Recent Developments in the Clinical Trials NCD Compliance

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September 18, 2006
Las Vegas, Nevada
1. CMS reconsideration of the Clinical Trials NCD

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)
• **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.
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
• 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