UC Irvine Health

COMPLIANCE PROGRAM POLICY: Clinical Research Billing Audit Policy

Effective Date: August 1, 2014

Last Updated:

I. POLICY

All UC Irvine Health departments engaged in clinical research may be reviewed periodically for research billing compliance. The Office of Research Oversight, known hereafter as ORO, will identify specific departments, researchers and research studies to be reviewed.

1. Routine retrospective audits, and as applicable for cause audits, will be conducted of billed clinical research claims with a primary focus on high risk protocols. High risk protocols are defined as those with:
    a. High volume of clinical services
    b. Mixture of services billed to the study and services billed to third party payers.

2. For all clinical trials, the coverage analysis will also be audited to ensure compliance with the Medicare National Coverage Determination.

3. The first patient on a newly enrolling protocol will be audited by the compliance auditors prior to the first claim submission to a third party payer or to the protocol sponsor.

4. Registration of research participants will be reviewed by the compliance auditors to ensure accurate registration of research participants in the electronic medical record system.

5. If a significant issue of non-compliance is determined in the auditing process, a focused review will be conducted as follows:
    a. All patients on the protocol will be audited from the point at which the problem began, or
    b. All patients on the protocol will be audited to the initiation of the study.

II. PURPOSE

The purpose of the clinical research billing audit it to provide an internal mechanism for quality assurance, quality improvement and education pursuant to research financial compliance and clinical research billing. In addition, ORO helps provide support on complying with all institutional polices and federal and state laws and regulations.

III. REFERENCES

- ✓ 21 CFR 50.25 (b)(3): FDA Regulation on Human Subjects, Informed Consent
- ✓ 42 CFR 405 Federal Health Insurance for the Aged and Disabled, § 203 FDA categorization of investigational devices
- ✓ 45 CFR 46.116(b) (3): Department of Health and Human Services (DHHS) Regulations on the Protection of Human Research Subjects
- ✓ American Medical Association (AMA) Code of Procedural Terminology (CPT)
- ✓ American Medical Association (AMA) Evaluation and Management Services Documentation Guidelines
- ✓ California Senate Bill No. 37, 2001. Health insurance: coverage for clinical trials
- ✓ Centers for Medicare and Medicaid Services (CMS) Medicare Claims Processing Manual, Pub 100-4; Chapter 32, § 69.6 (Billing for Clinical Trials)
- ✓ Centers for Medicare and Medicaid Services (CMS) Medicare National Coverage Determination for Clinical Trials 310.1
- ✓ Centers for Medicare and Medicaid Services (CMS) National Correct Coding Initiative Edits (NCCI Edits – Physicians)
- ✓ False Claims Act, 31 U.S.C. 3729
- ✓ Federal Register 65-Office of Inspector General (OIG) Compliance Program Guidance for Third Party Medical Billing companies, Hospitals, Individual and small group Physician Practices
- ✓ Federal Register 68, Office of Inspector General (OIG) Compliance Program for Pharmaceutical Manufacturers
- ✓ Office of Inspector General; Office of Management and Budget Circular A-100, A-21
- ✓ Patient Protection and Affordable Care Act (PPACA), HR 3590, § 2709. Coverage for Individuals Participating in Approved Clinical Trials

Original Adoption & Prior Revision Dates: New

Policy Owner(s): **Chief Compliance & Privacy Officer**
Research Compliance Officer

Approvals:

Executive Compliance Board	Insert Date
Governing Body	Insert Date

Attachment A

I. GUIDELINES

A. Ongoing Protocols: Retrospective Audits

1. ORO will obtain a list of all patients on the protocol being audited from the study coordinator and upload the list of patients into MD Audit Hospital Audit software. The software will be used to audit all claims for the patient in the designated time frame. The same list of patients will be loaded into MD Audit Professional to obtain the corresponding professional billing claims for the patients.

2. Compliance auditors will:

    a. Review the coverage analysis in OnCore® and verify the billed claims to ensure the following are coded on the claim correctly:

        i. Diagnosis code includes V70.7

        ii. Condition code 30 is present on claim billed to third party payer

        iii. Research study services have appropriate Q0, Q1 modifier

        iv. The ClinicalTrials.Gov registration number appears on the claim.

    b. All line items on the claim will be reviewed.

3. If items or services on the claim were billed to the wrong payer, the compliance auditor will identify each applicable line item and indicate “finding as research service item should be billed to sponsor”.

4. If all services on the claim should have been billed to the study, compliance auditor will indicate that the payer should be the study.

5. If all the services on the claim were related to the study and were correct, the compliance auditor will identify the items is correct by noting the field with “agree” on the claim level and in comments add “**study claim billed correctly”.**

6. If the patient is a Medicare Advantage (MA) patient and had research services billed that were billed to the MA plan, the compliance auditor will notate each applicable

line item and indicate "Research service should be billed to Medicare Fee for Service instead of to Medicare Advantage".

7. The same list of patients is entered into MD Audit Professional, and a listing of corresponding professional claims will be audited as above.

8. If all charges are correct and coded correctly, the report is sent to the Clinical Research Billing Unit Manager, the Research Compliance Officer, the Chief Compliance Officer, the Senior Director for Finance, the Principal Investigator, the study coordinator, the Department Administrator, and the Department Chair.

9. If there are errors in either the hospital or professional coding or charging, the auditors will send the report of the preliminary findings to the CRB.

