UTHealth
The University of Texas
Health Science Center at Houston

January 13, 2016

To: Giuseppe N. Colasurdo, M.D.
President

Re: **Executive Summary – Report on Clinical Trials Billing Audit #15-121**

Reason for the audit

We have completed our audit of clinical trials billing. This audit was performed at the request of the UTHealth Audit Committee and was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing.*

Objective, Scope, and Methodology

The objective of this audit was to assess the adequacy of UTHealth clinical trials billing processes and policies developed to comply with applicable regulations.

Auditing and Advisory Services (A&AS) reviewed UTHealth policies and procedures, researchers' compliance with the clinical billing policies, clinical trial administration as well as testing of controls around subjects' research-related clinical trials services billing for fiscal year 2015.

Conclusion

Overall, we found departmental management has developed clinical trials billing processes and policies that comply with applicable regulations. A recommendation was made to establish a detailed and formal reconciliation process and develop a monitoring plan over research billing. Details regarding the exceptions can be found in the attached report.

Daniel G. Sherman, MBA, CPA, CIA
Assistant Vice President

DGS:db

cc: Audit Committee

Attachments:

713.500.3160 phone 713.500.3170 fax
P.O. Box 20036
Houston, Texas 77225
www.uthouston.edu

UTHealth
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October 8, 2015

Report on Clinical Trials Billing Audit #15-121

We have completed our audit of clinical trials billing. This audit was performed at the request of the UTHealth Audit Committee and was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*.

BACKGROUND

Clinical trials are research studies that prospectively include human subjects. The primary purpose of a clinical trial is to identify health-related interventions to prevent, diagnose, or treat a disease. Clinical trials are conducted according to an approved protocol that outlines the categories of patients, tests, procedures and drugs to be administered, as well as consequences that will be measured. Clinical trials billing is highly complex due to the nature and scope of the research studies and often more than one entity is responsible for the charges incurred in a trial. Payments can be made by government and non-government sponsors, private insurance companies, Medicare/Medicaid contractors, as well as the patients themselves.

Medicare may pay for items and services in clinical trials under three policies:
(1) The Clinical Trial Policy (CTP);
(2) The Investigational Device Exemption (IDE) Policy; and
(3) Coverage with Evidence Development (CED).

The National Clinical Trial (NCT) identifier number is a unique identification code given to each study registered on ClinicalTrails.gov after the protocol information has been submitted by the responsible party and passed a review by the Clinical.Trials.gov staff. It is required for all trial/registry/study-related claims if it qualifies under a CTP, IDE, or CED study.

713.500.3160 phone 713.500.3170 fax
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Houston, Texas 77225
www.uthouston.edu

DEFINITIONS

Clinical Trial: A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Coverage Analysis: A systematic review of the study to determine if the "patient billable" services are eligible and/or approved to be billed out to third-party payers. Coverage analysis also delineates all procedures listed in the study protocol's schedule of events to determine where these services should be billed.

Informed Consent: A process in which researchers communicate with potential and enrolled participants about a clinical study. The goal of the informed consent process is to protect participants. All important information about the study must be given to the potential participant in a written document that is clear and easy to understand.

Principal Investigator (PI): The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol: The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Sponsor: The organization or person who oversees the clinical study and is responsible for analyzing the study data.

Standard of Care (SOC): Items and services related to the care of a patient participating in a clinical trial delineated as routine patient's care (i.e., items and services that a third party payer would cover if the patient was not enrolled in a clinical trial).

OBJECTIVE

The objective of this audit was to assess the adequacy of UTHealth clinical trials billing processes and policies developed to comply with applicable regulations.

SCOPE AND METHODOLOGY

Auditing and Advisory Services (A&AS) reviewed UTHealth policies and procedures, researchers' compliance with the clinical billing policies, clinical trial administration as well as testing of controls around subjects' research-related clinical trials services billing for fiscal year 2015.

AUDIT RESULTS

Clinical Trials Billing Program

The Clinical Research Finance (CRF) Team is responsible for developing clinical trials billing policies, providing education for clinical research staff, and overseeing a monitoring program for clinical trials billing and research study expenses. The CRF Team reports to the Office of Sponsored Project Administration. In order to evaluate UTHealth's clinical trials billing compliance program, A&AS determined whether the following elements were present:

- Written policies and procedures for clinical trials billing; and
- A program for ensuring and documenting that UTHealth personnel involved in the clinical trials billing process received proper billing training.

In response to The Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS) CMS MM8401, which outlines the mandatory reporting of an eight-digit NCT number on all research related claims, the university has developed HOOP 214 *Clinical Research Billing* (HOOP 214). The objective of HOOP 214 is to outline the requirements to identify clinical research patients, delineate routine costs and allowable research charges, as well as ensure appropriate billing occurs.

Through a review of policies and procedures, inquiry and interviews with the CRF Team, we developed flowcharts of the processes beginning with the coverage analysis and continuing through the billing of clinical trial services. We provided the flowcharts to the departmental management, which were adopted as part of their procedures. The CRF Team has held several training courses during FY2015 for employees who conduct clinical research or register research patients at UTHealth. The trainings outlined research billing procedures for clinical studies and established the responsible parties for appropriate research billing processes. The trainings covered several topics including clinical trials billing PI training, clinical trials billing administrator training, and coverage analysis billing grid submission training.

Clinical Research Billing Administration

UTHealth has four Institutional Review Boards (IRBs) responsible for the review of FDA-regulated research. The review is performed through the iRIS system where research protocols are submitted. To determine whether the CRF Team is adequately administering the Clinical Research Billing Program at UTHealth, A&AS verified the following:

- The iRIS risk assessment process is being followed;
- Coverage analyses are being submitted when necessary and are adequately reviewed; and
- The research accounts are closed out according to policy.

