine if prices were consistent. Our last day of fieldwork was February 5, 2014.

Of three findings in the original report, one was partially corrected and two were not corrected. University Medical Center continues to face challenges with the documentation of implants and charging implants to the patients' accounts.

The auditor's role in follow-up engagements is to compile corrective actions taken from effected Department/Division management, assess whether these responses are adequate or not adequate to correct reported deficiencies, and relay to management. It is the Department/Division management's responsibility to decide if any appropriate action should be taken in response to reported audit findings. It is also their responsibility to assume the risk by not correcting a reported condition because of cost or other consideration.

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We conducted the performance audit in accordance with generally accepted government auditing standards. Those standards required that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Sincerely,

Angela M. Darragh, CPA
Audit Director

AUDIT DEPARTMENT

Audit Report

University Medical Center Surgery Vendors Follow Up

May 2014

Angela M. Darragh, CPA, CISA, CFE
Audit Director

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BACKGROUND

University Medical Center performs various surgical procedures that involve the installation of medical device implants. For fiscal year 2013, UMC performed 16,756 such procedures in the Surgery Department, with gross revenue of $279,066,937 UMC is required by the Food and Drug Administration to report all deaths and serious injuries related to medical devices, such as implants. Failure to comply can subject UMC to various criminal or civil penalties up to $15,000 per offense and even imprisonment. The Centers for Medicare & Medicaid Services requires Ambulatory Surgery Centers to track implants for one year after the procedure.

In order to determine compliance with implant provisions in various regulations, we performed an audit of Surgery Vendors and issued a report on August 28, 2012. The original audit covered the period from July 1, 2011, through December 31, 2011. The objectives of the audit were as follows:

> *"To determine the effectiveness of documenting implants installed on the implant log and the accuracy of the implant log as required by the Food and Drug Administration. Also, to determine if the patients were properly charged for the implants installed. Additionally, to evaluate whether an implant tracking database was utilized as required by the Joint Commission Standards for tissues".*

The results of the original audit identified several areas that needed corrective action:

- There were cost variances with equal implant items of the same vendor.
- Charges for implants were not captured on the patient's account.
- Implant logs which were used, were inaccurate in documenting the implants installed. In some cases, implant logs were not used to document implants installed. Also, an implant database was not used to track implants from the supplier to the patient and vice versa.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of this audit is to determine whether corrective action was taken on the significant findings included in the *University Medical Center Surgery Vendors* audit report dated August 28, 2012. Our procedures consisted of reviewing the original audit report and

supporting documents, interviews with management and staff, examination of documentation, and performance of detailed tests and analyses.

The Centers for Medicare & Medicaid Services requires Ambulatory Surgery Centers to track implants for one year after the procedure. In order to test compliance with these requirements, we interviewed UMC Materials Management staff to determine if an implant tracking process or database had been established. The Food and Drug Administration (21 CFR Ch. 1), requires UMC to provide accurate documentation for event items implanted in patients. In order to test this, we selected the period of August through October 2013 and reviewed 25 records (25% of the population) for the following:

- Documentation of implants.
- Accuracy of implant logs.
- Verification that implant logs were scanned into the electronic medical record.
- Ensured that a compliant billing process was in place and that charges placed on patient accounts were accurate.

We also performed testing on 1,243 (100%) orthopedic and spine implant purchases from the same vendor for the testing period to determine if prices were consistent.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

RESULTS IN BRIEF

University Medical Center continues to face challenges with the documentation of implants and accurately charging patients. We found significant error rates related to appropriate implant charge capture and appropriate implant documentation. As a result, UMC continues to operate at-risk for negative findings from external reviewers.

Each finding includes a ranking of risk based on the risk assessment that takes into consideration the circumstances of the current condition including compensating controls and the potential impact on reputation and customer confidence, safety and health, finances, productivity, and the possibility of fines or legal penalties.

Implementation Rate

Status of Findings	Number of Findings	% of Total
Implemented	0	0.0%
Not Implemented	2	67%
Other	1	33%
Total	3	100.0%

DETAILED RESULTS

All Charges Not Captured (HIGH)

The initial audit found that 15 of 76 (20%) patients were not accurately charged for implants. During our follow up testing of 25 patient accounts (25% of the population), we found 9 patients were charged incorrectly or could not be verified (36% of the sample), as follows:

- In one instance the patient was overcharged by $10,855 due to an erroneous charge for a wasted item.
- In eight instances charges to the patients' accounts could not be verified as accurate due to outdated implant prices within the Star system used for pricing.

