

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
AUDIT & ADVISORY SERVICES**

**Clinical Research Billing Review  
Project #22-036**

**August 2022**



University of California  
San Francisco

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**Winona Ward**  
Assistant Vice Chancellor  
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**SUBJECT: Clinical Research Billing Review**

Audit and Advisory Services (“A&AS”) conducted a review of Clinical Research processes. The purpose of this review was to assess controls and processes to ensure appropriate billing for clinical research activities.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

Our review was completed and the preliminary draft report was provided to department management in June 2022. Management provided their final comments and responses to our observations in August 2022. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Committee, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn  
Chief Audit Officer  
UCSF Audit and Advisory Services



## EXECUTIVE SUMMARY

### I. BACKGROUND

As a planned audit for Fiscal Year (FY) 2022, Audit & Advisory Services (A&AS) partnered with Deloitte & Touche LLP and conducted a clinical research billing audit to assess the effectiveness, adequacy, and compliance of processes specific to the clinical research billing program.

The Office of Clinical Trial Activation (OCTA) is the centralized one-stop shop for clinical research activation, whose aim it is to streamline, standardize and improve support for the start-up of clinical research activities at UCSF. OCTA services include setting up trials in OnCore, providing coverage analysis, and opening and modifying Medical Center APeX billing accounts.

The formal Coverage Analysis process ensures compliant clinical research billing (CRB). A Coverage Analysis (CA) identifies all clinical items or services associated with a particular clinical trial, including identification of the financially accountable party, such as the trial sponsor, other funding source, patient, or a third-party payor.

Medicare's Clinical Trial Policy (NCD 310.1) mandates the coverage of routine costs for Qualifying Clinical Trials (QCTs) as well as items deemed "reasonable and necessary" to treat and diagnose complications arising from participation in a clinical trial. As part of this coverage, Medicare requires certain pieces of identifying information to be affixed to claim documentation for each subject including the National Clinical Trial (NCT) number of the trial, the Z00.6 ICD-10 code, Condition Code 30, and Q1/Q0 modifiers on applicable items and services.

As of June 1, 2013, all new studies at UCSF were required to receive Coverage Analysis before study activities begin, even if the study does not have any items or services that are or might be invoiced to Medicare. Coverage Analysis is necessary for all clinical research projects that have medical procedures or services provided to subjects at UCSF.

OnCore is a comprehensive Clinical Research Management System (CTMS) designed for clinical research operations and data management and is the system of record for coverage analysis of all clinical research studies conducted at UCSF. OnCore also supports biospecimen management and a registry platform for defined populations and/or clinical events. OnCore provides a secure, standardized, and reportable database, and permits efficient sharing of protocol information between the Study Team and the Coverage Analyst.

Due to the nature of clinical research billing processes, there is an inherent risk that claims are inaccurate / missing which may lead to billing issues and a potential loss in revenue. This was factored into our scope and internal audit procedures performed.

### II. AUDIT PURPOSE AND SCOPE

An internal audit was performed to evaluate of the effectiveness of the clinical research billing program. Consideration was given to adherence to billing determinations made in institution-approved coverage analyses; prevention of "double dipping," or charging more

than one payor for the same service; adherence to Medicare's clinical research billing guidelines (NCD 310.1), including affixing modifiers and other required information; and congruency of system records for tracking clinical research subjects within OnCore and APeX.

The scope of the review covered transactions and activities for Calendar Year 2021 at UCSF. The internal audit procedures included the following:

- Obtained visit data for all visits in Calendar Year 2021 for sample selection and selected 5 studies for review
- Reviewed billing determinations, claim filing, and research claims information for a pre-defined universe of clinical research studies selected from the full portfolio based on complexity of study, accrual, service line, study facility, and study type.
- Reviewed claim information for representative subjects selected randomly for each study with consideration given to duration on-study within the review period and payor.
- Reviewed maintenance and congruency of clinical research subject records across systems (OnCore, APeX) including ensuring all study-related services were provided during the appropriate enrollment period (consent date to off-study).
- Quantified over/under-payments from third party payors including "double dipping."
- Quantified error rates for research billing including adherence to coverage analysis determinations and inclusion of required information on research claims as defined by Medicare (i.e., NCT numbers, Q1/Q0 modifiers, Condition Code 30, and ICD-10 Z00.6 diagnosis codes).
- Provided high-level recommendations for improvement of clinical research billing processes to any identified issues from occurring in the future.
- Business process walkthroughs were not conducted with study team or clinical research billing program.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in June 2022.

