AUDIT DEPARTMENT

Audit Report

University Medical Center 340B Contracted Pharmacy Services

February 2013

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

AUDIT COMMITTEE:
Commissioner Steve Sisolak
Commissioner Chris Giunchigliani
Commissioner Lawrence Weekly

Audit Department

500 S Grand Central Pkwy Ste 5006 • PO Box 551120 • Las Vegas NV 89155-1120
(702) 455-3269 • Fax (702) 455-3893

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

February 21, 2013

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

Dear Mr. Burnette:

We recently completed an audit of the University Medical Center 340B Pricing Program with Walgreens. The 340B Pricing Program with Walgreens was selected as an audit area based on the risk to the hospital if there is non-compliance with the Federal regulations pertaining to institutes that qualify for 340B pricing. The audit covers the period of July 1, 2011 through January 31, 2012. The objectives of the audit are to:

- Determine whether the program implementation is in accordance with provisions of laws and regulations. This Includes UMC's two Outpatient Pharmacies.
- Evaluate the effectiveness of procedures in place over procurement, inventory, distribution, dispensing and billing of 340B drugs.
- Determine the profitability of this agreement with Walgreens.

In order to achieve our objectives, we examined pharmacy prescription queries from both Walgreens and UMC, documentation of federal regulations, and policies and procedures. We also interviewed management and staff.

We identified minor diversion and deficiency issues after reviewing the Walgreens agreement and data. We found the Lied Outpatient Pharmacy and the Outpatient Pharmacy were compliant with the 340B requirements. Further, the procedures in place over procurement, inventory, distribution, dispensing and billing of 340B drugs appear adequate. Based on our analysis of payments and income from the Walgreens contract, during the period of July 2011 through January 2012, UMC received an average of almost $200,000 a month for patients that chose to fill prescriptions at Walgreens.

A draft report was provided to the Acting Director of Pharmaceutical Services, and her response is included. We appreciate the cooperation and assistance of UMC Pharmaceutical Services staff.

Sincerely,

/s/ Angela Darragh

Angela M. Darragh, CPA
Audit Director

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TABLE OF CONTENTS

BACKGROUND 1

OBJECTIVES, SCOPE, AND METHODOLOGY 1

RESULTS IN BRIEF 2

DETAILED RESULTS 3

- **Prescriptions Filled for Non UMC Patients at 340B Prices** 3
- **Errors in Walgreens Provider Data** 4

Appendix A: Management Response Letter 6

BACKGROUND

Eligible covered entities may participate in the federal 340B Drug Pricing Program to achieve significant savings on outpatient drug expenses. The 340B Program requires drug manufacturers to provide covered outpatient drugs to covered entities at or below statutorily defined discount prices. The 340B Drug Pricing Program is codified as Section 340B of the Public Health Service Act. The Affordable Care Act expanded access to certain safety net providers including qualifying disproportionate share hospitals. There are two Program prohibitions-diversion and duplicate discounts. Diversion occurs when dispensing drugs to individuals who are not patients of the covered entity or dispensing drugs in an area that is not covered. Duplicate discount refers to receiving a 340B discount and a Medicaid rebate on the same drug. The Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs is the agency that administers the 340B Program.

University Medical Center of Southern Nevada (UMC) qualifies as a covered entity for 340B Drug Pricing Program. UMC meets the specified disproportionate share adjustment percentage outlined in the legislation for the most recent cost reporting period. UMC maintains an agreement with Walgreens Co. (Walgreens) to provide contract pharmacy services to UMC patients, which is allowed by 340B Program rules. The agreement expresses that UMC will purchase prescriptions at a reduced cost through the 340B Drug Pricing Program for participating Walgreens locations. Walgreens provides the 340B drug dispensing and inventory maintenance services, processes the prescriptions, and bills the patient's private insurer at the contracted rate for each 340B drug. Upon confirmation that the private insurer has paid Walgreens at the contracted rate for the prescription, Walgreens retains a fixed dollar amount plus a percentage of the reimbursement based upon the contacted rate received.