10. Discrepancies with the findings will be resolved with the CRB.

11. After the audit(s) are finalized, the final report(s) is sent to the individuals identified above as well as the PFS and applicable professional fee billing directors.

12. The list of claim corrections must be the sent to PFS and or the applicable professional fee billing department.

13. The compliance auditors will verify that billing corrections are completed.

14. If coverage analysis appears to be in error, the auditor will notify the person who completed the coverage analysis, Research Support Services and/or Cancer Center to verify. The auditors will ensure corrections are made to coverage analysis if needed.

B. <u>All Protocols: Coverage Analysis</u>

1. The compliance auditor will obtain a list from the local clinical trial management system (OnCore®) of new protocols entered into system and verify the list against the listing of approved protocols provided by the IRB. In addition, ORO will receive a monthly report from the Office of Research Support Services, known hereafter as RSS, of all of their completed coverage analysis in OnCore®.

2. Validate determination of billing risk made by the Clinical Research Finance Assessment Office, known hereafter as CRFA, and RSS utilizing:

    a. Audit Tools,

b. Protocol and/or Protocol Narrative,
c. Clinical Trial Agreement,
d. Subject Informed Consent, and
e. Budgets.

3. Studies with billing risks are reviewed to verify if trial is a "qualified clinical trial".

4. The compliance auditor will review the clinical trial agreement:
   a. Confirm that all items/services that are billable to the sponsor/research account per the contract are on the coverage analysis according to the timeline in the trial.
   b. Review contract for subject injury and adverse event payment and match it with the cost language in the consent.
   c. Identify the services the sponsor is paying for and verify that the coverage analysis does not show we are billing a third party payer for those services.

5. The compliance auditor will review the informed consent:
   a. Verify that the informed consent addresses patient financial responsibility and specifies items/services covered by the research and the sponsor
   b. The cost language for adverse events and subject injury is matched to the clinical trial agreement.

6. The compliance auditor will review the coverage analysis to:
   a. Identify the correct payer is documented in the coverage analysis
   b. Review study procedure section and schema in the protocol to compare items/services required by the protocol and those listed on the coverage analysis, not just those items listed in the study calendar
   c. Note any discrepancies that may generate a charge
   d. Verify that the designations of items/services in the coverage analysis are accurate and include supporting comments in OnCore®
   e. Verify that all HCPCS and CPT codes are correct
   f. Verify that HCPCS and CPT codes are appropriately identified as routine costs in a qualified clinical trial or should be billed to study
   g. Verify ClinicalTrials.Gov registration number appears in system
   h. Confirm that the coverage analysis is consistent with the protocol, the informed consent, and the clinical trial agreement

i. If the trial is a device trial, verify that Noridian has been notified of study and IDE approval letter is uploaded into OnCore®

j. Completed coverage analysis OnCore® can be used for patient level billing and invoicing

k. There are no billable items for services that are for research purposes only.

7. If coverage analysis appears to be in error, the compliance auditor will notify the person who completed the coverage analysis, RSS and/or Cancer Center to verify.

8. The compliance auditor will ensure corrections are made to coverage analysis, if needed.

9. Studies identified as not requiring a coverage analysis are verified by the following:

   a. Documentation available in OnCore®

   b. Verify accuracy of determinations that a coverage analysis is not required.

10. After review of the above elements, a preliminary report of audit findings is sent to the necessary personnel for corrections.

11. A final report of audit findings will be provided to CRFA, RSS, and the Principal Investigator.

12. If a corrective action plan is requested, appropriate personnel will have to respond in a timely manner.

13. After ORO has verified that the action plan has been implemented and all outstanding items have been fixed, the audit will close.

C. <u>New Protocols: First Patients</u>

1. The compliance auditors will be notified by the Clinical Research Billing Unit, known hereafter as CRB, of any protocol with a first patient enrollment. The compliance auditors will review the billing claims after review by the CRB.

2. The compliance auditors will:

   a. Determine if coverage analysis has been previously reviewed and validated by another compliance staff member

   b. If so, the audit will proceed. If not, the coverage analysis will be audited as described above in section a.

3. Compliance auditor will review the coverage analysis in OnCore® and billed charges to verify that:
    a. Charges are billed to appropriate payer
    b. HCPCS and CPT codes are correct
    c. HCPCS and CPT codes have appropriate modifiers on line items (Q0 and Q1)
    d. Diagnosis codes have been assigned correctly
    e. ClinicalTrials.Gov registration number appears in system
    f. If charges are correct and coded correctly, they will notify the CRB so that the bill hold can be released and the claims dropped.
4. If any errors are detected, the compliance auditors will notify the CRB to make the corrections. The compliance auditors will verify that corrections are made.
5. If errors are identified on the first patient, the process will be repeated for the second patient.
6. Verify that the CRB is using the coverage analysis as recommended.
7. If the coverage analysis appears to be in error, the compliance auditor will notify the person who completed the coverage analysis, RSS and/or Cancer Center to verify. The compliance auditor will ensure corrections are made to coverage analysis, if needed.

D. <u>Study Participants: Registration</u>

1. The compliance auditor will compare the subject enrollment log from the research regulatory binder with the CRB Subject Tracking Access Data Base to validate:
    a. All patients are registered correctly as a research visit and in a timely manner
    b. Date of consent is correct.
2. The compliance auditor will compare the enrollment log to list of patients pulled from Quest and validate:

a. All patients are registered correctly as a research visit and in a timely manner

b. Date of consent is correct.

3. If there are any discrepancies the CRB unit will be notified and will have to make the necessary corrections.