Recommendation

1. Properly document wasted items in the medical record.

2. Ensure accurate corrections to the implant inventory are performed within the Star system when applicable.

3. Implement procedures to verify that patient accounts are correctly charged for implants.

4. Correct the errors on patients' accounts reviewed during the audit and re-bill as necessary.

Insufficient Implant Documentation (MEDIUM)

The previous audit identified 5 out of 71 records (7%) had no implant logs and 11 out of 71 (15%) surgical records were incomplete or had errors related to implant logs. We tested 25 patient accounts (25% of the population) and found the following:

1. Two records (8% of the sample) showed no evidence of implant logs, either in the surgery record or within the electronic medical record system.

2. In one record (4% of the sample), the implant log in the surgery record was not the same implant log scanned into the electronic medical record system.

Additionally, the previous audit found that UMC was not tracking implants by an electronic database and recommended the implementation of such a system. We found that an electronic database was researched but not approved for purchase.

Recommendation

1. Ensure that all patients with implants have an accurate implant log documented and scanned.

2. Install an electronic database for the tracking of implants.

INTEROFFICE MEMORANDUM

TO:	ANGELA DARRAGH, DIRECTOR, CLARK COUNTY, AUDIT DEPARTMENT RANI GILL, UMC Corporate Compliance GREGG FUSTO, UMC CNO
FROM:	JOHN LISTON, UMC PURCHASING STANLEY SHELVER, UMC SURGERY
SUBJECT:	MANAGEMENT RESPONSE TO SURGERY VENDOR FOLLOW UP AUDIT
DATE:	MAY 16, 2014

We respectfully offer the following in response to the Clark County Audit Department's Controls audit dated 4/11, 2014.

Initial finding: All Charges Not Captured (HIGH)

A. The finding that cited there was an overcharge of $10,855 "due to an erroneous charge for a wasted item" was captured and noted in our audit system. The charge sheet that was received from the operating room did not follow the naming convention for wasted charges; it did not have a "W" in the left hand column meaning this item(s) was/were wasted.

A few days later when the Charge Auditor presented the surgery charge staff with the same vendor sheet, it had a "W" in the left margin. The surgery staff took immediate steps to remove the charges from that patient's record.

B. In 8 instances, charges to the patient's accounts could not be verified as accurate due to outdated implant prices within the Star system used for pricing.

Response: input corrective action to resolve the problem.

A. Based on this event, the surgery leadership initiated the following changes:

- The two staff who input charges were informed that if a vendor indicates the words "50% off:", this is the signal that the implants were wasted.
- The charge nurses and the circulating nurses were informed of the wording change.
- The material management / supply staff were informed of the wording change.
- If the wording is changed, there still needs to be a "W" marked in the left margin to indicate this item(s) were wasted.

B. There are approximately 10,000 line items in the surgery charge master. Throughout the year, vendors raise prices once and occasionally, twice per year.

- Every effort is made to stay current with price adjustments and increases. Prices are always updated at time of purchase or bill only invoice.

- There may be some outdates that are discovered. If / when that happens, they will be immediately adjusted.

Initial finding: Insufficient Implant Documentation (Medium)

There were 2 citations in this category:

1. Two records showed no evidence of implant logs, either in the surgery record or within the electronic medical record system.
2. In one record, the implant log in the surgery record was not the same implant log scanned into the electronic medical record system.

Response: input corrective action to resolve the problem.

1. To initiate change, the surgery leadership has now initiated a 100% review of each chart for both charges and accuracy of complete data. This includes the date, time, and signatures of all providers.

    a. This review process should also catch implant log matching: if there are certain procedures then the corresponding implant log sheet should be prepared.

2. In the event that the surgery record does not match the implant log, there are 2 sheets: one is provided by the vendor and one sheet for the implant log book.

    a. The vendor sheet should be used for charging purposes.

    b. The other document is used to complete the implant log.

Responses to the Recommendations:

1. Ensure that all patients with implants have an accurate implant log documented and scanned.

    a. It is the goal for records management that there is a 100% charge capture and a 100% medical record / implant log for each patient.

2. Install an electronic database for the tracking of implants.

    a. For the past 6 months, price quotes have been obtained, vendors interviewed, and a selection made to have the Pyxis system leased to track implants. The lease cost was $177,000.

    b. The system would track the order, the implant would be bar-coded when it arrived at the receiving dock, it would be logged into the surgery Pyxis, there would be storage data of the implant(s), and then it would be scanned as it was used in each operating room.

    c. The cost of the system has come at a time when UMC has financial challenges and is in the process of significant lay-offs. As a result, this system cannot be implemented. We will remain on a paper, log book, and 3-ring binder system.

