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BRENDAN KREMER
Chief Administrative Officer
8975

JOHN DICKERSON
Director, Center for Transplantation
8745

***Subject: UC San Diego Health System Center for Transplantation
Audit & Management Advisory Services Project 2014-12***

The final audit report for UC San Diego Health System Center for Transplantation, Audit Report 2014-12 is attached. We would like to thank all Transplant Program and Health System 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. While management corrective actions have been included in the audit report, we may determine that additional audit procedures to validate the actions agreed to or implemented are warranted. We will contact you to schedule a review of the corrective actions, and will advise you when the findings are closed.

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 destroy them at this time.

David Meier
Director
Audit & Management Advisory Services

Attachment

cc: D. Brenner
J. Bruner
L. Donaldson
B. Smith
S. Vacca
P. Viviano

UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

UC San Diego Health System
Center for Transplantation
September 2014

Performed By:

Mareline Godfrey, Auditor
Terri Buchanan, Manager

Approved By:

David Meier, Director

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I. Background

Audit & Management Advisory Services (AMAS) has completed a review of the UC San Diego Health System (UCSDHS) Center for Transplantation (Transplant Center). This report summarizes the results of our review.

The Transplant Center is a nationally recognized multi-organ transplant program that manages a broad spectrum of transplant services¹, including:

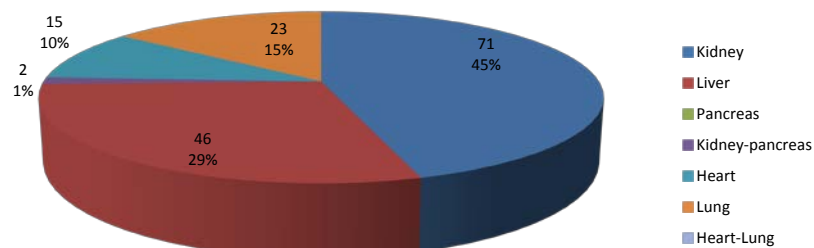
- Adult Kidney Only (AKO), certified in August 1977;
- Adult Pancreas Only (APA), certified in July 1999;
- Adult Liver Only (ALO), certified in August 1997;
- Adult Lung Only (ALO), certified in September 1995;
- Adult Heart Only (AHO), certified in August, 2012;
- Adult Heart-Lung (AHL), certified in August 30, 2012; and
- Ventricular-Assisted Device (VAD)², certified in November 2013

UCSDHS is one of the only two San Diego-based systems and eight California-based systems offering the VAD program.

The following graph provides information about the number of each type of transplant performed by the Transplant Center during calendar year 2013.

Figure 1³

**CASD-TX1 UCSD Medical Center
Organ Transplants Performed in 2013**



¹ All transplant services, with the exception of AHO (see footnote 2) renewed certification in 2008. The AHO and AHL programs were certified in March 1994 and February 1995, respectively. Both programs were subsequently inactivated in 2007, and then reactivated in 2010.

² The VAD Program is approved by The Joint Commission (TJC).

³ Data obtained from OPTN site; OPTN refers to the Transplant Center as the UCSD Medical Center.

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Transplant Center data is reported to regulatory agencies each calendar year based on the date of transplant. In 2013, UCSDHS transplant programs performed a total of 157 transplants, which represented a 17% increase when compared to 2012. The table below shows the number of transplants performed in 2012 and 2013, by organ type.⁴

Organs	2013	2012	Increase (Decrease)
Kidney	71	76	-5
Liver	46	33	13
Pancreas			0
Kidney-pancreas	2	3	-1
Heart	15	5	10
Lung	23	16	7
Heart-Lung		1	-1
All Organs	157	134	23

Transplant Center activities are highly regulated and monitored by a number of national organizations including:

- The Organ Procurement and Transplantation Network (OPTN);
- The United Network for Organ Sharing (UNOS);
- The Scientific Registry of Transplant Recipients (SRTR); and
- The Centers for Medicare and Medicaid Services (CMS).

UNOS holds the federal contract to operate the OPTN, which was established by the 1984 National Organ Transplant Act. Organs are allocated to transplant centers and their candidates in accordance with the UNOS organ allocation policy. Transplant centers are required to submit outcome statistics to UNOS online using the UNOS UNet system. The statistics are used by CMS and other regulatory agencies to assess and report on transplant program performance. These statistics are also made available to the general public through the SRTR.

