

# Importance of the Clinical Research Billing Process: Opportunities & Challenges

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## Structure of CRB Webinars

- **Session 1: Opportunities & Challenges**
- Session 2: CRB: A Team Effort
- Session 3: Clinical Trial Agreements
- Session 4: Informed Consents
- Session 5: Study Budgets & CRB Billing Rules
- Session 6: Medicare Advantage & CRB
- Session 7: Specific Issues in Billing & Coding

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## Objectives

1. Review potential penalties associated with clinical research billing non-compliance
2. Discuss how clinical research billing compliance risk connects not only to privately sponsored research but also to federally sponsored and investigator-initiated research
3. Walk through information flow for clinical research billing process
4. Explain opportunities to avoid lost revenues from inconsistent research billing processes
5. Introduce approaches for operations solutions AMCs have adopted nationwide

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## Why?

- Increased audits & investigations
- Recent settlements
- Risk of inconsistent approaches between medical center billing and physician billing
- Lost opportunities for budget negotiations

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## Perspective & Themes in Series

- These sessions are provided from a legal and compliance perspective and not from a clinical orientation
  - ✓ this is usually how government regulators will view billing issues
- Breaking down silos
  - ✓ clinical research falls under the jurisdiction of several government agencies which often do not coordinate their regulations
- Clarity of documents is critical
  - ✓ government regulators are often not clinicians and will interpret and use terms differently than clinicians and study documents may be interpreted differently than their intended meaning

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## Compliance Risks

- Not having a consistent clinical research billing process or operations safeguards can lead to:
  1. Billing for services that are already paid by the sponsor (double billing)
  2. Billing for services promised free in the informed consent
  3. Billing for services that are for research-purposes only
  4. Billing for services that are part of a non-qualifying clinical trial and do not qualify for coverage
  5. Billing Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor (Palmetto)

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## Documents subject to claims audit by government agencies:

- Protocol
- Clinical trial agreement & budget
- Informed consent
- FDA status documents
- Medical records
- Any other documents that could be relevant

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## What are some of the laws implicated?

- U.S. False Claims Act
- U.S. Civil Monetary Penalties Law
- California False Claims Act
- California Insurance Fraud Laws
- Numerous other statutes and regulations touch clinical research billing

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## Confronting Myths about Clinical Research Billing & Medicare

- Realities:
  1. Medicare does not always pay for “standard of care”
    - SOC is not a Medicare concept
    - Medicare has its own rules and defined terms set by statutes, regulations, and local Medicare contractors
  2. NIH and CMS do not coordinate
    - Unfunded services for NIH-sponsored studies are not automatically billable to Medicare
  3. CRB compliance laws apply to all clinical research studies and not just industry-sponsored studies

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## Is compliance risk associated only with industry-sponsored studies?

- Clinical research billing compliance is important for safeguarding all federal grants
- A federal grant is threatened if double-billing occurs or any of the other compliance risks occur, including inappropriate cost transfers
- One federal grant review can lead to entire institution's NIH grants being audited
- Investigator-initiated studies need to be mindful of clarity of study documents

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## The 3 C's of Research Billing Compliance

- **Coordination** of study information across multiple study documents
- **Communication** of relevant study information to the billing process
- **Cooperation** among departments and offices that may not usually work together

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## Communicating....

- Who are the patients enrolled in a research study?
  - ✓ The billing process must be able to identify who the research patients are
- Which services are part of the protocol?
  - ✓ Even standard of care protocol services must be coded under Medicare rules
- Which protocol services should not be billed to the patient or the patient's insurer?
- Is the medical center billing office and the physician billing office treating the study in the same way?

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## Important concepts for building solutions

- Build processes and controls to manage information and coordinate information to ensure research billing errors do not occur
- Establish "front-end" and "back-end" safeguards:
  - Front-end: Billing tools that synchronize study information and guide which services are billable to payors/patient and which are chargeable to the study (example: Medicare Coverage Analysis)
  - Back-end: Processes to use the billing tools to direct charges appropriately
- Data management of research enterprise: studies, enrolled subjects, study events, housing of study documents

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## Developing billing tools as a solution

- Many organizations have developed processes to conduct “Medicare Coverage Analyses” (MCAs) as a tool and safeguard
- An MCA is a tool that applies billing rules to the protocol’s schedule of events
- An MCA can:
  - coordinates relevant study information
  - assist in the budgeting process
  - serve as a billing tool
  - provide a financial and compliance auditing platform