UNIVERSITY MEDICAL CENTER
Surgery Vendors Follow-Up
Findings, Recommendations, and Corrective Actions Status
As of May 2014

AUDIT DEPARTMENT
Angela Darragh, CPA, CFE, CISA, CHC
Director

Original Report Issuance Date: August 2012

Finding	Recommendation(s)	Corrective Actions Status
1 - All Charges Not Captured (HIGH)		**NOT IMPLEMENTED**
During our original implant testing, we found charges for some devices were not captured on the patient's account. Fifteen of the 76 implant purchases, or 20%, missed some of the implant items on the PO. One account did not include any items on the purchase order.	Develop a system to assure all charges are documented on the various OR charge sheets and a reconciliation process implemented for posting of charges on the patient's account. Prior to data entry of surgical charges, a chart review should be performed. This would entail verifying that start and stop times are recorded, and perfusion documents, charge documents and implant logs are all present.	During our follow up testing of 25 patient accounts (25% of the population), we found 9 patients were charged incorrectly or could not be verified (36% of the sample), as follows: • In one instance the patient was overcharged by $10,855 due to an erroneous charge for a wasted item. • In 8 instances charges to the patients' accounts could not be verified as accurate due to outdated implant prices within the Star system used for pricing. **Recommendation:** 1. Properly document wasted items in the medical record. 2. Ensure accurate corrections to the implant inventory are performed within the Star system when applicable. 3. Implement procedures to verify that patient accounts are correctly charged for implants. 4. Correct the errors on patients' accounts reviewed during the audit and re-bill as necessary. **Response:** A. Based on this event, surgery leadership initiated the following changes: The two staff who input charges were informed that if a vendor indicates the words "50% off:", this Is the signal that the implants were wasted. The charge nurses and the circulating nurses were informed of the wording change. The material management / supply staff were informed of the wording change. If the wording Is changed, there still needs to be a "w" marked In the left margin to indicate this Item(s) was wasted.

Finding	Recommendation(s)	Corrective Actions Status
		B. There are approximately 10,000 line Items In the surgery charge master. Throughout the year, vendors raise prices once and occasionally, twice per year. Every effort is made to stay current with price adjustments and increases. Prices are always updated at time of purchase or bill only invoice. There may be some outdated that are discovered. If and when that happens, they will be immediately adjusted.
2 - Insufficient Implant Documentation (MEDIUM)		**NOT IMPLEMENTED**
Our original testing of the perioperative nursing records found five records out of 71, or 7%, had no logs and 11 records out of 71, or 15%, were incomplete or had errors. Surgery uses a manual database to track implants. There is currently no consistent process in place to assure the implants used are recorded in the perioperative report or attached to an implant log that should be attached to the perioperative report.	Assign staff to create a database to track implants electronically. Require that implants used in procedures are documented in the patient's medical records and put a reconciliation system in place to assure that documentation is completed.	To follow-up, we tested 25 patient accounts (25% of the population) and found the following: 1. Two records (8% of the sample) showed no evidence of implant logs, either in the surgery record or within the electronic medical record system. 2 . In one record (4% of the sample), the implant log in the surgery record was not the same implant log scanned into the electronic medical record system. An electronic database was researched but not approved for purchase. **Recommendation:** 1. Ensure that all patients with implants have an accurate implant log documented and scanned. 2. Install an electronic database for the tracking of implants. **Response:** 1. To initiate change, the surgery leadership has now initiated a 100% review of each chart for both charges and accuracy of complete data. This includes the date, time, and signatures of all providers. a. This review process should also catch implant log matching: if there are certain procedures then the corresponding implant log sheet should be prepared.

Finding	Recommendation(s)	Corrective Actions Status
3 - Vendor Contracts and Pricing (Low)		**OTHER**
The hospital has a number of signed contracts with some spinal implant vendors, letters of commitment based on group purchasing organization prices for others, and, in some cases, only a verbal agreement. UMC does not enter these implant items in the purchasing system to be reused on future purchase orders, and no one from surgery verifies the pricing on the vendor packing slip. A cursory check for correct prices is done when the vendor's packing slip is received prior to creation of the PO. However, with the volume of implant items, it is difficult to do this on a manual basis. Also, the hospital was charged freight on some of the implant surgical procedures due to the lack of specific vendor contracts and a 2008 guideline for freight.	Develop contracts for all implant vendors for best and consistent prices on implantables. The new contracts should consider cost of the implants versus the reimbursement received from the hospital's managed care contracts. Also, the contracts should have language that addresses freight charges. Assign a material number to the implant items and enter into the purchasing system so that the same item can be selected for future purchase orders, allowing prices to be verified electronically.	Our follow-up testing found in 7 instances (0.56% of the population), that price differences for the same implant device within the same vendor occurred. However, the low error rate of 0.56% was considered immaterial. Therefore, the finding was classified as "other" status. We discussed our original recommendation with the Director of Materials Management and the Purchasing Manager.