SAN DIEGO: AUDIT & MANAGEMENT ADVISORY SERVICES
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October 6, 2014

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Subject: ***Hemophilia and Thrombosis Treatment Center Business Operations***
Audit & Management Advisory Services Project 2013-77

The final audit report for Hemophilia and Thrombosis Treatment Center Business Operations, Audit Report 2013-77, is attached. We would like to thank all those involved 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 destroy them at this time. AMAS also requests that draft reports not be photocopied or otherwise redistributed.

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Director
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Attachment

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UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Hemophilia and Thrombosis Treatment Center
Business Operations
October 2014

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Project Number: 2013-77

Table of Contents

I. Background

Audit & Management Advisory Services (AMAS) has completed a review of the UC San Diego Health System (UCSDHS) Hemophilia and Thrombosis Treatment Center (HTC). This report summarizes the results of our review.

United States Hemophilia Treatment Centers that meet certain regulatory criteria receive federal funding from the Maternal and Child Health Bureau of the Department for Health and Human Services and are therefore considered to be "covered entities" under the Public Health Service Act. That designation makes them eligible to purchase certain clotting factor[1] products at a discounted price. To qualify, Centers must ensure that program income derived from providing clotting factor to patients be reinvested into the Center to support clinical programs and to provide other patient care services including nursing, social services, physical therapy, screening programs, and physician training. The Health Resources and Service Administration (HRSA) is responsible for providing oversight and ensuring that Centers remain in compliance with applicable 340B Program requirements.

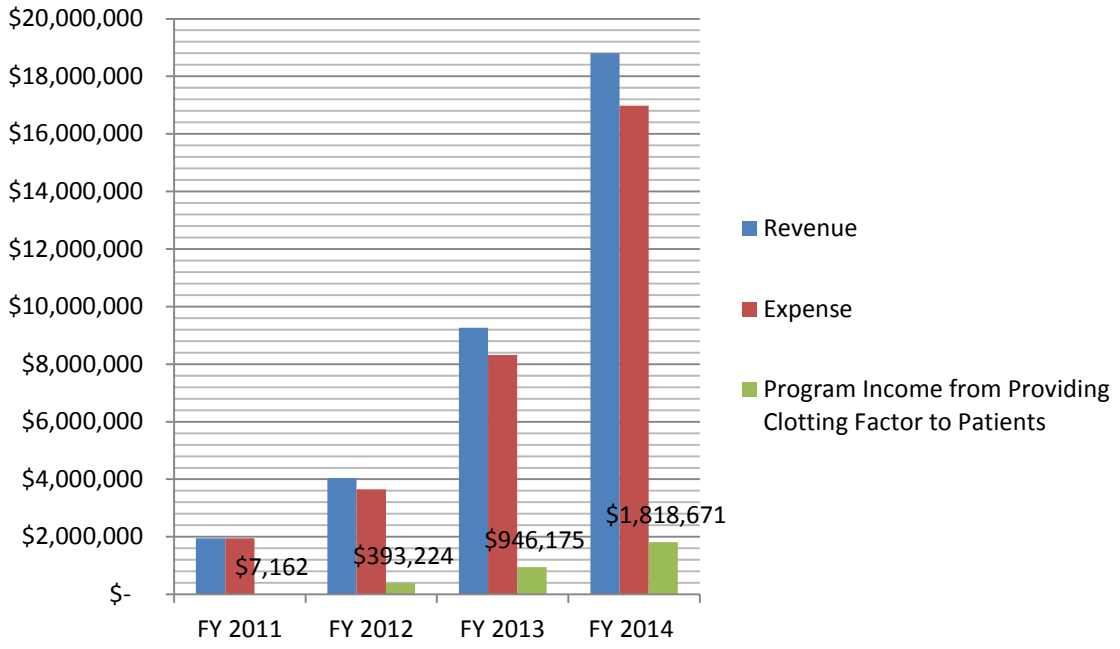
The UCSDHS HTC, founded in 1989, is an advanced, multidisciplinary treatment program that provides medical and other support services to adult patients (and their families) diagnosed with hemophilia,[2] Von Willebrand Disease[3], and other bleeding and thrombotic disorders[4]. It is one of the few Centers in the United States that specializes exclusively in adult hemophilia care. HTC provides comprehensive services at the UC San Diego Medical Center in Hillcrest, and specialized services to patients with thrombotic disorders at the Moores Cancer Center (MCC), located on the La Jolla Medical Center campus. In 2010, the *Total Hemophilia Care* clotting factor homecare program was launched. The HTC also partners with Rady Children's Hospital San Diego (RCHSD) to facilitate the transition of adolescents diagnosed with hemophilia or other bleeding disorders to its adult treatment program, and also collaborates with the Los Angeles Orthopedic Hospital Hemophilia Treatment Program. Center personnel are available in the clinic or by telephone seven days a week and 24 hours per day to ensure that patient medical needs are assessed and treated on a timely basis.

