Clinical Research Billing
Compliance

University of Maryland Baltimore
Office of Research & Development
Center for Clinical Trials
Objectives

The Objectives of this Training are to:

• Increase your understanding of the regulatory and financial issues associated with clinical research billing

• Discuss key clinical research financial and budget considerations

• Introduce procedures associated with clinical research billing at the University of Maryland Baltimore
Outline

- Clinical Research Billing Administrative Support
  - Description
  - Importance/Implications
  - Regulatory Developments

- Medicare Clinical Trial Policy

- UMB/CCT Clinical Research Billing Analysis Services
  - Procedures and Supporting Tools
  - Financial and Budget Considerations
  - Roles and Responsibilities
Clinical Research Billing
What is Clinical Research Billing Compliance?

- Identification of clinical research items or services that can or cannot be billed to third-party payers

- Assurance that processes are in place to bill third-party payers only for items or services allowable under research billing rules

- Harmonization of relevant portions of study documents in accordance with research billing rules
Why is this important?

- Office of the Inspector General (OIG) work plans regularly include clinical research billing in its top compliance initiatives
- OIG FY 2010 federal budget requests over $2 billion for fraud and abuse audits
- Medicare “double billing” has been the subject of numerous OIG/DOJ investigations/settlements
- From a research and business perspective, it is important to determine conventional care vs. “research only” items and services
Regulatory Developments:
OIG Draft Research Compliance Program Guidance

OIG Issued a Draft Research Compliance Program Guidance (CPG)

71312 Federal Register / Vol. 70, No. 227/ Monday, Nov. 28, 2005/Notices

• Issued November 2005; no information on when it will be finalized
• CPG is a major OIG initiative developed to assist the health care community in preventing and reducing fraud and abuse in Federal programs
• Eight (8) Basic Compliance Program Elements

• Website http://oig.hhs.gov/compliance/compliance-guidance
OIG Draft Research Compliance Program Guideline

Synchronizing with Medicare Rules:

“A problem related to the failure to accurately and completely report support from other financial sources is the charging of both award funds and Medicare and other health care insurers for performing the same service. This is clearly improper and has subjected institutions to fraud investigations.”

Draft OIG Guidance for Recipients of PHS Research Awards (November 28, 2005)
OIG/DOJ Settlements and Fines

- Rush University Medical Center-$1 million settlement December 2005
  - Improperly billed Medicare for physician and hospital outpatient cancer research services as routine care costs under the Medicare Clinical Trial Policy (CTP)
  - Violations were attributed to the absence of “synchronization of the Medicare rules, the compensation arrangements with the sponsors, & the financial discussion in the Informed Consent.”
  - Voluntary self-disclosure to DOJ in 2003
  - Corrective Action plan mandated by OIG
  - Was among the first settlements related solely to the CTP on clinical trials
  - Focused only on cancer trials
University of Alabama at Birmingham - $3.35 million settlement April 2005

- Falsely billed Medicare for researcher’s time spent on patient care when no patients had been seen & clinical research trials that were also billed to the sponsor of the grants

- Whistleblower: compliance officer and academic physician
The Medicare Clinical Trial Policy (CTP)
What is the Medicare Clinical Trial Policy (CTP)?

• The CTP is the principal billing rule for services provided during a clinical research study.

• Allows billing only for items and services that are considered “routine costs” during “qualifying clinical trials.” [NOTE: These are defined terms]

• Issued by the Centers for Medicare & Medicaid Services (CMS) (formerly HCFA) under the U.S. Department of Health & Human Services (DHHS) – CMS decided twice in 2007 not to revise CTP

• Policy Intention: To encourage Medicare beneficiaries to participate in clinical trials without penalties.

http://www.cms.hhs.gov/ClinicalTrialPolicies/
President Clinton – “Many seniors and people with disabilities were reluctant to participate in trials for fear they would lose their Medicare coverage. Assuring Medicare beneficiaries that their routine costs will be covered is expected to increase their participation in clinical trials. Medical researchers believe that higher participation by older Americans and those with disabilities in clinical trials could lead to faster development of therapies. The knowledge gained from clinical trials will lead to better health care for Medicare’s more than 39 million beneficiaries.”

Effective date: September 19, 2000
Why emphasize Medicare billing rules for clinical research services?

• Medicare is considered the “Golden Standard” by which many commercial payers base their coverage decisions, including coverage for clinical research services

• Several States have passed legislation requiring commercial payers to follow the Medicare rules

• Institutions are expected to follow the Medicare CTP and develop internal structures to address the coverage issues
Current Medicare CTP

“Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.”

“Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial” with specific exceptions.
The Medicare CTP

- BASIC RULE:
  
  *Medicare may cover routine costs during qualifying clinical trials*

- Note:

  Medicare is a set of regulations with defined terms:
  
  - “Routine costs”
  - “Qualifying clinical trials”
What are “routine costs”? 

Routine costs as defined in the Medicare CTP include: 

- Conventional care 
  - Items or services that are typically provided in the absence of a clinical trial; 

- Services to detect, prevent or treat complications (services for patient safety) arising from the provision of an investigational drug 

- Items or services required for the provision of the investigational item or service 
  - Example: IV administration of study drug, etc
What are not “routine costs”?