For each clinical trial initiated thru iRIS, a billing risk questionnaire is completed by the department and submitted along with the protocol. Based on the information provided on the billing risk questionnaire, the CRF Team performs a risk assessment to determine whether a coverage analysis is needed. The coverage analysis outlines services billable to the research or insurance payors in order to ensure clinical costs are allocated to the appropriate entity. A&AS selected a judgmental sample of 12 weekly risk assessments performed by the CRF Team. We obtained evidence demonstrating studies submitted to the IRB through iRIS were regularly reviewed by the CRF Supervisor. We also verified coverage analyses submitted were properly reviewed to ensure clinical costs are allocated to the appropriate entity and approved by the CFR Supervisor prior to the start of the trial.

Billing of Clinical Trials Services

A&AS obtained the list of UTHealth active clinical trials with coverage analysis from the CRF Team and randomly selected a sample of five clinical trials for testing. For each trial, we met with the study staff to observe the processes and procedures followed and compared them to the process flowcharts.

We found most individuals in our sample have a strong understanding of the pre-award processes such as the coverage analysis submission and obtaining the NCT number; however, of the study coordinators in our sample, several stated they were unaware of their responsibility to perform reconciliations to ensure charges are billed (either to the research sponsor or patient where appropriate). Additionally, the study coordinators were unaware of their responsibility to coordinate with the proper personnel to ensure NCT numbers are included in the claim when applicable.

We also obtained a listing of active clinical trials where a coverage analysis was not submitted. We then selected a random sample of five clinical trials and obtained the study protocols from the iRIS system. Each protocol was reviewed to determine

whether the trial contained a patient care component, which would require the preparation of a coverage analysis. We found four out of the five selected active trials in our sample (appropriately) did not contain standard of care procedures and therefore did not require a coverage analysis. For the one trial containing a standard of care procedure, evidence was obtained to support that a study budget was submitted. The trial was added to our sample of five trials with coverage analysis for further testing.

For each of the six clinical trials selected, we obtained the research patient list and judgmentally selected one study subject from each clinical trial. For each of the study subjects, we obtained and reviewed the charge information for potential duplicate charges/payments. We also mapped all charges to the coverage analysis to determine whether the charges were billed according to the protocol and to verify whether the mandatory NCT number was included when applicable. HOOP 214 states:

> *"it is the responsibility of the PI to ensure that the clinical research billing of his or her studies is in compliance with all laws and regulations and adhere to university policy."*

We found three out of the six claims reviewed did not include the mandatory NCT number. Non-compliance with the use of the NCT number could result in FDA public notices of noncompliance, withholding of NIH funds, FDA sanctions, and/or CMS rejection of the billing claim.

Our testing also revealed a claim was incorrectly submitted to the research patient when the informed consent form indicated there should be no charges to the patient. Although the study staff was alerted by the patient, this issue could lead to potential billing compliance violations. If a reconciliation had been performed, the incorrect billing could have been identified.

These issues were discussed with the CRF Team, who had already started performing random monitoring site visits. These site visits consist of reviews of research patient registration, scheduling, and billing for compliance with IRB-approved research documents. The CRF Team also offers individualized training and guidance to study staff for the studies that started before the implementation of HOOP 214.

Recommendation #1:

We recommend the CRF Team work with the Medical School Dean's office to develop a process to:

1a Oversee a monitoring program for clinical research billing; and

1b Provide additional training to PI/Study staff in order to establish a detailed and formal reconciliation process that includes reviewing all services charged for the

study participants and the insertion of the NCT number on clinical research claims.

Management's Response:

- The Clinical Research Finance (CRF) team will work with staff from the Department of Internal Medicine and the School of Biomedical Informatics to develop a Clinical Research Billing (CRB) tool in REDCap to improve communication and reconciliation.
- The CRF team will create a responsibility document with an attestation statement to provide investigators and research staff upon approval of a coverage analysis. A copy of the signed responsibility document will be imaged in documentum with the coverage analysis approval.
- The CRF team will continue to monitor clinical trials through random selection, per request, and per cause.
- The CRF team will continue to build awareness of the CRB process by presenting at various training and stakeholder meetings around campus. The CRF will maintain sign-in sheets and agendas.

Responsible Party: *Michael Tramonte, Sr. Vice President, Finance and Business Service*

Implementation Date: *09/01/2016*

Further, A&AS obtained the list of clinical trials closed during the audit period. In many cases, the program sponsor allows the PI to retain unused funds to be used at their discretion. Upon project completion or termination, surplus (residual) balances are transferred to a sponsored project residual account. Each PI is assigned a project account to enable transfer of sponsored program residual balances. In order to ensure there is not an excess accumulation of residual balances, projects with balances greater than 10% require submission of a justification at the project close-out. Our sample contained five projects with remaining funds over $100,000 that were also over 10% of the study budget after study close-out. For each study in our sample, we reviewed a copy of the study close-out form to identify whether the documented justification was reasonable. Based on our review, the studies we tested were closed according to the policy and the justification for unused balances appeared reasonable.

CONCLUSION

Overall, we found departmental management has developed clinical trials billing processes and policies that comply with applicable regulations. Opportunities exist to

establish a detailed and formal reconciliation process and develop a monitoring plan over research billing.

We would like to thank the Office of Sponsored Projects Administration, the CRF Team and the individual Research Coordinators and Billing Managers throughout the institution who assisted us during our audit.

Daniel G. Sherman, MBA, CPA, CIA
Assistant Vice President

DGS:db

cc: Audit Committee
Michael Tramonte
Heather Cody
Karen Niemeier

Senior Manager: Nathaniel Gruesen, MBA, CIA, CISA, CFE
Auditor Assigned: Diarra Boye, Auditor

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