### III. **SUMMARY**

The results of the internal audit identified opportunities for UCSF to enhance the current design of the clinical research billing process. The areas of potential improvement in the design regarding the clinical research billing process are briefly summarized below and discussed more thoroughly in the "Observations and Management Corrective Actions ("MCA")" section that follows:

The specific observations from this review are listed below.

1. Instances of non-adherence to clinical research billing guidelines (NCD 310.1) were identified.
2. One instance of double charging of a procedure was noted.
3. The Claim and Coverage Analysis were not always in alignment and there were missing determinations in the Coverage Analysis.
4. Procedures were potentially billed to research in error.
5. Study visit data was not always found for study visits that were expected to occur.

**IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (MCAs)**

<b>No.</b>	<b><u>Observation</u></b>	<b><u>Risk/Effect</u></b>	<b><u>Recommendation</u></b>	<b><u>MCA</u></b>
1	<p><b><i>Instances of non-adherence to clinical research billing guidelines (NCD 310.1) related to coding concepts were identified.</i></b></p> <p>Coding concepts reviewed during the audit included appropriate NCT number, revenue codes, condition codes, diagnosis codes and modifiers.</p> <p>Missing information identified included:</p> <ul style="list-style-type: none"> <li>• One instance of a missing ICD-10 code.</li> <li>• One instance of a missing NCT number.</li> <li>• Fifteen out of 290 samples had missing Q1 modifiers.</li> </ul>	<p>If claims do not adhere to mandated clinical trial policy (NCD 310.1 guidelines), service rendered for research may be charged incorrectly to the patient and/or payor. Claims may also be rejected/denied and returned to the provider. While payers may not deny claims specifically based on modifier information, it is a best practices data requirement by CMS that should be adhered to for all payers to minimize risk.</p>	<p>Management should consider:</p> <ul style="list-style-type: none"> <li>• Analyzing whether inaccuracies were caused by manual intervention (i.e., coders, billers, or other personnel) or by systematic malfunction. If the inaccuracies were derived by individuals (i.e., coders, billers, etc.), management should develop and provide the appropriate training to the responsible individuals. If the inaccuracies were developed from a system or interface issue, management should collaborate with the Information Technology (“IT”) department to pinpoint and resolve the issue.</li> <li>• Reviewing the identified claims that were inaccurately billed to identify opportunities for training and/or workflow implementation to capture missed charges.</li> </ul>	<p>Research Revenue Cycle validated that the charges were routed correctly and commercial claim logic is applicable to these charges and functioning appropriately per UCSF Health policy.</p> <p><b>Responsible Party:</b> Clinical Research Billing Program, Departments with Clinical Trial Study Teams Office of clinical research compliance/Regulatory Affairs</p> <p><b>Completion Date:</b> August 2022</p>
2	<p><b><i>One instance of double charging of a procedure was noted.</i></b></p> <p>One procedure was duplicated on a claim and was also charged in excess. The estimated cost of additional billing was \$1,847.66 to Aetna.</p>	<p>There is a risk that the manual process to submit, complete, and reconcile orders in addition to charging procedures could result in illegible documentation, manual errors, and/or missing documentation. As such, orders and charges may be lost and/or incorrectly captured which may</p>	<p>Management should consider:</p> <ul style="list-style-type: none"> <li>• Reviewing aforementioned charges to ensure no paybacks are required.</li> <li>• Conducting training for research staff including but not limited to CRCs, research nurses, and all clinical staff who complete, manage, and finalize research orders.</li> </ul>	<p>The procedure was reviewed and investigated, but it was unable to be ascertained that a double charge of a procedure did occur. Further investigation will occur to validate whether the charge is appropriate on the CMS 1450 claim form.</p> <p><b>Responsible Party:</b></p>