Effective June 2007, CMS issued new Conditions of Participation for transplant centers primarily relating to performance outcomes, and the quality of transplant programs based on reports to UNOS. At that time, transplant programs were required to submit an application for re-certification to CMS attesting that the Conditions of Participation have been met. Pre-transplant costs recovered through the Medicare Cost Report are typically a major source of revenue for transplant hospitals, and non-compliance with CMS Conditions of Participation may result in the inability to recover those costs. The nature and extent of non-compliance may also impact a hospital's status for participation in Medicare and Medicaid programs. The criteria for the reimbursement of medical services related to organ transplantation are found in Section 1881 (d) of Title XVIII of the Social

⁴ Source: OPTN, Transplants Performed for TXC = CASD-TX1 UCSD Medical Center (Based on OPTN data as of June 13, 2014).

Security Act.

In March 2006, the Transplant Center established a Quality Assurance and Performance Improvement (QAPI) program. Only a handful of transplant centers in the country have implemented similar programs. The QAPI program monitors measurable elements to identify opportunities for improvement. A QAPI Coordinator who reports directly to the Director of Patient Improvement and Patient Safety (PIPS) collaborates with personnel in the various transplant programs to facilitate the collection, validation and reporting of transplant data. The QAPI team meets monthly to discuss reports relating to donor declines, regulatory compliance, and other indicators to assess significant components of performance outcomes and measures.

Since 2006, the Transplant Center has operated with a staff of 45 Full Time Equivalents (FTE), of which 26.5 FTEs report directly to the Transplant Center Administrative Director (Director). Since that time, the following new or improved processes and/or systems have been implemented:

- The transplant patient system flag was initiated in 2006 and a pre-transplant Charge-Hold Process was initiated in 2008 to allow a pre-billing review and allocation of transplant service charges to the appropriate account.
- Improved time reporting tools for Medical Director administrative time and staff work hours.
- Deployment of the TeleResults⁵ system to improved program reporting of transplant patient data.

At the time of our review, the Transplant Center was experiencing significant organizational change. In March 2014, the Director left the University, and the Assistant Director was appointed Acting Director. In addition, the implementation of Epic Enterprise revenue cycle modules modified the manual and electronic workflows in Patient Care Information Systems (PCIS) that allowed the Transplant Center Business office to complete a per-billing review of transplant patient charges and allocate them to pre and post-transplant activities. The Acting Director continues to work with Epic and Revenue Cycle personnel to program a similar workflow in Epic. In addition, Transplant Center administration is considering purchasing the new Epic Phoenix module to replace TeleResults. The module being considered will eliminate the duplicate and manual processes that sometimes contribute to data errors.

The Acting Director, in partnership with the new Chief Administrative Officer (CAO)⁶, is working to ensure that organizational changes to Transplant Center operations provide assurance that CMS Conditions of Participation are maintained. The Transplant Center Business Office coordinates with various UCSDHS transplant programs and departments including Surgery, Finance, PIPS and the regulatory office in managing the various organ

⁵ TeleResults is an organ disease and transplant management system typically used to manage daily care of transplant patients.

⁶ The Chief Administrative Officer for Anesthesia, Musculoskeletal, Neurosciences, Radiology and Surgery oversees the Transplant Services, which falls under the Surgery group.

transplant programs clinical and financial operations.

II. Audit Objective, Scope, and Procedures

The objective of our review was to perform an overall assessment of the business process control environment in the Transplant Center Business Office and the transplant programs. Based on our preliminary assessment, we focused our detailed review on evaluating transplant data collection and validation, and financial management processes.

We performed the following procedures to achieve the project objective:

- Reviewed relevant OPTN, CMS and Medical Center Policies (MCPs) related to transplant programs;
- Interviewed the prior Transplant Center Director, current Acting Director, Charge-Hold Coordinator, Operations Manager and Information Systems Administrator;
- Interviewed the UCSDHS Director for Reimbursement, and Decision Support Financial Analysts;
- Reviewed current available external regulatory review reports;
- Evaluated selected SRTR Reports, OPTN/UNOS and CMS Compliance Reports, and traced information to the data sources;
- Analyzed available Transplant Center Financial Results reports, cost center budget variance reports for FY12-13 and July 2013-February 2014, and an internal tracking report (referred to as Phase III report); and
- Validated selected financial and statistical data for FY2012-13 for the Kidney Transplant Program.

III. Conclusion

Based on our review procedures, we concluded that Transplant Center business process controls were generally adequate, and helped to ensure that CMS Conditions of Participation and other regulatory requirements were met.