Per a Memorandum of Understanding (MOU) effective August 14, 2009 between HTC and UCSDHS Pharmacy Home Infusion Services (PHIS), PHIS provides support services and ancillary supplies to HTC patients on behalf of the HTC 340B Program. UCSDHS

[1] A clotting factor, also called a coagulation factor, is any one of a group of substances including Factor VIII that must be present in blood for it to clot.
[2] Hemophilia is a rare bleeding disorder which prevents normal clotting. Patients diagnosed with this disease produce little or no clotting factor.
[3] Von Willebrand disease is the most common inherited bleeding disorder, in which a clotting protein called von Willebrand factor is deficient or defective.
[4] Thrombosis is the formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system.

HTC contracted with Red Chip of Nevada (RCE) to provide management services for the purchase, inventory, billing and collection of the blood factor prescribed to HTC patients.

The HTC has experienced significant financial growth since FY 2010-11 as shown in the graph below. Program income of $7,162 was realized in FY 2011, and increased to $393,224 in FY 2012. FY 2013 program income grew to $946,173 (a 141% increase over the prior period). For the FY 2014, program income totaled $1,818,671 (a 92% increase over prior period).



Program income for hospital based units is reallocated to the hospital retained earnings account during the year end fiscal close. As of May 31, 2013, the HTC had cumulative program income of $1,279,215. As noted above, HRSA requires that all program income, which is primarily derived from clotting factor proceeds, be reinvested in the Program as a condition of participation. The continued financial growth will allow the program to move to a larger facility and expand the number and type of program services provided.

The Center of Disease Control conducted a study of 3,000 people with hemophilia[5], the results of which stated in part: "those who used a hemophilia treatment center were 40% less likely to die of a hemophilia-related complication compared to those who did not receive care at a treatment center. Similarly, people who used a treatment center were 40% less likely to be hospitalized for bleeding complications." A reduction in the number of hemophilia patient hospitalizations could result in a significant savings to

[5] http://www.cdc.gov/ncbddd/hemophilia/aboutus.html

hospitals due to the high cost of providing clotting factor to inpatients, which cannot be purchased at the reduced 340B price. The clotting factor prescribed to an inpatient typically costs several thousand dollars per day.

With the assistance of Medical Center Decision Support, we obtained data on hospital admissions for patients with a diagnosis of hemophilia for the period July 1, 2011 through March 31, 2014.

	FY 2012	***FY 2013***	***July 1 through March 31, 2014***	***Total***
Hospital admissions^ linked to a **primary** diagnosis of hemophilia, unique medical record number+	4	3	1	8
Hospital admissions for HTC patients* (% of all admissions) **(primary diagnosis of hemophilia)**	4 (100%)	2 (67%)	1 (100%)	7
Hospital admissions^ linked to a **primary or secondary** diagnosis of hemophilia, unique medical record number+	30	40	22	92
Hospital admissions for HTC patients* (% of all admissions) **(primary or secondary diagnosis of hemophilia)**	13 (43%)	29 (72.5%)	14 (63.6%)	56
^Includes multiple inpatient admissions for the same patient with a diagnosis code of 286.0, 286.1, 286.2, 286.4 or 286.52 +Multiple hospitalizations for the same patient with primary diagnosis of hemophilia were eliminated *Patient medical record numbers were linked to HTC clinic encounters				

II. Audit Objective, Scope, and Procedures

The objective of our review was to evaluate HTC business operations and related process controls with a focus on financial management and reporting, and compliance with HRSA requirements.

