Research Billing Compliance: A Case Study

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NYU School of Medicine

Three Phases to Research Billing Compliance

<table>
<thead>
<tr>
<th>Setup</th>
<th>Activity</th>
<th>Reconciliation</th>
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<tbody>
<tr>
<td>Information gathering</td>
<td>Research Encounter Tickets</td>
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<td>Protocol</td>
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<td>Investigator’s Brochure</td>
<td>Recon Dashboard entry</td>
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Case Study Scenario

- Phase IIB, blinded, randomized trial testing Study Drug A in conjunction with Standard Drug treatment for 12 weeks
  
  » CTA draft with draft budget from Sponsor
  » Protocol
  » IND# XXXXXX
  » Investigators Brochure
  » ICF Draft
Where Do We Start?

Reading and Evaluation of the protocol, protocol summary, ICF draft, and sponsor budget.

Identifies both items and services as part of the project using the protocol visit schedule AS WELL AS any other items and services noted in the protocol but not necessarily captured in the visit schedule (i.e. physician office visits, specific labs, imaging requirements and pharmacy requirements such as storage, mixing, and dispensing)

3 Questions for Analysis

1. Is it a qualifying clinical trial?

2. Are the items and services routine costs?

3. Are the routine costs reasonable and necessary?
Is it a qualifying trial?

• Must meet the four requirements:
  – 1. Evaluation of item or service falls within a Medicare benefit category AND not statutorily excluded from coverage
  – 2. Trial must have therapeutic intent. Cannot be designed to test toxicity or disease pathophysiology, **exclusively**.
  – 4. Trial must be “**deemed**” to automatically meet seven desirable characteristics.

Source: CMS National Coverage Determination on Clinical Trials, 2000

Seven Desirable Characteristics

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

3. The trial does not unjustifiably duplicate existing studies

4. The trial design is appropriate to answer the research question being asked in the trial.

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.

6. The trial is in compliance with Federal regulations related to the protection of human subjects

7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Source: CMS National Coverage Determination on Clinical Trials, 2000
Deemed Trials

Deemed by AHRQ to be highly likely they meet the seven desirable characteristics. Deemed trials have the following in common:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA.
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and the VA.
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are IND exempt under 21 CFR 312.2(b)(1) until the qualifying criteria are developed and the certification process is in place. (certification never implemented).

Source: CMS National Coverage Determination on Clinical Trials, 2000

Case Study: Is this a qualifying clinical trial?

YES

Meets the four characteristics of a qualifying trial and the seven deemed characteristics.

Sponsored by industry however it has a valid IND#
What are the Routine Costs in a Clinical Trial?

- Generally available to Medicare beneficiaries.
- Typically provided absent a clinical trial (termed conventional care)
- Required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Needed for reasonable and necessary care arising from the provision of an investigational item or service (i.e. for the diagnosis and treatment of complications).

Source: CMS National Coverage Determination on Clinical Trials, 2000

Are the items reasonable and necessary?

- Medical decision made by the PI/Co-investigator and documented in the medical chart.
  - Discussions often initiated by reviewing staff with PI regarding reasonable and necessary qualifications.
## Determining Routine Care

### Protocol Visit Schedule

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## Proposed Sponsor Budget

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1. CT Scan within 6 months of enrollment
Proposed Sponsor Budget

• Indicates some items and services will not be covered by Sponsor and should be billed to third party.

**THIS NECESSITATES A MEDICARE COVERAGE ANALYSIS**

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What is a Medicare Coverage Analysis?

A systematic review of clinical trial related documents to determine the Medicare billing status of items and services that are documented in the research protocol.

Source: Huron Consulting Group Clinical Trial Billing and Medicare Coverage Analysis Training Presentation, 2006

We require an MCA for any project citing items and services to be billed to a 3rd party.
Initial MCA

We identify the visit grid and replace the costs with symbols identifying Non-Billable items (though paid by the sponsor), Items billable to the Sponsor, and items billable to 3rd party.

Medicare Coverage Analysis

National Coverage Determinations
Specific non-coverage determinations
Local Coverage Determinations
Geographic Region
Surrounding Regions
Standard of Care Methodologies (Medical Association Guidelines and/or journal articles)
Case Study: MCA

1. Screening CT scan – Protocol allows for any CT-scan done within 6-mos to be used, otherwise, a new CT-scan is required. 

