Recent Developments in the Clinical Trials NCD Compliance

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September 18, 2006
Las Vegas, Nevada

Overview

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2. Clarifications: What is a Qualifying Clinical Trial?
3. Clarifications: What is sufficient therapeutic intent?
4. The increased important role of the Medicare contractor medical director
5. Operational Issues: Lessons applied from clinical trials billing compliance to the entire institution (the Rush experience)

Getting on the same page

- **Current Clinical Trials NCD:**
  - **Medicare covers "routine costs" during "qualifying clinical trials"**
  - **A qualifying clinical trial is a research study that:**
    - **Investigates an item or service that falls in a Medicare benefit category**
    - **Enrolls patients with diagnosed disease**
    - **Is designed with therapeutic intent**
    - **Has seven desirable characteristics (4 ways a study is deemed to have the desirable characteristics)**
  - **Routine costs include:**
    - **Conventional care**
    - **Detection, prevention, treatment of complications**
    - **Administration of investigational item**
  - **Note: "All other Medicare rules apply" to routine costs**

CMS Reconsideration of the Clinical Trials NCD

- **NCD Issued: September 19, 2000**
- **Rush University Medical Center Settlement: December 2005**
- **CMS Q&As: February 2006**
- **Reconsideration Notice: July 10, 2006**
- **Anticipated Final Revisions: April 10, 2007**

Clarifications: What is a Qualifying Clinical Trial?

- **In February 2006, CMS responded to the following during an AHLA audioconference:**
  - **QUESTION 1.** What is the test for a Qualifying Clinical Trial? Is the test: a) the three "requirements" (benefit category; enrollment of diagnosed patients; therapeutic intent) plus the seven "desirable characteristics; or b) is presence of the seven desirable characteristics through a deemed trial sufficient to establish a qualifying clinical trial?
    - **CMS RESPONSE 1.** All qualifying clinical trials must be deemed and meet all 10 requirements.

Clarifications: What is a Qualifying Clinical Trial?

- A qualifying clinical trial is a clinical trial that has:
  - **3 necessary "requirements" *and***
  - **7 "desirable characteristics"**
    - Currently the only way to meet the 7 desirable characteristics is for the study to be "deemed" by CMS to have all 7 desirable characteristics

- If a research study is not a qualifying clinical trial, then no items or services associated with the trial can be billed to Medicare
  - However, Medicare will cover treatment of complications

- If a research study is a qualifying clinical trial, the "routine costs" of the study can be billed to Medicare, if Medicare would have paid for the services outside of a trial

Clarifications: What is a Qualifying Clinical Trial?

- **Part 1: The 3 "necessary requirements"**
  - The study must investigate an item or service that is in a Medicare benefit category
  - The study must enroll patients with diagnosed diseases
  - The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service

- **Part 2: The study must be "deemed" to meet the 7 "desirable characteristics" – only certain types of studies are "deemed":**
  - Funded by certain government agencies
  - Funded by co-op groups that receive funding from government
  - Conducted under an FDA-approved IND application
  - Exempt from IND requirements

Clarifications: What is sufficient therapeutic intent?

- **There are usually two places therapeutic intent is evidenced in a clinical trial:**
  - **Protocol**
  - **Informed Consent**

- **Protocols typically list objectives and often sort the objectives into primary objectives and secondary objectives**

Clarifications: What is sufficient therapeutic intent?

- **In June 2006, at an AAHC meeting, CMS indicated that therapeutic intent must be evidenced as a "primary objective"**

- **Rush's Experience:**
  - **Medicare contractor has rejected coverage for trials that do not have therapeutic intent as one of the primary objectives**

Clarifications:
What is sufficient therapeutic intent?

- **Where does this cause the greatest challenges?**
  - Phase I drug studies
  - Investigator-initiated studies
  - Studies with poorly crafted objectives
  - Studies in which the informed consent negates therapeutic intent identifies in the protocol's primary objectives

The increased role of the Medicare contractor medical director

- **February 2006 CMS Q&As:**
  - **"It is the responsibility of the local contractor to determine whether or not a trial has therapeutic intent."**
- **Providers must remember that Medicare is a Federal program administered locally by private contractors:**
  - **Local Medicare contractors issue local determinations of whether items and services are "reasonable and necessary"**
  - **If CMS has not made national determinations, then the local Medicare contractor is free to make local determinations**
  - **Medicare contractor medical directors can disagree with each other**

The increased role of the Medicare contractor medical director

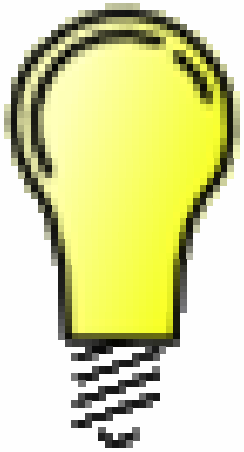
- **Pivotal advice from CMS to Rush in October 2005:**
  - **Get to know your medical director!**
- **Providers should establish a relationship with the local Medicare medical director**
  - **Bring interpretation questions to the medical director**
  - **Rush sponsored a 1-day symposium for Chicago-area academic medical centers to "Meet Your Medical Director" and discuss clinical trials billing**

Lessons applied from clinical trials billing compliance to the entire institution

- **In the course of developing its clinical trials billing compliance structures, Rush identified a gap in its compliance program: medical necessity compliance reviews**

- **Common response from investigators:**
  - **“But this is what I do all the time”**

Lessons applied from clinical trials billing compliance to the entire institution



Lessons applied from clinical trials billing compliance to the entire institution

- **Rush's response:**
  - Develop medical necessity compliance reviews
  - Evolve from coding reviews to medical necessity reviews
  - Review the continuum of treatment for a patient to determine whether services ordered are "reasonable and necessary" and meets Medicare rules
  - Ensure medical necessity is documented in the medical record
  - Creates a stronger, more effective compliance program