

**Next Steps In Clinical
Research Billing**

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Objectives

- Recognize the importance of an ongoing training program and steps necessary for maintaining and disseminating research billing information to stake-holders.
- Identify how some institutions deal with non-qualifying research projects
- Recognize the steps to building an information repository of Medicare related coverage information
- Describe the issues to consider when contemplating an internal audit or monitoring of the research billing operations and next steps when potential irregularities are discovered.

Where We Have All Been

- Trying to interpret the Clinical Trials Policy (CTP) and create a compliant research billing process.
- Learning that a clinical research operation takes a village...and then some.
- Agonizing over consequences of the fits and starts of a new billing process.

Where Do We Go From Here

Things We've Learned After Establishing a Research Billing Process

- For many institutions and research enterprises, it's a financial eye-opening experience.
- Better budgeting and tighter budgeting controls
- Better revenue collections
- Better communications and relationships with institutional stake-holders
- Better subject reporting and tracking.

Things We've Learned After Establishing a Research Billing Process

The need for better technological solutions to manage volume and quality.

Integration of research information with registration and billing information

The process is extremely labor intensive, manual, and dependent on a lot of different people at the institution

There is a need for constant education and training

There is a need for constant internal review of the process and operation.

Successful Strategies Being Utilized

- Development of standard operating procedures around conducting MCA's and qualifying analyses.
- Creating a reference document with frequently used NCD and LCD information.
- Using previous MCA's for similar types of studies to provide guidance on determining routine care services
- Engaging frequent reports on volume and costs to create trends
- Frequent internal reviews
- Scheduled Management updates

Polling Question #1

True or False: A completed Medicare Coverage Analysis for one type of clinical trial can be used for a similiary type of clinical trial at a later time?

There Are Still More Questions

The CTP

Three categories to deal with when reviewing research projects:

- Qualifying Clinical Research
- Device Trials
- Other Research that defies the current rules but remain within a working definition of clinical research

Qualifying Clinical Trials

- Tools or algorithms to establish qualifying clinical trials based on the CTP regulations.
- To do or not do a Medicare Coverage Analysis – The risks and what it takes. Who is qualified.
- What happens when internal and external changes upset the current operation
- The use of the new modifiers Q0 and Q1 (replacing QV, QA, and QR effective January 2008)

Device Trials

- The current CMS regulations for device trial coverage remains unchanged by the current Clinical Trials Policy.
- Better review of sponsored agreements related to the billing for devices and costs to institutions
- Leveraging LCD information for coverage.

What is happening with non-qualifying clinical research

- Is it even considered clinical research? (educational studies, comparisons of approved drugs, etc) and does the CTP apply?
- Limited guidance from CMS on the scope of the NCD. What's an institution to do?
- Institutional risk assessment and business decisions that allow for research to move forward.

Polling Question #2

A coverage review of a clinical trial concludes it is a non-qualified based on the current CMS Clinical Trials Policy. What can be done?

Non- Qualifying Clinical Research (Continued)

- What is the risk and what is happening?
- What happens when you can't bill Medicare? Does the research stop?
- Utilizing the local contractor/FI for decision making and precedent setting.

Internal Reviews – Auditing versus Monitoring

Having a plan of consistent and thorough internal review is critical to the success of a research billing program.

Evaluating the touch points and gate keeper points of the system to analyze effectiveness of objectives

Complex internal processes necessitate the constant review and updating. What is working and what isn't?

Tweaking the process to accommodate new information and better, streamlined processes

Internal Reviews – Auditing versus Monitoring

Monitoring

- General review of systems and processes to ensure compliance with external and internal requirements

Auditing

- Detailed analysis of compliance with rules, internal policies and practices

What should be reviewed and when?

- MCAs, bills, processes, hand-offs and touch points
- Timing is everything

What is your purpose in auditing and/or monitoring? Are you meeting those objectives?

Ensure that the end points reach the goal and don't become an end in themselves

What Do You Do When You Find a Billing Irregularity

- Define the irregularity
 - Overpayment
 - Systems Error or Lack of Internal Controls
 - Potential Fraud or Abusive practices
- Have the charges already been submitted to a 3rd Party Payer?
 - Refunds and Corrective Action
 - When an overpayment refund becomes more than just a refund (trigger to OIG)
- Immediate Steps
 - Stop gap measures or establishing a bill hold and review process to identify the issue in the process

Issues Surrounding Self Disclosure

- Engage competent counsel
- Protection of the Attorney/Client Privilege and the Attorney Work Product Doctrine
- Define the scope of the problem
- Assess path to disclosure (relationships are everything)
 - FI/Carrier overpayment refund (review your Contractors policies)
 - Voluntary Disclosure Protocol (OIG)
 - Department of Justice

Polling Question #3

True or False: A billing irregularity is discovered during a routine internal review of the clinical research billing system. This irregularity must be disclosed to the government immediately.

SUMMARY

- Many institutions involved in clinical research billing processes are evolving their practices beyond the basic scope of the CTP based on new information collected about their research enterprises.
- More questions continue to be asked related to the fine-tuning of research billing operations.
- Further evolution of staffing and resources needed for a compliant billing system.
- Internal review and external audits

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