The Transplant Center has experienced challenges with transplant charge allocation and transplant data management since Epic Enterprise was implemented in October 2013. Previous systems and related workflows were not compatible with the Epic system. Required modifications to workflows, additional staff training, and evaluation of the current database are in process.

We identified opportunities for improvement to the timeliness and validation data submissions to regulatory agencies, and financial statement review and monitoring processes.

These issues are discussed in more detail below.

IV. Observations and Management Corrective Actions

A. Transplant Data Submission and Validation

Data provided to UNOS and CMS was not submitted timely or validated prior to submission in some cases during calendar year 2013.

The OPTN requires validation and reporting of information on transplant candidates, recipients and donors, which need to include all deceased and living organ donors, potential transplant recipients, and actual transplant recipients. Regulations governing transplant data requirements include the following:

- CMS Conditions of Participation (42 CFR 482.80a) and UNOS Policy 7 on data submission standards require at least 95% of the information no later than 90 days after due date established by the OPTN; and 100% of the expected forms within six months of the due date.
- Health System Transplant Program Policy Manuals require that 95% of all expected forms to be completed within six months of the due date.
- The OPTN requires a 60% compliance rate for the LDF forms for living kidney donors who donate between February 1, 2013 and December 31, 2013.

To achieve regulatory and policy compliance, UNOS records are assessed semi-annually. The Transplant Center Programmer monitored the list of outstanding forms in UNet, and sent out weekly reminders to personnel responsible for completing the forms. The QAPI team reporting schedule also included bi-annual and quarterly updates for monitoring UNOS reporting compliance.

In the past, the Transplant Data Analysts⁷, and in some cases, the Transplant Coordinators⁸ obtained the data needed to complete the required forms in UNet from Epic and TeleResults. The patient data⁹ was then forwarded to the Data Coordinator in paper form for input into UNet. The person that entered the data into the system was the same person that reviewed and validated the accuracy of the data prior to submission.

Due to the staff turnover that occurred over the past six-months, Data Analyst responsibilities for completing the UNet forms were re-delegated to the Transplant Coordinators with the clinical background required to ensure that accurate patient data is submitted. However their clinical workload sometimes prevented them from sending the data to UNOS timely.

⁷ Only larger transplant programs such as Kidney and Liver have Data Analysts.

⁸ Transplant Coordinators are Registered Nurses (RN) assigned in each program for each phase of the transplant, including Pre- and Post-transplant, Waitlist, and Live Donor.

⁹ ABO is the blood group identifier for donor and recipient patients. UNOS requires that a second person validate the ABO for donor and recipient on UNOS forms prior to submission, which required a variation in the process. The Transplant Coordinator provided the ABO information to the MSO for entry into UNet. The Transplant Coordinator then logged into the system to validate and submit the information.

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An electronic interface could not be established between TeleResults and Epic Enterprise. Therefore, staff had to access data in Epic and manually input it into TeleResults. Although Transplant Center personnel have continued to make a good attempt to collect and submit transplant program data by the due date, they were not always successful.

We selected a sample reports judgmentally from UNOS on June 03, 2014 for focused review. Four of the six organ compliance reports submitted to CMS in the 4th Quarter of calendar year 2013, and one of two UNOS Living Donor Follow-Up (LDF) for full calendar year 2013 were not compliant with timely data submission and validation regulations.

CMS 10/01/2013 - 12/31/2013

- Adult Kidney Program: 51% compliance, 93 of 191 records expected were received late (greater than 90 days after the due date);
- Adult Pancreas Program: 66% compliance, 1 of 3 records expected was received late;
- Adult Lung Program: 97% compliance, 3 of 93 records expected were received late; and
- Adult Liver Program: 76% compliance, 24 of 101 records expected were received late.

UNOS 01/01/2013-12/31/2013

- LDF¹⁰ records for Kidney: 85.71% compliance, 10 were received late (greater than 6 mos. from expected date).

Management Corrective Actions:

1. On July 1, 2014, Transplant RN Coordinators were permanently delegated the responsibility for UNOS data submission and validation. The required patient data is reviewed, validated, and input into UNet prior to the due date.
2. Transplant Center management will present a business proposal to the Chief Information Officer to replace the TeleResults system with the Epic Phoenix transplant module. This module is expected to minimize the current duplicate data entry and manual processes needed to submit patient data, and will also upload data electronically into UNOS, which will facilitate timely data submission.