We completed the following audit procedures to achieve the project objective:

- Reviewed case management studies and other pertinent articles related to the treatment of Hemophilia patients;
- Reviewed HRSA 340B Program regulations, and related UCSDHS policies;
- Evaluated HTC MOUs with UCSDHS Administration, and PHIS;

- Analyzed the MOU between the UCSDHS HTC and RCE;
- Met with the HTC Medical Director, Program Coordinator and other key personnel;
- Contacted the HRSA Representative for Western Region IX;
- Interviewed the following UCSDHS personnel that coordinate with HTC management:
    - Director of Ambulatory Pharmacy Services
    - Financial Services Accounting Manager
    - Director of Reimbursement
    - Director of Budget and Financial Forecasting
    - PHIS Manager
    - Health Sciences Research Compliance Analyst
    - Director of the Office of Coverage Analysis Administration (OCAA);
- Evaluated and analyzed the following financial reports and supporting documents:
    - RCE monthly financial reports including but not limited to the *Accounts Receivable Reconciliation Report*;
    - UCSD Medical Center Report: *Account Code Level Budgeter 110, flexed budgets vs actuals*;
    - Detailed financial data compiled by Financial Services;
    - HRSA Report: *Factor Replacement Product Data Sheet/Program Income Report* and supporting documentation; and
    - Financial Link *Statement of Operations*;
- Evaluated the PHIS recharge process;
- Obtained and analyzed data related to hemophilia patient hospitalizations; and
- Assessed HTC clinical research study management practices and reviewed the results of an internal review conducted by the Health Sciences Research Compliance Program of one HTC clinical research project.

The scope of this project did not include a detailed audit of selected clinical research projects being conducted in the HTC. The Health Sciences Research Compliance Program (RCP) will assess HTC clinical research activities to its general monitoring program.

III. Conclusions

We concluded that business process controls associated with the HRSA 340B Program were generally effective. Center management collaborates with the HRSA Western District IX Director to ensure that 340B Program compliance is maintained as business practices are revised. The Director of Ambulatory Pharmacy Services coordinates with the PHIS Manager and HTC personnel to purchase, manage and distribute clotting factor to patients, and analyze RCE reports for accuracy.

Although Program financial transactions and reporting will be transitioned from the Medical Center to the Medical Group, the Health System Chief Administrative Officer for Medicine Programs will continue to provide oversight to the Program to manage the

clinical relationship between the HTC and related clinical services. HTC cumulative program income will be transferred from hospital financial system to the Medical Group to facilitate the payment of expenses for the expansion of clinical services after the Center relocates later this year. In addition, until HTC finances are transferred to the Medical Group, they will need to continue to obtain their financial information from various sources because clinical program transactions are included in an accounting index with other programs.

We also concluded that the HTC has realized substantial growth in its patient base and associated program income. However, additional space, staff resources, and administrative expertise were needed to plan and implement additional patient services. During this review, management made some progress on improving the business operating environment and related process controls.

A new Program Manager and Clinical Research Coordinator have been hired. The Program Manager has experience with hospital and Medical Group administrative and billing processes and systems. The number of clinical research projects has steadily increased, requiring that the standard UC San Diego study management procedures and systems be adopted. Ongoing training for clinical research support staff will be critical to ensure compliance with policy.

The HTC is currently located in licensed clinic space in the Hillcrest Medical Center Medical Offices South building, which did not provide enough space to allow HTC to expand patient services in a single location. However, during our review Health System and HTC managements agreed that the Center could lease space in a non-licensed La Jolla facility, which would provide the additional space needed to increase the type and number of patient services provided in the clinic. HTC had planned to relocate by the end of 2014. However, relocation plans have been delayed, which has created concerns about the continued inability to expand program resources and provide additional patient services.

The most significant reporting issue is the basis used to allocate indirect costs to HTC operations, which must comply with HRSA guidelines. We also identified clinical research staff training as an opportunity to improve business operations. These issues are discussed in the next section of this report.

IV. Observations and Management Corrective Actions

A. HRSA Reporting

The FY 2013 financial report to the Hemophilia Network required an adjustment to the indirect cost allocation.

