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Date: May 13, 2019

To: Ruben Mesa, M.D., FACP
Director, Mays Cancer Center

From: John Lazarine, Chief Audit Executive
Internal Audit & Consulting

Subject: Audit Report – Cancer Center Clinical Trials Billing Audit

As part of our FY 2019 Audit Plan, we recently completed the Cancer Center Clinical Trials Billing Audit. Attached is the report detailing the results of this review.

We appreciate the cooperation and assistance we received from the Mays Cancer Center throughout the review.

Respectfully,

John Lazarine, CIA, CISA, CRISC
Chief Audit Executive
Internal Audit & Consulting Services

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Cancer Center Clinical Trials Billing Audit (Project # 18-02)

May 13, 2019

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Executive Summary

As part of our approved annual Audit Plan we conducted an audit of the UT Health San Antonio MD Anderson Cancer Center (Cancer Center) clinical trials billing process. The audit objectives, conclusions, and recommendations follow:

Audit Objective

The objective of this audit was to determine the adequacy of processes and controls over the billing for cancer clinical trials at the Cancer Center.

Conclusion and Corrective Actions

Overall, the adequacy of the processes and controls over the billing for cancer clinical trials at the Cancer Center could be enhanced. Although the Cancer Center's current processes and controls over the billing for clinical trials are manually intensive and heavily dependent on the institutional knowledge and diligence of three key individuals involved in the process, they provide reasonable assurance regarding the accuracy and completeness of the billing process. However, with the volume of clinical trials expected to grow, and if any of the three individuals currently involved in the process were to be unavailable or leave the Institution, the risk of billing errors and omissions could increase. Therefore, enhancements to the clinical trials billing process should be made to reduce these likelihoods.

While the process for ensuring the accuracy and completeness of the billing will remain highly manual, there are opportunities to develop reporting enhancements that will make data more readily available which should decrease the amount of time currently required to manually pull data and assist staff in performing reconciliations between EPIC and Velos. In addition, the processes and controls currently in place need to be documented to ensure that new or temporary team members involved in the billing process can perform the required processes and controls in a consistent, repeatable manner. Lastly, there should be increased oversight and monitoring by periodically spot checking the accuracy and completeness of the charges worked in the EPIC Research work queue.

Although Audit reviewed and assessed the billing process, we did not perform detailed transactional testing of the billing data. Testing would require an extensive manual review of individual patient charges in EPIC, Sponsor invoicing (derived from procedures performed on a group of patients involved in a clinical trial) and a comparison to a contractual budget/coverage analysis. However, in reviewing, assessing and documenting the billing process, Audit did follow data through the process. Based on our walkthrough, the volume of transactions and the general dollar amounts of individual transactions, the financial impact of any errors or omissions would not be significant.

Based on this review, Management has developed and committed to the following action plans to strengthen the existing processes and controls:

- Develop additional reporting to reduce the amount of time and effort needed to collect and analyze data used in the reconciliation process.
- Increase the level of oversight and monitoring of the billing process, by periodically performing spot checks of the accuracy and completeness of the charges in the Epic Research work queue.
- In order to help ensure that the consistent execution of the processes and controls is not solely dependent on the three individuals currently performing them, management will document and periodically review the procedures to ensure that, when needed, they are updated.

Acknowledgement

We appreciate the courtesy and cooperation we received from the Cancer Center staff throughout the audit.

BACKGROUND

The mission of UT Health San Antonio MD Anderson Cancer Center (Cancer Center) is to conquer cancer through research, prevention and treatment. Cancer Center researchers lead the way in cancer research and clinical trials, with 146[1] trials currently being conducted. For the period of September 1, 2017 through December 1, 2018 the Cancer Center received over $3.9 million (97% from private sponsors; 3% federal funding) in funding for clinical trials.

The Cancer Center Clinical Trials Office provides administrative, regulatory, research and budget support and educational services to researchers conducting cancer related clinical trials. An overview of the Cancer Center clinical trial billing process is illustrated in ***Appendix B***, and for further reference a glossary of clinical trial terminology is included in ***Appendix C***.

SCOPE & METHODOLOGY

The scope of this review included current operational, oversight and monitoring activities associated with clinical trials conducted within the Cancer Center. In order to determine the adequacy of processes and controls over the billing of cancer clinical trial sponsors, Audit performed a process walkthrough and mapped the clinical trials operational procedures conducted by the Cancer Center through extensive flowcharts. Audit focused on assessing expected processes, procedures and controls established to mitigate risks related to clinical research collection efforts for contracted sponsors. In addition, we contacted MD Anderson to compare billing processes and controls to determine if there were any opportunities or best practices that could be shared. Based on discussions with our counterparts at MD Anderson, no significant process or control gaps were identified.

