Taking the Fear Out of Clinical Research Billing

Heather Cody, MHA
Assistant Director, Clinical Research Finance

Fear

Clinical

Definition

Clinical research billing is the act of invoicing for patient clinical procedures dictated in a research protocol.
Jeopardy

FINAL JEOPARDY

Abbreviations  Risks  Safeguards
100  100  100
200  200  200
300  300  300
Abbreviations – 100 Points

This item is required for investigational device use in a clinical study in order to collect safety and effectiveness data.

What is an IDE: Investigational Device Exemption?

Abbreviations – 200 Points

Before a marketing application is approved pharmaceutical companies must apply for this designation.

What is an IND: Investigational New Drug?

Abbreviations – 300 Points

It is mandatory to report this item on claims for items or service provided as specified in the “Medicare National Coverage Determination Manual”, Section 310.1.

What is a NCT: National Clinical Trial Number?
Risks – 100 Points

This occurs when the same service is paid for by two parties.

What is double billing?

Risks – 200 Points

In 2013 a major university paid a $1.5 million fine after this type of violation.

What is False Claims Act?

Risks – 300 Points

1) The investigational item itself
2) Items solely for data collection and analysis
3) Items and services customarily provided by the research sponsor free of charge for an enrollee

What are items considered research?
Safeguards – 100 Points

The delineation of procedures dictated in the research protocol according to payor.

What is a coverage analysis?

Safeguards – 200 Points

1) Item falls into a Medicare benefit category
2) Has therapeutic intent
3) Enrolls patients with a diagnosed disease

What are the criteria for a qualifying clinical trial?

Safeguards – 300 Points

This process compares planned activities to actual results in order to determine clinical research billing compliance.

What is Reconciliation of clinical trial patient billing?
Final Jeopardy
The most notable victims of clinical research billing errors.

Who are our patients?

Questions?