Not covered – Items and services done in the context of establishing inclusion or exclusion in the study are non-covered entities. 

Final CT scan also not covered as no NCD/LCD or medical association guidelines exist to support coverage.

Sponsor’s response:

“Go ahead and bill the scans to insurance and we’ll cover any that are twice denied with proof of denial.”

NO – This would constitute fraudulent billing on our part to knowingly bill for tests or items having no coverage support based on our MCA.
Case Study: MCA

Frequency of labs across the course of the trial.

**Covered** – Protocol and Investigator's Brochure show study data from earlier trials documenting potential anemic and electrolyte imbalances from study medication – NCD on Clinical Trials allows for clinically-appropriate monitoring. NCD on CBC and Basic metabolic also support frequency for anemic and electrolyte imbalance treatment.

Case Study: MCA

PI wants to bill 3rd party for V6 Office Visit

**Cannot Bill** – Institutional perspective calls into question receiving a PI-fee from sponsor as well as billing 3rd party for basic E&M office visit. Could be seen as double-dipping.
Case Study: Completing Pre-Enrollment Requirements

• Comparison of final ICF cost/reimbursement language with CTA and billing plan.
  • No signature on CTA without review and agreement of language
  • Subject Injury language in CTA and ICF must agree AND address Medicare Secondary Payer issues
    » Sponsor cannot be payer of last resort i.e., it is not acceptable to bill Medicare for Subject Injury with sponsor covering SI if Medicare denies claim.
Case Study: Enrollment

At the time of subject enrollment, the research team is required to submit a research encounter ticket to the central office (OCT) as well as send a hard copy of the ticket to the impacted service providers.

Service Providers flag subject as research in registration system (FND)

OCT logs in ticket info into database and reconciliation dashboard and routes ticket to impacted institutional billing groups (hospital, professional services, etc.)

Research Encounter Ticket

![Image of Research Encounter Ticket]

NYU Medical Center / Bellevue / HJD
RESEARCH ENCOUNTER TICKET

Clinical Research Trial Information

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<tr>
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[Table of Encounter Information]
Research Encounter Ticket

• Items and services on the research ticket are informed directly from the matching visit from the final billing plan, indicating where services are taking place, and to whom they should be billed. In this case all services are billable to the study account.

• This ticket is routed both to the hospital billing group as well as the professional billing groups for EKG’s and Radiology.

Case Study: Enrollment

• Point of Service registration areas flag the research subject’s account as research (FND) which prevents the bill from dropping.

• Before bill can be dropped, it must be reconciled by the billing group. This means the billing group must verify services were conducted (services appear in billing system) and the matching ticket they received via email matches those services.

• If the bill and the ticket “matches” then the bill is considered “OK to drop” and is sent to the appropriate payer, either 3rd party or in this case, the study account.
Case Study: Enrollment

- Hospital and Professional groups provide monthly or quarterly invoices to School of Medicine for services provided in the context of research.

- Central Office (OCT) verifies charges against actual research ticket (validating the charge) and authorizes the financial transfer.

- If billing items to a 3rd party, ticket information will note to use the QV modifier or V70.7 code on claims being submitted to accurately reflect protocol-related charges.

Billing Compliance System Control Points

Central Office creates billing plan, conducts MCA, creates research encounter ticket templates for researchers.

**RECORD OF TRUTH**

All tickets are emailed to Central Office. Monthly enrollment required and matched to monthly tickets. Any enrollment noted that does not have a ticket is followed-up.
Billing Compliance System Control Points

Ticket information is entered by OCT into shared Reconciliation Dashboard.

All impacted service providers are obligated to log into dashboard and reconcile tickets with research status and bills before bill can be processed and dropped.
Billing Compliance System Control Points

If a ticket does not match the bill, i.e. the research charge is not reconciled to the ticket, the OCT is contacted and follows up:

• Charges don't match ticket
• No ticket on file
• No charge in billing system for ticket
• No registration of subject as research-related.

Billing Compliance System Control Points

Escalating interventions with PI’s and research teams for non-compliance with billing plan, ticketing, and enrollment information.

1. Written notification and reporting to Dept. Chair and Institutional Senior Management
2. Suspension of research study accounts
3. Potential institutional suspension from engaging new clinical research projects.
QUESTIONS?