Routine costs do not include:

- The investigational item or service (whatever is being studied) – unless the investigational item or service would be covered outside a clinical trial
- Items or services solely for research purposes (e.g., data collection)
- Items or services solely to determine trial eligibility
- Items or services paid for by the sponsor
- Items or services promised free in the informed consent
What are not “routine costs”?

Items and services not generally available:
- Those lacking a Medicare benefit category
- Those which are statutorily excluded
- Those that fall under a national non-coverage policy
  Examples include: cosmetic surgery, hearing aids
- Investigational item unless covered outside a clinical trial
- Items and services solely to satisfy data collection and analysis
- Items and services provided by research sponsors free of charge to enrolled subjects
What is a Qualifying Clinical Trial?

A qualifying clinical trial is a clinical trial that:

- Has 3 “necessary requirements”

AND

- Is 1 of 4 types of trials “deemed” to have 7 “desirable characteristics”
Qualifying Clinical Trials: Necessary Requirements (3)

The 3 “necessary requirements” are:

1. The study must investigate an item or service that is in a Medicare benefit category (Drug/Biologics)
2. The study must enroll patients with diagnosed diseases rather than healthy volunteers
3. The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service or disease pathophysiology.
Qualifying Clinical Trials: Desirable Requirements (7)

The 7 desirable characteristics are that the:

1. Principal purpose is to test whether the intervention potentially improves the participants’ health outcomes
2. Trial is well-supported by scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common use
3. Trial does not unjustifiably duplicate existing studies
4. Trial design is appropriate to answer the research question
Qualifying Clinical Trials: Desirable Requirements (7) (continued)

5. Trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
6. Trial is in compliance with Federal regulations relating to the protection of human subjects
7. The trial is conducted according to the appropriate standards of scientific integrity
Qualifying Clinical Trials: Trials “Deemed” to be Qualified

**NOTE:**
CMS does not allow investigators to self-certify that the 7 desirable characteristics are present – CMS identifies certain types of trials that CMS considers to always have these desirable characteristics.

These are called “Deemed Trials”
Qualifying Clinical Trials: “Deemed” Trials

Clinical trials deemed by CMS to have the 7 desirable characteristics are those research studies that are:

• Funded by certain government agencies: NIH, CDC, AHRQ, CMS, DOD, and VA
• Funded by centers or co-op groups that receive funding from the government agencies above
• Conducted under an Investigational New Drug application (IND) reviewed by the FDA
• Exempt from IND requirements under 21 CFR 312.2(b)(1)
Qualifying Clinical Trials - Summary

A qualifying clinical trial is a research study that:

Meets the 3 “necessary requirements”

AND

Is a “deemed trial”
Sponsor Contract or Grant Considerations in Clinical Research Billing

• Anything paid for by the sponsor or the grant cannot be billed to Medicare, even if the service is a routine cost during a qualifying clinical trial

• Contracts must specify how the sponsor payments for items or services are allocated

  – Lump sum payments in contracts can cause billing confusion
Sponsor Contract or Grant Considerations

• Contracts should clearly state what portion of the payment is being paid for: overhead, administrative services, data collection (as distinct from paying for health care services)

• Payments for any service should not exceed fair market value
Informed Consent Elements

- Every research study must have a section in the Informed Consent Document (ICD) disclosing any additional costs the subject may incur by participating in the trial.

- This *financial disclosure language* may promise certain services provided by the sponsor. Anything provided by the sponsor in the ICD cannot be billed to Medicare.

- The ICD financial disclosure language should be harmonized with the compensation arrangement and coverage information for the study events at the time the IRB approves the final Informed Consent Document.

  - The ICD should mention that copays on items and services that are considered conventional are the responsibility of enrolled subjects.
Key Points

- Items or services during qualifying clinical trials *may be* billed to Medicare

- Routine costs during qualifying clinical trials *may be* billed to Medicare

- Conventional care is considered a routine cost
  - Investigators should be able to provide rationale for designation of Conventional Care
Key Points

- Investigational items or services may be paid by Medicare if a local Medicare contractor allows coverage.
- Medicare has special regulations regarding investigational devices.
- Reasonable and necessary items/services for the detection & treatment of complications arising from all clinical trials are considered routine costs.
- If the sponsor contract or grant pays for any service provided to a patient, it cannot be billed to Medicare.
Key Points

• If a research study is not a qualifying clinical trial, then the only items or services associated with the trial that can be billed to Medicare are those items/services needed for the diagnosis and prevention of complications.

• If a research study is a qualifying clinical trial, only the "routine costs" of the study can be billed to Medicare, if Medicare would have paid for the services outside of a trial.
Why is Clinical Research Billing Compliance Important?

“Should HCFA find that a trial’s principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage or routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the [Social Security] Act.”

“Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial’s principal investigator may be pursued.”

CMS Medicare Clinical Trial Policy
COORDINATION is KEY

Lack of coordination of documents with the Medicare rules could result in:

- Billing for items or services paid for by the sponsor
- Billing for items or services that do not meet the definition of “routine costs” under the Medicare rules
- Billing for “routine costs” that do not meet “all other Medicare rules”
For Questions Please Contact Center for Clinical Trials

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