For purposes of this audit a "prescriber" can be a physician, an Advance Practitioner of Nursing (APN) or a Physician's Assistant (PA).

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of the audit are to:

- Determine whether the program implementation is in accordance with provisions of laws and regulations.

- Evaluate the effectiveness of procedures in place over procurement, inventory, distribution, dispensing and billing of 340B drugs.
- Determine the profitability of this agreement with Walgreens.

Fieldwork concluded on December 7, 2012. Our procedures included interviews of Pharmacy and Medical Services departmental staff, examination of Walgreen data, UMC patient accounts and supporting documentation. We downloaded prescription data, including 11,360 prescriptions for the period of July 2011 through January 2012 and compared the patients on other UMC systems to verify they appropriately received 340B pricing. We also obtained the list of physicians used by Walgreens to verify 340B applicability and ensured each was a UMC employee. We followed up on any discrepancies to determine whether they were properly given 340B pricing. Finally, we analyzed revenue from Walgreens and payments for drug costs to determine whether UMC was benefiting from the relationship.

We conducted this performance audit in accordance with generally accepted government auditing standards except for the standard relating to personal independence. An auditor working on the engagement has an immediate family member in County management. Generally accepted government auditing 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 and that any threats to independence were appropriately mitigated through audit supervision.

RESULTS IN BRIEF

We identified minor diversion and deficiency issues after reviewing the Walgreens agreement and data. We found the Lied Outpatient Pharmacy and the Outpatient Pharmacy were compliant with the 340B requirements. Further, the procedures in place over procurement, inventory, distribution, dispensing and billing of 340B drugs appear adequate. Based on our analysis of payments and income from the Walgreens contract, during the period of July 2011 through January 2012, UMC received an average of almost $200,000 a month for patients that chose to fill prescriptions at Walgreens.

DETAILED RESULTS

Prescriptions Filled for Non UMC Patients at 340B Prices

During our testing, we found that electronic prescriptions were being filled at Walgreens under the 340B program. However, UMC does not currently have the capability to submit prescriptions electronically. As a result, we found 2,163 prescriptions that were from patients visiting non-UMC clinics. The estimated 340B cost for those prescriptions totaled $96,736. Each of these will need to be reviewed and potentially reversed from Walgreens 340B pricing. Samples of 15 questionable prescriptions were sent to Walgreens for address verification of the scripts. All were identified as originating from non-UMC clinics.

Only prescriptions from a UMC facility or (ADAP) Aids Drug Assistance Program/Ryan White grant drugs can be filled at Walgreens under the 340B drug prices. Some prescribers from the original list UMC supplied to Walgreens were no longer working at a UMC facility or worked at other non-UMC clinics. When the agreement was signed it was prescriber specific, not UMC clinic specific. When physicians left UMC, they were not removed from Walgreen's list of qualified providers.

Providing 340B priced drugs to non-UMC patients constitutes diversion, which is a 340B violation. The Healthcare reform law provides penalties that can be levied against a covered entity that violates the statutory prohibition against diverting 340B drugs to individuals who are not patients of the covered entity. Specifically, the covered entity may be liable to the manufacturer for the amount equal to the reduction in the price of the diverted drug and the amount of interest due.

Recommendation

The list of potential prescriptions of non-UMC patients was sent to Walgreens in November 2012 to be researched and reversed if from a non-UMC clinic. In June 2012, a Walgreens barcode was added to UMC scripts to help identify whether the prescription filled at Walgreens is for a UMC patient.

We recommend that the Director of Pharmacy assign staff to periodically review the physicians in the Walgreens database to assure compliance with the 340B regulations, as UMC is ultimately responsible as the covered entity.