¹⁰ Living Donor Follow-Up (LDF) is one of the required forms for living donor patient information required by UNOS. This form is updated at the 6-month patient follow-up care, and again at every year thereafter within a period of two years.

B. Financial Results Review and Monitoring

A formal Transplant Center financial monitoring process for central and individual transplant program cost centers had not been developed.

In FY 2013, transplant services reported 182 transplant cases¹¹ that generated total gross charges of \$53 million, as reflected in the Transplant Center Financial Results report.¹²

We noted that complete financial information was not readily available from one source for several months after Epic Enterprise was implemented. During the post implementation transition period, Transplant Center management continued to rely on the Finance Department Reimbursement and Decision Support groups to generate and monitor financial results. We were provided with the following financial reports that were being generated for Transplant Center management at the time of our review:

- Flexed Budget vs. Actual (Flexed Budget Summary): This monthly report was generated by the Decision Support Financial Analysts for each individual transplant program cost center. It compared month-to-date and year-to-date inpatient charges and operation expenses to the original and flexed budgets to identify budget variances, and the gain or loss from operations.
- Hospital Budget Variance by Cost Center (Budget Variance): This report was also generated from TSI. It was similar to the Flexed Budget Summary report, but it only included expenses by category.

To better understand the Transplant Center process for analyzing financial transactions and results, we selected the Kidney Transplant Program transactions for focused review.

In FY2013, the Transplant Center Financial Results report included 85 completed kidney transplant cases¹³, which generated \$15 million in gross charges¹⁴ and a total margin of \$241 thousand from all hospital cost centers involved in full episode of transplant care. However, those statistics include the gain or loss from other hospital cost centers that supported kidney transplant services.

¹¹ The number of cases is based on patient discharge date for the period reported. This number does not always equal OPTN reported cases. The variance (usually one) may be attributed to a transplant case where the patient's hospital discharge date falls into the succeeding period.

¹² The Transplant Center Financial Results report is a high-level financial report presented to the executive management quarterly and annually. It includes gross charges for all hospital cost centers that provide services to transplant patients for the purpose of identifying the contribution of the full transplant service to the UCSDHS. The Transplant Center is just one of the many components for the full transplant service.

¹³ The volume of transplant cases reflected in the Financial Results is based on total actual transplant cases as of transplant patient discharge date within the period reported. The transplant volume in 110 Summary report is based on the number of transplant cases billed for the reporting period. OPTN reports are based on the volume of actual transplant cases completed during the reporting period.

¹⁴ Gross charges are based on a model developed from contract terms.

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The June 30, 2013 Flexed Budget Summary and IFIS Expanded Budget Summary reports for the Kidney Transplant Program cost center showed a deficit of (\$906 thousand). The following table summarizes the results of Program operations (amounts are in millions).

Kidney Transplant Cost Center	Actual	Budget	Variance
Revenues	\$ 5,812	\$ 6,832	\$ (1,020)
Operating Costs	\$ 6,718	\$ 6,361	\$ 357
Gain (loss) from Operations	\$ (906)	\$ 471	\$ (1,377)
# of Transplant Cases	89	104	(15)

The prior Director took an active role in analyzing Transplant Center financial results and did not delegate that responsibility to other personnel. Because Transplant Center Business Office personnel had not been involved in analyzing financial reports and transactions, they were not able to provide us with a copy of analyses performed in prior years. Decision Support Financial Analysts generated financial reports, and they contacted the MSO or the Acting Director when there are significant budget variances that required justification. The MSO assessed those variances brought to her attention. However, a consistent procedure for completing a detailed financial transaction review and reconciliation was not in place. Due to the recent change in reporting structure and other administrative and operational changes in the Transplant Center, the CAO and the Acting Director recently initiated regular meetings to review past and current financial reports to assist with FY 2014-15 budget preparation.

Regular monitoring and reconciliation of the financial transactions for each of the transplant program cost centers will provide reasonable assurance that the financial results of transplant operations are accurately reported, and resources are effectively managed.

Management Corrective Actions:

1. Effective July 1, 2014, the Transplant Center Director and the CAO meet monthly with the Decision Support Financial Analysts to review the overall financial statements and those specific to each of the cost centers, in addition to the regularly scheduled quarterly and annual meetings.
2. Transplant Center management will:
 - a. Complete a routine review of the financial transactions to ensure accuracy of actual revenue charges and expenditures for each of the transplant program cost centers, and effectively monitor the results of operations.
 - b. Develop a formal process for completing a monthly reconciliation of the revenues and expenditures posted for each of the transplant program cost centers.