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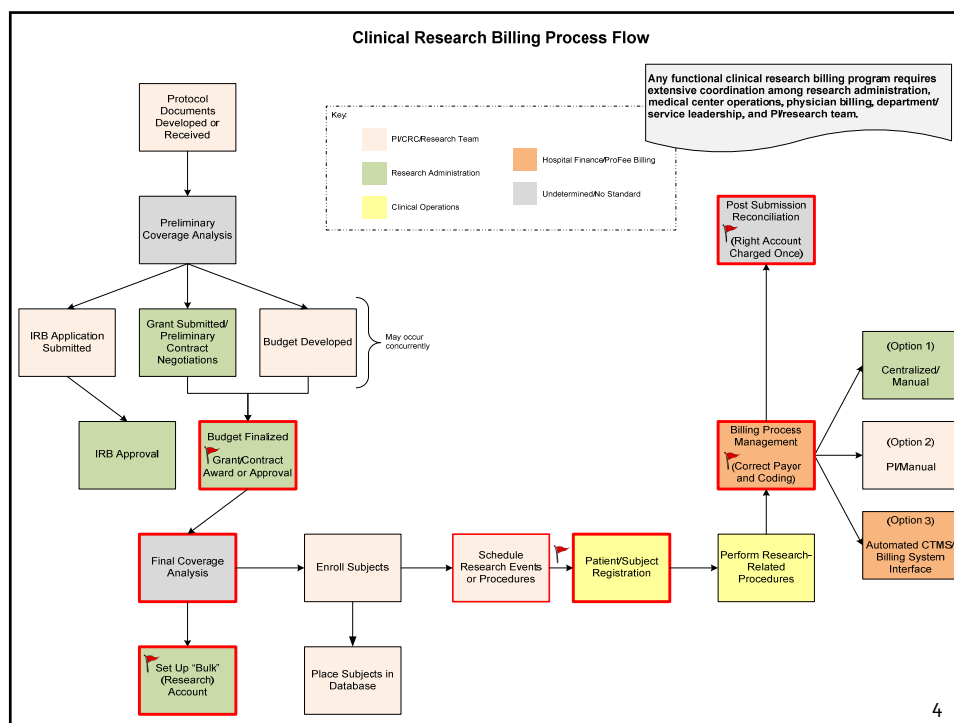
## Hypothetical MCA: managing study information

	Code	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Comment
Physical Exam	99201-99215		M	M	M	M	
EKG	93000	M	M	M			
Drug 123	J0123	S	S				
Infusion	96400	M	M				
Urinalysis	81000		NB	NB			
Ultrasound	93990			ICF			
Patient Diary	N/A		NB	NB	NB	NB	

M=Medicare  
S=Sponsor  
ICF=Free in Informed Consent  
NB=Not billable to Medicare

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## Opportunities

- Managing research billing compliance can improve financial viability of studies
- Using Medicare billing rules and a consistent process at initial stage of the study can improve management level reporting for studies
- Having a common research rate at an institution provides for consistent budgeting and reducing compliance risk for violating Medicare rules and OMB circular obligations

## Using Billing Rules for Budgeting

- If the sponsor has offered to pay for services that are usually covered by insurance, but has not offered to pay for non-covered services, then consider negotiating so that the final budget pays for the non-covered services
- MCA allows a tool to document reasoning why services are not covered and could be used as a communication tool with sponsor

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## Common Clinical Research Billing Process Solutions for AMCs

- Common features:
  - A department or office is designated as the coordinator outside the compliance office
  - CRB process is made a part of operations
  - Coverage analyses are developed for each clinical research study
  - CRB information is coordinated between medical center and physician offices
  - Training on CRB process is mandatory
  - Charge/claims audits conducted

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## Common Clinical Research Billing Process Solutions for AMCs

- Most AMCs have undertaken permutations of three approaches to implementing clinical research billing processes and developing MCAs:
  1. Centralized office
  2. Decentralized processes with heavy auditing
  3. Hybrid approach based on clinical specialty

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## Clinical Research Billing Process Solutions

- Approaches:
  - Centralized:
    - Mandates that all research study budgets be developed and negotiated centrally
    - All MCAs developed by a central office
    - Accounts for research patients held until reviewed against coverage analyses
    - Most FTE intensive, but lowest risk model

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## Clinical Research Billing Process Solutions

- Approaches:
  - Decentralized:
    - Departments are trained to develop MCAs
    - Charges are split at the point of charge capture
    - Initially less disruptive of revenue cycle
    - Often results in re-working claims
    - Success dependent upon hundreds of people – heavy auditing of activities needed
    - FTEs for training and auditing needed due to high risk

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## Clinical Research Billing Process Solutions

- Approaches:
  - Hybrid
    - Some departments can achieve proficiency in MCAs and develop them on their own
    - Central office develops MCAs for departments that have small number of studies
    - Central office oversees training and performs quality review checks
    - Back-end for directing charges varies with hybrid models
    - Additional FTEs required, but fewer than decentralized and centralized models

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## Take-away Points

- Relevant study information must be communicated to the billing process
- Each clinical research study has its own configuration of services that are billable and not billable to patient or insurance
- Developing a consistent research billing process manages compliance risk and helps enhance budgeting process

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## References for further reading

- *Clinical Research Compliance Manual: An Administrative Guide*, Aspen Publishers (2010) (various authors, including L. Murtha and R. Meade)
- Meade, R., et al. "Medicare Coverage for Cancer Research," *Journal of Clinical Research Best Practices*, 6 (3): 1-5, March 2010
- Murtha, L., et al. *Healthcare Compliance Professionals Guide to Clinical Trials*, HC Pro, Inc. (2008)
- Boyd, C.; Meade, R. "Clinical Trial Billing Compliance at Academic Medical Centers," *Academic Medicine*, 82(7):646-653, July 2007
- Meade, R.; Popa, A. "Managing Billing Compliance During Clinical Research Amid Changing Medicare Coverage," *Journal of Health Care Compliance*, 9: 5-11, Sept/Oct 2007
- Murtha, L; Steiner, J. "Clinical Research Billing: Process and Monitoring Issues," Chap. 3, *Clinical Research Law and Compliance Handbook*, Jones and Bartlett (2006)
- CMS National Coverage Determination 310.1 ("Routine Costs in Clinical Trials")

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## Recent public research-related settlements

- Tenet, 2010: \$1.9 million
- Yale University, 2006: \$7.6 million
- University of Connecticut, 2006: \$2.5 million
- Cornell University, 2006: \$4.4 million
- Rush University Medical Center, 2005: \$1 million

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• Questions

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