November 19, 2018

PATTY MAYSENT
Chief Executive Officer, UC San Diego Health
7970

Subject: ***Clinical Research Billing Encounter-Linking Pilot***
Report 2019-09

The final report for Clinical Research Billing Encounter-Linking Pilot, Report 2019-09, is attached. We would like to thank all members of the department for their cooperation and assistance during the review.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

David Meier
Director
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Attachment

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UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Clinical Research Billing Encounter-Linking Pilot
Report No. 2019-09
November 2018

FINAL REPORT

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I. EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed a review of Clinical Research Billing (CRB) Encounter-Linking Pilot (Pilot) as part of the approved audit plan for Fiscal Year 2018-19. The review was conducted in collaboration with the Research Compliance team within UC San Diego Health (UCSDH) Compliance Advisory Services (Compliance). The objective of our review was to evaluate whether Encounter Linking Pilot processes were effective, resulted in accurate and compliant clinical research charging and billing practices for studies participating in the pilot, and did not lessen the current billing accuracy rate.

We concluded that CRB Encounter Linking processes were generally effective, and generally resulted in the accurate processing of charges to the patient or study account for studies participating in the pilot. Further evaluation on the CRB Office workload impact, and development of a proper training, communication and rollout plan by management would be key factors for an effective enterprise wide rollout of the Encounter Linking process.

However, our review identified some key observations that should be considered prior to an enterprise wide deployment of the new Encounter Linking workflow, such as the need to add complex studies to the Pilot, recurring risks of inaccurate or untimely Velos data, and lack of a safety net in the review of charges before routing. Also, additional or expanded training may be needed, and certain technical issues should be resolved before enterprise-wide deployment. The results from the review, including key observations, were presented to the CRB Steering Committee on November 13, 2018 for their consideration in the further deployment of Encounter Linking to the research community. We also determined that Encounter Linking appeared effective in addressing issues identified in a prior AMAS audit in 2016, therefore the management action plans related to that review have been closed.

II. BACKGROUND

Audit & Management Advisory Services (AMAS) has completed a review of Clinical Research Billing (CRB) Encounter-Linking Pilot (Pilot) as part of the approved audit plan for Fiscal Year 2018-19. The review was conducted in collaboration with the Research Compliance team within UC San Diego Health (UCSDH) Compliance Advisory Services (Compliance). This report summarizes the results of our review.

Under a program initiated by UC Office of the President in 2010, UC San Diego (UCSD) implemented a new Clinical Research Billing (CRB) process using a clinical trial management system (CTMS), Velos, in order to facilitate clinical trial management and promote accurate clinical research billing. A CRB Steering Committee comprised of faculty and staff developed a process to automate reconciliation of research related events and associated billing. Effective October 26, 2013, Velos electronically interfaced with the Epic Enterprise billing system (Epic) through a research charge router, Work Queue (WQ) 1914, on a daily basis to direct billable study charges per the Coverage Analysis (CA) to the research bulk account, the study participant and/or their insurance. The Velos-Epic interface logic appeared to be primarily working as designed when Velos data was complete and updated timely, however, the process faced some workflow and system challenges.

In response to these challenges, UCSD Health (UCSDH) management initiated a pilot project to evaluate an Epic-designed Encounter Linking workflow for CRB. The purpose of the Pilot was to ensure the new workflow functionality was stable and process sustainable without sacrificing compliance. Following the results of the Pilot, management would consider an enterprise-wide scale roll-out plan.

The CRB Encounter Linking workflow reviewed charges at the patient encounter level, through linking of study procedures in Epic. Charges for linked encounters routed to a new workflow, known as the Research Billing Review (RBR). The Velos-Epic algorithm segregated linked charges into study-related and non-study, and the CRB Team conducted a manual review of charges for linked encounters to ensure appropriate routing of charges for research procedures.

A Pilot 2.0 was initiated in early 2018 and as of May 2018, 38 studies had been added to the Pilot from five departments: Shiley Eye Institute, Cardiology, Stem Cell Center, Pediatrics and Surgery. Under Pilot 2.0, the study team performed linking for study encounters. A separate initiative, Pilot 3.0, was initiated in August 2018, in which the CRB Office performed the encounter linking function, based on Velos event reports and communication from study teams. As of September 2018, there were 15 studies in Pilot 3.0, including 13 studies from Moores Cancer Center (MCC).