No.	Observation	Risk/Effect	Recommendation	MCA
		<p>further constrain the research billing process and lead to a loss in revenue.</p>		<p>Clinical Research Billing Program, Departments with Clinical Trial Study Teams, UCSF clinical staff</p> <p><b>Target Completion Date:</b> September 30, 2022</p>
<p><b>3</b></p>	<p><b><i>The Claim and Coverage Analysis were not always in alignment and there were missing determinations in the Coverage Analysis.</i></b></p> <p>There was one instance of a lab which should have been billed to research per the Coverage Analysis but was considered Standard of Care (SOC) on the claim and the lab was billed to Anthem. The estimated total cost of the lab was \$219. The lab was not reported on ZZ claim report, confirming observation.</p> <p>Additionally, several items in the coverage analysis did not have research or standard of care (SOC) determinations for all study visits throughout the study, such as telephone encounters.</p>	<p>There is an operational risk if the Coverage Analysis is not completed adequately. The Coverage Analysis can be considered a translation of procedures associated with trial Schedule of Events into revenue cycle billing and coding. Items not documented correctly cannot be coded and thus will not be reimbursed.</p>	<p>Management should consider:</p> <ul style="list-style-type: none"> <li>• Reviewing aforementioned charges to ensure no paybacks are required.</li> <li>• Obtaining business process for each department which completes clinical trials</li> <li>• Define institution wide processes and training for clinical trial billing</li> <li>• Conducting training for research project leads who oversee end-to-end clinical trial management and routinely complete CA.</li> <li>• Identifying an appropriate resource to perform reconciliation, provide education, and quality assurance to identified resources.</li> </ul>	<p>Charges have been re-reviewed and corrected, errors reviewed with RSCH Rev Cycle charge reviewer.</p> <p><b>Responsible Party:</b> Clinical Research Billing Program, Departments with Clinical Trial Study Teams Office of clinical research compliance/Regulatory Affairs</p> <p><b>Completion Date:</b> August 2022</p>
<p><b>4</b></p>	<p><b><i>Procedures were potentially billed to research in error.</i></b></p> <p>Two instances of an Echocardiogram (professional fee) were billed to research but there was no indication that they were required for the study visit.</p> <p>Two instances of an Echocardiogram (EKG) (service fee) were billed to research</p>	<p>There is a risk that the manual process to submit, complete, and reconcile orders, procedures in addition to the CA could result in illegible documentation, manual errors, and/or missing documentation. As such, orders and charges may be lost and/or incorrectly</p>	<p>Management should consider:</p> <ul style="list-style-type: none"> <li>• Reviewing aforementioned charges to ensure no paybacks are required.</li> <li>• Obtaining business process for each department which completes clinical trials</li> <li>• Conducting training for research staff including but not limited to CRCs, study managers, and</li> </ul>	<p>Charges have been re-reviewed and corrected, errors reviewed with RSCH Rev Cycle charge reviewer.</p> <p><b>Responsible Party:</b> Clinical Research Billing Program, Departments with Clinical Trial Study Teams Office of clinical research compliance/Regulatory Affairs</p>

No.	Observation	Risk/Effect	Recommendation	MCA
	<p>without any indication that this was required for study visit.</p> <p>Four instances were identified where there was no documentation of blood draw or EKG billed to research for study visits.</p> <p>Therefore, these events potentially occurred at a research facility generating no charges in system.</p>	<p>captured which may further constrain the research billing process and lead to a loss in revenue.</p>	<p>departmental financial associates who sign off charges</p>	<p><b>Completion Date:</b> August 2022</p>
<p><b>5</b></p>	<p><b><i>Study visit data was not always found for study visits that were expected to occur.</i></b></p> <p>During the course of review, encounters or related Hospital Billing (HB) and Professional Billing (PB) claims were not found for 11 study visits that were expected to occur.</p> <p>Therefore, the reviewers were unable to validate that study dates occurred with accuracy.</p>	<p>Without complete and accurate records in OnCore and APeX to indicate precisely when study visits occurred, there is the potential for confusion and gaps in ascertaining that study visits occurred according to the study protocol. This could lead to missed or inaccurate charges.</p>	<p>Management should consider:</p> <ul style="list-style-type: none"> <li>• Reviewing aforementioned identified missing data to verify that studies did not occur where they were expected to occur.</li> <li>• Obtaining business process for each department which completes clinical trials.</li> <li>• Conducting training for research staff including but not limited to CRCs and study managers to ensure study visit data reflects actual visit dates.</li> </ul>	<p>Charge routing logic was investigated and determined to have been routed correctly per billing designations in the Coverage Analysis. Conversion to telehealth visits and corresponding billing claims revisions were in response to the global COVID-19 pandemic, per “DHCS guidance letter for Medi-Cal Payment for Telehealth and Virtual/Telephonic Communications Relative to the 2019-Novel Coronavirus (COVID-19)” dated 1/05/21.</p> <p><b>Responsible Party:</b> Clinical Research Billing Program, Departments with Clinical Trial Study Teams Office of clinical research compliance/Regulatory Affairs</p> <p><b>Completion Date:</b> August 2022</p>