How CMS's Anticipated Update to the Clinical Trials NCD Will Affect You

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History of the Clinical Trials 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

Timeline for Reconsideration/Revision

Notice issued: July 10, 2006

Initial public comment period closed: August 9, 2006

Draft revised "Clinical Research Policy" due: January 10, 2006

Additional 30 day comment period

Final revised policy: April 10, 2006

"Establishing a baseline" – The Clinical Trials NCD Now

Under the 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

"Establishing a baseline" – The Clinical Trials NCD Now"

Under the current Clinical Trials NCD:

- Medicare does not cover:
  - The investigational item or service if it would not be covered outside the clinical trial
  - Items and services being paid for by the sponsor
  - Items and services promised free in the informed consent
  - Items and services during a non-qualifying clinical trial (unless to treat complications)

Device trials utilize the device trial regulations for determining potential coverage of costs during the trial

"Establishing a baseline" – The Clinical Trials NCD Now

Policy goals of current Clinical Trials NCD:

- To cover the same items and services during a clinical trial as are covered outside a clinical trial, providing the items and services are not being paid for by the sponsor (or promised free in the informed consent)

- Ensure that Medicare beneficiaries are not penalized for enrolling in clinical trials and encourage Medicare beneficiaries to enroll in clinical trials

Basic Points on the Reconsideration

CMS will change the name of the rule to: the Clinical Research Policy

CMS asked for comments on 10 issues

CMS sets out three overarching goals of the revised Clinical Research Policy

Goals of the Revised Clinical Research Policy

1) to allow Medicare beneficiaries to participate in research studies

2) to encourage the conduct of research studies that add to the knowledge base about the efficient, appropriate, effective, and cost-effective use of products and technologies in the Medicare population, thus improving the quality of care that Medicare beneficiaries receive

3) to allow Medicare beneficiaries to receive care that may have a health benefit, but for which evidence for the effectiveness of the treatment or service is insufficient to allow for full, unrestricted coverage.

Issues Identified by CMS

Clarify payment criteria for clinical costs in research studies other than clinical trials

Devise a strategy to ensure that Medicare covered clinical studies are enrolled in the National Institute of Health (NIH) clinical trials registry website

Develop criteria to assure that any Medicare covered clinical research study includes a representative sample of Medicare beneficiaries, by demographic and clinical characteristics

Clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials

Remove the self-certification process that was never implemented

Issues Identified by CMS

Clarify the scientific and technical roles of Federal agencies in overseeing IND Exempt trials

Determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy

Clarify how items/services that do not meet the requirements of 1862(a)(1)(A) but are of potential benefit can be covered in clinical research studies as an outcome of the National Coverage Determination process

Clarify whether and under what conditions an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries

Discuss Medicare policy for payment of humanitarian use device (HUD) costs.

Top Issues for the Reconsideration

What is sufficient therapeutic intent?

Reconciling the clinical device regulations and the Clinical Trial Policy

Clarity on coverage for the investigational item or service

How to deal with investigational procedures?

The need for clear definitions of terms

Things that won't change

ecause they are not controlled by the NCD process)

Medicare will not be able to pay for items and services that are being paid for by the sponsor.

Medicare will not be able to pay for items and services that the provider promises free to the patient or the patient's insurer in the informed consent.

Items and services will still need to be individually analyzed. Medicare is unlikely to grant coverage for "everything" in a clinical trial.

What to do in the meantime

Providers should develop internal structures that:

- **Track clinical trials being performed at the provider site and develop a system to identify a research patient**
- **Ensure that items and services paid for by the sponsor are not billed to Medicare**
- **Ensure that items and services promised free in the informed consent are not billed to Medicare**
- **Identify items and services that are for research purposes only**

What to do in the meantime

Providers should develop internal structures that:

- Plot out the items and services required by the protocol
- If provider has independent investigators who sign sponsorship contracts, work with investigators to receive information on what items and services are being paid by the sponsor
- Identify local Medicaid Program's expectations
- Add medical necessity programs to compliance program audit and monitoring plans

Managing Compliance Risks

Clinical trials billing remains ones of the biggest compliance risks for providers that perform research – that won't change

Structures must be developed that manage the flow of information from the clinical trial to bill properly

Billing compliance should be thought about prior to finalizing the informed consent so that the added-costs section of the informed consent properly reflects the coverage posture of the items and services

Peers within a local research community must learn to work together

With compliance structures that focus on a) identification of research patients, b) identification of items and services that can be billed to third-party payors or should be billed to an internal research fund, c) and managing the flow of information, a research compliance program can be flexible enough to respond to the revised Clinical Trial Policy and manage risk now