The primary scope and objective of this audit was to gain an understanding and assess the adequacy of the Cancer Center's billing process. As such, Audit did not conduct detail transaction testing. The audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing* as promulgated by the Institute of Internal Auditors.

SUMMARY RESULTS

Overall, the adequacy of the processes and controls over the billing for cancer clinical trials at the Cancer Center could be enhanced. Effectively addressing the following opportunities, such as documenting standard operating procedures and increasing oversight and monitoring efforts will help strengthen the current processes and ensure that they are performed in a consistent manner.

[1] *Figure as of 03/31/2019, provided by the Cancer Center.*

Standard Operating Procedures

Currently, the process for managing the Cancer Center's clinical trials billing is very manually intensive and is heavily dependent on the institutional knowledge, diligence, and professional judgment exercised by the three individuals tasked with this responsibility. While these individuals have generally done a good job of performing these tasks, there is an opportunity and need to make enhancements since the billing process and procedures are not documented. Should any of these three key employees be unavailable for any period of time, the absence of written standard operating procedures, could cause errors in the billing and collection process, if new or temporary staff members are assigned to these activities without proper guidance and documented procedures.

Based on direct observation and discussions with key personnel, Audit performed a walkthrough of the process and developed flowcharts of the overall administrative process and procedures (inception to close-out) for a privately sponsored clinical trial within the Cancer Center. These flowcharts were provided to the Clinical Trials Office to assist management and staff in documenting the billing and collections processes and procedures within the Cancer Center.

Oversight and Monitoring

The Cancer Center's Clinical Trials Office should enhance its oversight and monitoring controls in order to reduce the risk of billing errors. Currently, the Cancer Center has limited resources dedicated to ensure that fees for service of patients within a clinical trial are correctly assessed in UT Health San Antonio's (UT Health) medical records system (EPIC) and properly billed to the sponsor or the patient and/or insurance provider.

When a cancer clinical trial patient receives services from UT Health all of the patient's charges are sent to a 'Research queue' within EPIC to be reviewed by Cancer Center staff in order to determine the correct payee. The billing process and procedures at the Cancer Center is a high volume and very manually intensive process. Cancer Center staff must determine whether the patient charges are considered part of the clinical trial or standard of care that should be billed to the patient and/or the patient's insurance provider.

A. *Standard of care - charges billed to the patient and/or the patient's insurance provider.*

   If the charge is not considered part of a clinical trial or is part of the clinical trial but predetermined at the onset of the study to be the responsibility of the patient, the Cancer Center employee will release the charge from the work queue and allow the charge (fee for service) to continue through the normal billing process for standard of care in which the patient and/or the patient's insurance provider (depending upon the patient's benefits) will be billed for the services performed.

OR

B. *Covered by the Clinical Trial - charge is billed to the Sponsor in accordance with the clinical trial research agreement.*

> If the charge is considered part of a clinical trial and not standard of care, the Cancer Center employee will zero out the charge in EPIC in order to prevent the charge from being passed to the patient and/or insurance provider in error. The sponsor is then billed for all charges of participants within the study (clinical trial*)* by Cancer Center staff on *a* periodic basis, usually monthly or quarterly, through another system outside of EPIC called Velos[2].
>
> EPIC and Velos do not interface, thus charges are not transferred between the systems. The sponsor is billed based upon the service provided to the patient. Charges to the sponsor are based on contracted rates for specific milestones recorded into Velos by Cancer Center staff. All billings to the sponsor in conjunction with a clinical trial are processed and tracked through Velos.

In addition to the specialized billing knowledge required for cancer clinical trials, there are limited automated controls and staffing in place to determine whether an error in billing has occurred since information is not reconciled between EPIC and Velos.

Without additional monitoring, such as spot checks or a reconciliation process, there is a risk that charges could be incorrectly billed. This could result in uncollected funds if a charge is incorrectly zeroed out in EPIC and assumed to have been properly billed to the sponsor. The level of financial impact would depend upon the number of charges that may have been improperly zeroed out. Billing errors could result in incorrectly billing government health care and/or private insurance companies.

Audit did not quantify the impact of improper billing. Testing would involve an extensive manual review of individual patient charges in EPIC, Sponsor invoicing (derived from procedures performed on a group of patients involved in a clinical trial) and a comparison to a contractual budget/coverage analysis. However, based on our walkthrough of the process, and a review of the current volume and sum of charges, Audit does not believe that the financial impact would be significant should errors occur.