Errors in Walgreens Provider Data

While testing the Walgreens database of prescriptions filled under the 340B program, we noted the following discrepancies in the data maintained by Walgreens to identify UMC patients eligible for 340B pricing:

- Three Drug Enforcement Agency (DEA) numbers shown on the Walgreens report belong to physicians not reported to Walgreens.
- A total of thirteen individuals have the same DEA number. This is UMC's DEA number that is used for Residents when they write prescriptions.
- Two Nurse Practitioners (APNs) shown with DEA numbers in fact do not have a DEA number. The number reported by Walgreens belongs to physicians who do not practice at UMC.
- There are three physicians that have two DEA numbers each.
- Four physicians on the Walgreens list are associated with a DEA number belonging to a physician that does not work at UMC.
- NPI numbers for 2 physicians were incorrect.
- One Nurse Practitioner displayed a National Provider Identifier (NPI) number belonging to a UMC Quick Care physician.

Prescribers are required to obtain a separate DEA registration for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed by a person. Prescribers are required one registration if they are only prescribing, regardless of the location(s) of where they are prescribing within the same state.

A NPI is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). The NPI is a unique identification number for health care providers. Healthcare providers and organizations must obtain an NPI for use in all HIPAA standard transactions. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes.

These discrepancies appear to be the result of a combination of Walgreens and UMC errors due to a lack of control in the way UMC sends Walgreens the prescriber list. As a result, 66 non-qualifying prescriptions will need to be reversed by Walgreens.

As the covered entity, UMC holds responsibility and accountability for compliance with all requirements of diversion of covered drugs to individuals other than patients of the covered entity. Any prescriptions found to be non-compliant with the 340B requirements must be reversed and any revenue received from Walgreens must be returned.

Recommendation

The issues indentified in this finding were provided to Walgreens in August 2012 and corrected. In September 2012, Walgreens reversed the 66 prescriptions for the non-qualifying prescriptions and this was reflected in the revenue submitted to UMC for that month. We recommend that the Director of Pharmacy periodically review data available from the Walgreens website to assure compliance with the regulations and assure information given to Walgreens is accurate and correct. Also, we recommend that the Director of Pharmacy work with Human Resources and/or Medical Staff to obtain prompt notification of prescriber terminations.

UMC
UNIVERSITY MEDICAL CENTER

INTEROFFICE MEMO

To: Rani Gill, Corporate Compliance Officer
Clark County, Audit Department

From: Mary Staples, PharmD, Acting Director of Pharmaceutical Services

Subject: Response to Walgreen's Audit

Date: February 15, 2013

Thank you for the internal audit draft report that was completed by your department examining the Walgreen's 340b process. We appreciate the work your staff did on this important project which did identify some areas for improvement and identified areas of concern for us.

Finding: Prescriptions from non-UMC providers were being filled at Walgreen's under the 340b program. The list of prescriptions were sent to Walgreen's to be researched and reversed.

Recommendation: Director of Pharmacy to assign staff to review the Walgreen's database to assure compliance with the 340b program.

Response: Management agrees that control of prescriptions needs to be tighter. Additional security of a barcode on UMC prescriptions was added to ensure that prescribers are valid UMC employees and thus, the prescription qualifies for use of 340b inventory. Both the barcode and prescribers NPI must match to UMC data for the prescription to flow through the 340b process. Management agrees to:

- Assign staff to review the Walgreen's database to ensure compliance with 340b program on a regular basis

- Hold quarterly conference calls with Walgreen's to identify and rectify any issues that arise

Finding: Physician database at Walgreen's contained errors with discrepancies in DEA numbers, incorrect NPI numbers and prescribers with more than one DEA number.

Recommendation: Director of Pharmacy to coordinate with HR and Med Staff office to ensure prompt notification of prescriber termination. Director of Pharmacy to assign staff to review the Walgreen's database to assure compliance with the 340b program.

Response: Management agrees that information in Walgreens' database is subject to errors due to frontline staff at Walgreens entering incorrect information. Addition of barcode security to UMC prescriptions will ensure a second check in Walgreens' system to allow the prescription to flow through the 340b process. Management agrees to:

- Assign staff to review UMC physician database in Walgreens' system on a regular basis
- Hold quarterly conference calls with Walgreens to identify and rectify any issues that arise