HTC is required to submit a *Factor Replacement Product Data Sheet/Program Income Report* to the Western States Regional Hemophilia Network of HRSA

annually. The federal mandate requires that income derived from 340B Program price discounts be used to maintain or expand supporting services and/or to provide clotting factor replacement products to uninsured patients. Income must be used for expenses that are considered to be relevant to patient health, education and supportive services necessary to provide comprehensive care to patients served by HTCs. In addition, per client management, our region has always been held to an 8% indirect cost limit on the HRSA grant. This limit was also enforced via a UC-wide waiver, which 95% of the HTC 340B programs in our region adhere to.

Because the HTC was a smaller operation in prior years, financial reports submitted to HRSA prior to FY 2012-13 did not include an indirect cost assessment. However, due to the increase in the number of patients served and use of hospital resources, the July 2013 MOU between the HTC and the UCSDHS included an 8% negotiated indirect cost rate, assessed on operating expenses less the cost of clotting factor products. The MOU also discusses the annual HTC budget process and specifically states that the following expenses will be included in the budget to ensure that federal regulations are met:

- Cost of drugs payable to the manufacturers;
- Management services contract with RCE;
- UCSD Pharmacy Services;
- Salary for the Medical Director;
- Salaries for essential professional and administrative staff;
- A percentage of the hemophilia nurse's salary funded by the Health System;
- A percentage of the Ambulatory Pharmacy Director's salary;
- Equipment and services needed for direct patient care;
- Community Services that benefit the education of patients and providers about hematology and thrombosis disorders; and
- Other allowable direct and indirect costs. Beginning in FY 2012-13, the indirect cost rate was negotiated and established at 8% of operating expenses.

When the FY 2012-13 financial report was prepared and submitted to HRSA, the agency returned it with questions about expense allocations and the indirect cost calculation. To address those questions, Pharmacy management included a separate direct expense line item pharmacy billing and operations expenses of $59,421, and calculated indirect costs of 8% on the adjusted total expense. The revised report was accepted by HRSA in FY 2013-14.

Financial reports not prepared in strict compliance with federal requirements can raise questions and potentially decrease confidence in Center management.

Management Corrective Action:

HTC and Ambulatory Pharmacy management will utilize the revised method for reporting direct costs and calculating indirect costs from FY 2012-13 when preparing the report for FY 2013-14.

B. PHIS/HTC MOU

The MOU between PHIS and HTC is outdated.

This MOU was last approved on May 5, 2009 and signed by the prior HTC Medical Director. The HTC has grown significantly over the last 5 years, which could have an impact on the cost of services provided by PHIS to HTC.

PHIS provides pharmacy services to HTC patients on behalf of the HTC's 340B Outpatient Hemophilia Factor Distribution Program. Those services include procurement, storage and distribution of blood factors and ancillary supplies and managing incoming income. Through intercampus recharge, at the end of each month, HTC pays PHIS three cents per unit of factor dispensed for private patients and two and a half cents per unit of factor dispensed for government patients. In addition to this fee, they reimburse for supplies provided by PHIS to the HTC patients. This charge structure was agreed upon five years ago based on time studies, salaries and services provided when the contract became effective. PHIS and HTC management at that time agreed upon these charges to cover the cost of the provided services with a minimal return for PHIS.

Given the significant growth of the HTC, in order to ascertain that all costs are being covered by PHIS and to assure all parties involved that there is minimal return, the agreement should be revamped and the charge structure revisited.

Management Corrective Action:

HTC and Ambulatory Pharmacy management will review and update the terms and charge structure of the HTC/PHIS MOU to ensure that all costs are detailed and covered and agreed upon by both parties.

C. Clinical Research Staff Training

Clinical research support staff would benefit from additional training on the clinical trial management system and procedures included in the Health System clinical research management policy.

The Health System implemented Health System Policy (MCP) 342.2, *Clinical Research Billing* on July 1, 2013. This policy provides guidance for managing

study related charges in the clinical trial management system (Velos) and the billing system (Epic).

The Study Coordinator was not reconciling study bulk accounts and expenses charged to clinical trial funds in the campus financial system because she had not requested system access and sufficient training had not been obtained.

The HTC Program Administrator was aware of the new policy, and worked with the staff to ensure that they were provided with the system access and training needed to comply with policy requirements. However, because the systems and procedures are new, additional training would be beneficial.

Management Corrective Action:

HTC management has identified support staff training needs and supports staff attendance at new training applicable to their job responsibilities. In addition, they have required that staff participate in additional clinical research training and updates provided by the RCP and the OCAA.