Management and staff[3] are currently working on ways to further reduce the risk of errors within the billing process by adding medical codes to the procedures listed in Velos which correspond with EPIC. In doing so, it will make it easier for staff to analyze the patient's clinical trial charges and determine which ones should be billed to sponsors. Additionally, the added medical codes will allow staff to reconcile billing information between EPIC and Velos by comparing all charges (sponsor paid and the charges that were zeroed out in EPIC) by procedure code to ensure charges were correctly billed to the proper entity.

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[2] *Velos is a clinical trial management system that is used to assist the research team in the tracking and reporting of patient related activities.*

[3] *Currently, there are collaborative efforts underway between the Cancer Center and the Clinical Trials Office, under the Office of the Vice President of Research, to work on medical coding that will be added to Velos. The Applications System Analyst working on this project works primarily on Velos and is technical support for both departments, but officially reports to the Office of the Vice President of Research.*

Added Controls

During this audit, Management successfully implemented a key control that ensures all patients who have an active status[4] in Velos are appropriately and timely flagged in EPIC. Cancer Center staff are now provided a daily exception report of all cancer trial patients that have completed a patient consent form but have not been entered into Velos timely[5]. Should a patient's active status not be properly entered into Velos, the system will not flag the patient in EPIC as a clinical trial patient, which could result in patients and/or their insurance providers paying for a charge that was supposed to have been paid by the Clinical Trial Sponsor.

Risk Ranking: Medium

Recommendation

The Director of the Cancer Center should:

1. Ensure all pertinent operating procedures relating to the administrative process (to include billing of sponsors) for cancer clinical trials are appropriately documented and accessible to staff.

2. Enhance monitoring efforts, including the performance of spot checks, within the clinical trials administrative process to help further ensure the accuracy and completeness of the charges billed.

3. Continue collaborating with the Clinical Trials Office under the Office of the Vice President of Research to align medical coding from EPIC with Velos in order to improve monitoring efforts to reduce the risk of billing errors.

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[4] *Active Patient Statuses in Velos are: Consent Signed, Waiver of Consent, Pre-Screen, Screening/Eligibility, Pre-Screen Failure, Screen Failure, Re-Screen, Enrolled and Follow-Up.*

[5] *Consent forms are required by department policy to be entered into Velos within 24 hours of receipt from the patient.*

Management Response

1. The Mays Cancer Center is currently updating all our SOPs related to clinical research and new SOPs covering these processes are being developed and implemented. In addition, Cancer Center leadership recognizes the need for additional personnel to assist Ms. Valdez with research billing and we are currently recruiting for such an individual.

2. Spot checks are being performed quarterly by the CTO Finance Manager. An SOP is under development to cover this process.

3. The Mays Cancer Center CTO will continue to collaborate with the VPR CTO on process improvements, including those mentioned above.

Appendix A – Audit Issue Ranking Definitions

The audit issue was ranked according to the following University of Texas System Administration issue ranking guidelines:

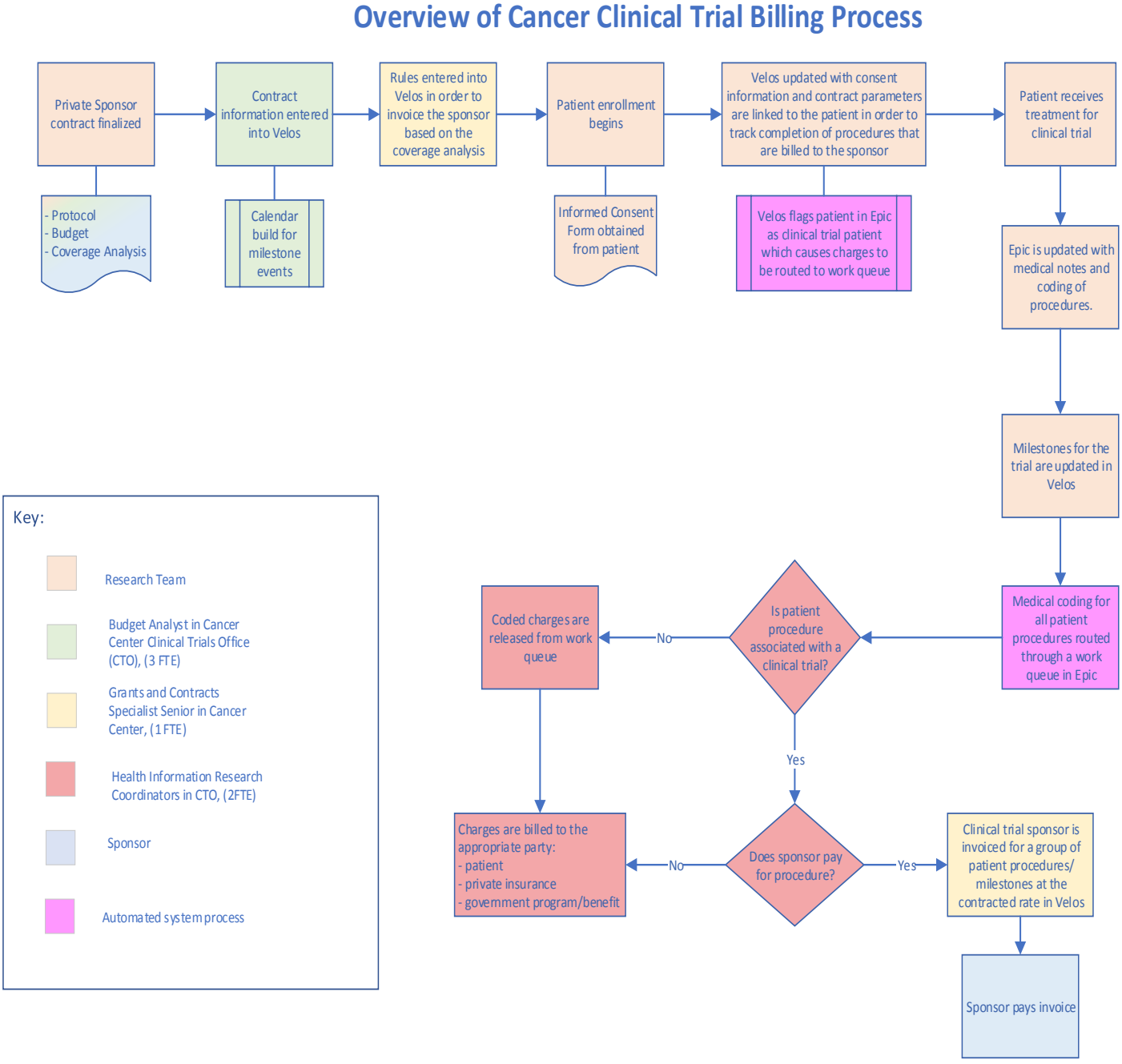
- ***Priority*** – A Priority Finding is defined as an issue identified by internal audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of UT Health San Antonio or the UT System as a whole.

- ***High*** – A finding identified by internal audit that is considered to have a medium to high probability of adverse effects to UT Health San Antonio either as a whole or to a significant college/school/unit level.

- ***Medium*** – A finding identified by internal audit that is considered to have a low to medium probability of adverse effects to UT Health San Antonio either as a whole or to a college/ school/unit level.

- ***Low*** – A finding identified by internal audit that is considered to have minimal probability of adverse effects to UT Health San Antonio either as a whole or to a college/ school/unit level.

Appendix B – Overview of Cancer Clinical Trial Billing Process



Appendix C – Glossary

Budget: Details the cost of each procedure required by the study.

Calendar: Schedule of all procedures required by the study that is assigned to each participant in the clinical trial.

Clinical Trial: A clinical study in which participants are assigned to receive one or more treatments so that researchers can evaluate the effects of the treatment on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Clinical Trial Agreement/Contract: An agreement between the Health Science Center and the financial sponsor. The contract includes multiple documents such as the Budget, Coverage Analysis, and Protocol.

Coverage Analysis: Identifies the party responsible for the costs of each clinical service performed as part of a research project. The coverage analysis indicates all of the procedures required by the study plan as well as the number of times a procedure is performed.

EPIC: The Health Science Center's system used to store patient medical records.

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.

Informed Consent Form: The consent document which a participant signs prior to being enrolled in a clinical trial.

Milestone: Time points in the study in which the Institution expected payment from the research sponsor. Milestones are comprised of specific procedures or events that need to have been completed in order to invoice the sponsor.

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.

Research Team: Includes the Principal Investigator, Data Manager, Study Coordinator and Study Nurse who are responsible for administration of the clinical trial.

Sponsor: The organization or person who oversees the clinical study and is responsible for analyzing the study data and who may be responsible for a certain level of study funding.

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

Velos: Clinical Trial Management System application that supports the management of common administrative, financial and research activities such as subject enrollment, calendars, budgets and various project statuses.