III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

The objective of our review was to evaluate whether Encounter Linking Pilot processes were effective, resulted in accurate and compliant clinical research charging and billing practices for studies participating in the pilot, and did not lessen the current billing accuracy rate. In order to achieve our objective, we performed the following:

- Selected a judgmental sample of 30 subjects from the Pilot 2.0 studies, and for each subject (for study procedures with dates of service between study Pilot 2.0 implementation date to June 30, 2018)[1]:
    - Identified completed research procedures, per Velos and traced each study procedure to the encounter in Epic to determine whether linking was performed,
    - Evaluated whether charges for linked encounters were appropriately routed within the Research Billing Review (RBR) workflow in accordance with the study CA, and
    - Analyzed whether issues identified in prior AMAS audit would be effectively resolved through the Pilot;
- Interviewed a judgmental sample of study coordinators to confirm study events and obtain feedback on the CRB Encounter Linking process;
- Interviewed the following staff to get an understanding of Velos reports, impact on WQ1914 with the new workflow, Encounter Linking workflow logic, and CRB review status monitoring reports:
    - CRB Office Director,
    - UCSD Health Information Services (IS) Business Financial Analyst,
    - Velos Application Support Manager;
- Analyzed the root cause of any discrepancies identified through review of the audit trail for charge routing, and coordination with the UCSDH IS team as appropriate;
- Evaluated cutover processes from current CRB process for studies migrating to new workflow;
- Reviewed WQ1914 reports for charges from Pilot studies;
- Reviewed CRB Dashboard at defined time points to evaluate timeliness of encounter review by CRB team and any reports/metrics used;
- Evaluated the proposed centralization of encounter linking function (Pilot 3.0); and
- Summarized and presented AMAS and Compliance results and observations to the CRB Steering Committee.

IV. CONCLUSION

Based on our review, we concluded that CRB Encounter Linking processes were generally effective, and generally resulted in the accurate processing of charges to the patient or study account for studies participating in the pilot. Further evaluation on the CRB Office workload impact, and development of a proper training, communication and rollout plan by management would be key factors for an effective enterprise wide rollout of the Encounter Linking process.

Our review identified that only 40% of the total study encounters (with charges) were linked or appeared in the RBR and of the total study encounters, 6% had charges that were routed inappropriately.

[1] AMAS and Compliance reviewed the same sample of studies and subjects, with AMAS tracing charges from the point of origin to the study account/patient account, and Compliance performing a claims level review working backward from the claim to the patient account.

Causes for discrepancies varied, but primarily related to previously-identified issues unrelated to the Encounter Linking workflow, including late or erroneous Velos data entry by study teams (non-compliance with Velos Guidelines), and incorrect administration of case rates for certain studies. In a few cases, discrepancies were a result of the Encounter Linking workflow, if encounters were not linked or charges inappropriately routed in the RBR by the CRB Office.

Timelines for CRB team review of charges in the RBR appeared reasonable. Additional tools for management monitoring and reporting may be considered if the Encounter Linking workflow is fully deployed.

Our review identified some key observations that should be considered prior to an enterprise wide deployment of the Encounter Linking workflow including:

- Level of Complexity of Pilot Studies: Studies of increased complexity (mixed billing to third-party payors and study) should be added in the Pilot to further evaluate the linking workflow and compliance.

- Reoccurring Risks: Non-compliance with Velos Guidelines noted in prior audits of the current CRB workflow remained, and impacted appropriate routing of study charges. Continued reinforcement of practices to facilitate effective and compliant billing, coupled with oversight and accountability from a performance management standpoint are key considerations for an effective CRB process.

- Lack of Safety Net: The Encounter Linking workflow is reliant on timeliness and accuracy of encounter linking, and if not linked, charges would route to the patient account. The current WQ 1914, which holds unmatched charges (based on Velos-Epic algorithm) within a defined timeframe from Velos dates for further review, will be phased out if Encounter Linking is deployed.

- Formalized Training: Reinforcement of linking timeliness and expanding training to all relevant personnel who perform linking should be considered.

- Technical Issues: A continued need for dedicated IS support for research was required. Our review noted issues with professional fee charges on hold and, instances of linked charges not appearing in the RBR that need to be evaluated.

- Pilot 3.0: The impact on the CRB Office workload of centralizing the encounter linking function needs to be considered, in addition to the continued reliance on Velos data as the source for routing charges, which may not be accurate or captured timely.

The results from the review, including key observations, were presented to the CRB Steering Committee on November 13, 2018 for their consideration in the further deployment of Encounter Linking to the research community. We also determined that Encounter Linking appeared effective in addressing issues identified in a prior AMAS audit in 2016, therefore the management action plans related to that review have been closed.