Physician Practice Compliance Conference

HCCA PHYSICIAN COMPLIANCE CONFERENCE

"CLINICAL TRIAL BILLING COMPLIANCE"

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I. The Medicare National Coverage Decision for Clinical Trial Services

A. NCD Issued September 19, 2000

B. Medicare pays for routine costs of qualifying clinical trials

C. What is a "qualifying trial"?

D. What are routine costs?

E. What are NOT routine costs?

F. Clinical device trials: an added twist

G. Don't forget: Regular Medicare rules still apply

H. The effect of the contract with the sponsor

I. The effect of the informed consent

II. Compliance Implications of the National Coverage Decision

A. Every clinical trial is its own billing creature

B. A Medicare coverage analysis must be done for all services in every clinical trial

C. The protocol, sponsor contract and informed consent must be coordinated to ensure provider is not submitting claims violating the NCD rules, double-dipping by billing for services already paid for by the sponsor, or billing for services promised free in the informed consent

D. Government enforcement of the NCD is increasing as the government and providers begin to understand the implications of the NCD

E. Providers should begin a comprehensive review of their billing practices for all clinical trials

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III. Compliance Challenges Involving Principal Investigators

A. PIs are both scientists and health care practitioners

B. PIs are dedicated to advancing health care science and not always focused on the billing implications

C. PIs may not be the best choices for business administrators or negotiators with the sponsors

D. PIs must be careful not to be swayed by bad billing advice from sponsors

IV. Operationalizing the NCD – What Needs to be Done

A. The clinical trial compliance processes should be centralized to ensure consistent approach

B. PIs should develop budgets before sponsor contracts are signed

C. Prior to signing the sponsor contract, the protocol should have a coverage analysis performed to determine whether the proposed sponsor support will cover the cost of the clinical trial (i.e., supporting services that cannot be billed to Medicare and lost physician time in performing administrative work related to the research)

D. Once the coverage analysis is performed, if the sponsor's proposed support does not cover the costs of the clinical trial, then terms should be renegotiated.

E. Once the contract is signed, the financial information in the patient's informed consent should be carefully crafted to coordinate with the coverage analysis.

F. The provider must develop a process that identifies a service during a clinical trial as being routine care and billable to Medicare or billable to the sponsor (e.g., the encounter form can be modified with special checkboxes).

G. The provider must develop a process to inform ancillary services (e.g., labs, radiology, pharmacies) that an ordered service is part of a clinical trial.

H. Don't forget about commercial payors! A pre-certification process must be established to determine the correct billing posture for services to a patient who is insured by a commercial payor.

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