

Research Billing Compliance Overview

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Research Compliance

- Research Billing Compliance Overview – Vonda Whalen
- Research Non-Compliance issues and Best Practice for Remediation Strategies – Melissa Fink
- Common Rule and Single IRB 2018 Changes – Melissa Fink

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Research Billing Compliance Overview Discussion Topics

- What are clinical trials?
- Who pays for services in a clinical trial?
- Types of clinical trials for billing compliance
- How to determine what services are billed to study and to insurance
- Coverage Analysis review of services related to trial
- Risk of non compliance

What are Clinical Trials?

Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans.

- Determine which medical approach works best for certain illnesses or groups of people.
- Produce the best data available for health care decision-making.

Who covers the cost?

- President Clinton's executive order in 2000 directed CMS to cover routine costs in qualified clinical trials for Medicare beneficiaries.
- CMS' Clinical Trials National Coverage Determination (NCD 310.1) set forth the rules for implementation of this executive order.

Protecting Resources

Medicare will pay for routine costs for items or services including:

- Conventional care (provided absent the trial)
- Providing the investigational item (administration of non covered chemo agent)
- Monitoring the effects of the investigational item & preventing complications from the investigational item
- Providing reasonable and necessary care arising from the investigational item for the diagnosis or treatment of complications.

Protecting Resources

Medicare will NOT pay for

- Investigational item or service.
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management of the patient. For example, monthly CT scans for a condition usually requiring only a single scan.
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.
- Items and services that Medicare does not define as reasonable and necessary.

Types of Trials

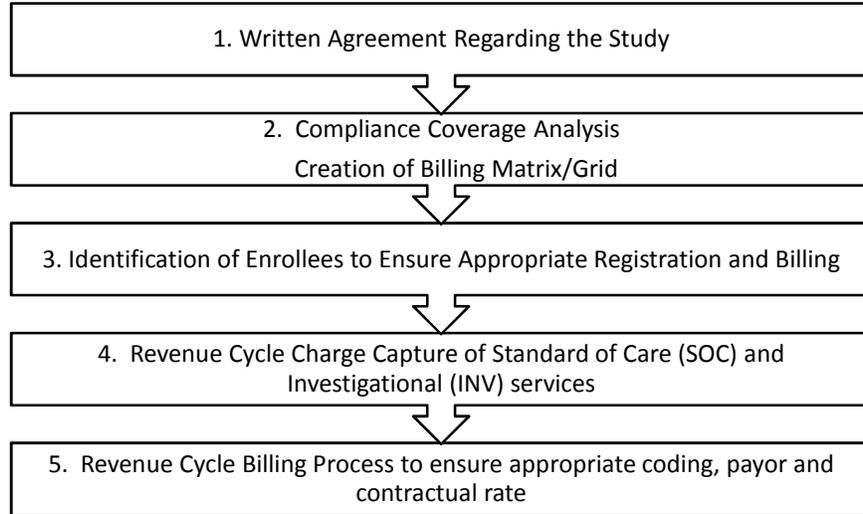
Drug Trials

- Usually uses drugs that are experimental (not commercially available)
- May use commercially available drugs off-label (for indications, route or dosage that are not included in the FDA approval).
- Some trials use combinations of drugs that have not been approved by the FDA.

Device Trials

- Usually involve implantable devices that are not commercially available and are either experimental or similar to approved devices but are improved and still need to be proven to be safe

Components of Clinical Trial Process



Qualified and Deemed

In order to receive Medicare coverage of routine costs a clinical trial must be both:



Qualified

Deemed

Requirements for Medicare Coverage of Routine Costs:

For trial to be "**Qualified**" must answer yes to the following:

- Are the services included in a Medicare Benefit Category?
 - The services may not be excluded from coverage. Examples of services excluded include cosmetic services and hearing aids.
- Is the patient diagnosed with a disease?
 - Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
- Is there a therapeutic intent present?
 - Services may not be designed to test toxicity or disease pathophysiology exclusively.

Requirements for Medicare Coverage of Routine Costs:

For trial to be "**Deemed**" must answer yes to one of the following:

Is the trial funding from a designated list?

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA

Is the trial conducted under an investigational new drug (IND) application reviewed by the FDA or is the IND trial exempt from having an IND application reviewed by the FDA?

- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified.

Who will be billed and who will pay?



Consequences of Non-Compliance



Compliance's role is to collaborate with our partners conducting clinical trials.

