

The 3 C's of Research Billing Compliance: Collaboration, Challenges and Compromise

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AGENDA

- Collaboration
 - What Does it Take to Make It Work?
- Challenges
 - What Are the Practical Challenges Facing Administrators Today in Billing?
- Compromise
 - How To Meet the Demands of Issues and Change

Themes of presentation

- Issue-spotting operational points
- Identifying realities
- Recognizing solutions do not come easy
- Accepting that “everyone is in it together”

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Collaboration

- **col-lab'o-ra'tion** *n.*, to work jointly with others or together especially in an intellectual endeavor

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Challenge

- **chal-inj**, *n.*, A test of one's abilities or resources in a demanding but stimulating undertaking

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Compromise

- **kom-pruh-mahyz**, *n.*, A settlement of differences in which each side makes concessions

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The 3 C's in Compliance: combined working definition

- ***A test of the research enterprise's ability to work together in a demanding, dynamic way where information is communicated, processes are coordinated and priorities of the whole are recognized.***

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Collaboration, Challenge or Compromise?

- Medicare "double billing" has been the subject of numerous OIG/DOJ investigations/settlements
- OIG 2009 Work plan includes Clinical Trial Billing in its top "compliance" initiatives
- From a research and business perspective, it is important to track clinical customary care vs. "research only" or "routine research cost"
- You don't want to be on front page of your local newspaper or the next national example

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Collaboration Means Everyone Knows the Medicare Basics of Billing

- Medicare generally does not reimburse for purely experimental medical care, even if there is no other source of payment
- If a service/item is provided or reimbursed by another payor (including industry-sponsored, federally sponsored clinical trials and or by private insurance), Medicare cannot be billed
- If a services is promised free in the informed consent, it cannot be billed to Medicare
- Know the issues of coding properly for clinical trials with Medicare

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Collaboration: Partners in the Process

- The “Research Enterprise:”
 - Investigators
 - Contracting Office/Tech Transfer
 - Finance/Billing
 - Coordinators
 - Hospital administration
 - University administration
 - Registrars
 - IS Staff
 - HIM Department
 - Pharmacy and Lab Support
 - Patients

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Collaboration: Charge Capture

- Don't allow clinical departments to create "workarounds" outside of the billing system to handle financial interactions with hospital ancillary departments
- Remember that productivity and utilization data may be skewed because all clinical activity is not entered into the systems
- Technologists in ancillary departments may not know which charges are covered by the award

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Collaboration and Coordination of Medicare Reimbursement and Third-Party Research Grants

Government research grants:

- If a research grant from a Federal, State, or local government entity is earmarked for particular services to patients, Medicare does not pay for the same services.
- This rule applies regardless of whether the governmental entity pays the grant directly to the provider, or indirectly through some other entity.

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Collaboration: Patient Financial Services

- Clinical trials-related hospital Accounts Receivable had missing or incorrect research account information
- Patient Financial Services may not have a system to monitor the status of bills which have been forwarded to hospital accounting departments for review or payment
- Patient Financial Services may not maintain an Accounts Receivable aging report for clinical trials

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Challenges in Clinical Trial Billing

- Biggest challenge to billing: coordination of study information
- Billing rules are still ambiguous 9 years after release of Medicare's Clinical Trial Policy
- Medicare delegate sweeping coverage discretion to the Medicare Contractors, which allows differences from region to region
- Commercial insurers are mixed in their understanding of research

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Challenges in Clinical Trial Billing

- Most billing systems were not constructed with research in mind
- Research organizations are typically separate from clinical billing departments, thus requiring a strong systems link or strong communication
- Research is decentralized and Investigators/Coordinators often find “workarounds”
- Clinical trials patients are often not identified
- Charge capture and segregation of charges

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Challenges in Clinical Trial Billing

- Clinical Trial Billing should be viewed as a business cycle—including all financial and administrative aspects of the process
- Where does Billing Compliance belong and who pays for it?

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Critical Challenges Facing Administrators

- Budget Preparation
- Contract Language
- Protocol Approval
- Consenting Subjects/Informed Consent
- Registration of Subjects
- Billing Requirements
- Treatment of Residuals

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Challenge: the Budgeting Process

- Determination of the full cost to perform the trial
- Medicare Coverage Analysis
- Comparison of the trial cost estimate to the funding provided by the trial sponsor
- Negotiation with the sponsor to address shortfalls
- Approval of budget
- Contract review
- Development of a Billing Plan
- Consent and contract review to see if they match the funding

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Challenge - Registration of Subjects

- Information collected at the time of registration is insufficient to ensure the proper account is charged for trial-related procedures
- Trial subjects are not provided a clear sense of potential financial obligations
- Patients receiving treatment related to a clinical trial must be identified as research patients and noted in the medical record with trial name, sponsor and protocol #

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Challenge: Managing Receivables from Trial Sponsors

- Ensure clinical trial agreement complies with institutional A/R policies (e.g., Sponsors Payment Schedule)
- Standard process for monitoring and reporting achievement of study milestones
- Mechanism to generate sponsor invoicing
- Ensure proper collections and check receipts process

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Challenge: Ongoing Monitoring and Reconciliations

- It is critical that an effective system of reconciliation/monitoring is employed to ensure that research only charges are not billed to payors
- There may be the potential in the clinical order entry system to tag research tests/services as “research only,” in which case, the charges get held in the billing system and do not get charged to payors

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Challenges in the Medicare Clinical Trial Policy

- Budgeting: Services, reimbursement and payment; knowing which services are “routine”
- Subject Registration: Ensuring entry of the appropriate secondary or tertiary V70.7 diagnosis code
- Routine Cost Communication: Ensuring provider communication of “Q0/Q1” procedural code modifiers to charge entry personnel
- HCFA 1450 and HCFA 1500 Review: Ensuring coding and document review prior to claim submission; Internal, ongoing monitoring

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Compromise: Areas for Discussion Within the Research Enterprise

- Need procedure for handling dropped or denied charges once vetted
- Discounts for research costs should be agreed upon and applied appropriately
- Residual balances policy should be in place
- Responsibility for pass through costs to sponsors should be upfront

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Compromise: Initiate Change in Your Clinical Trial Billing Process

- Develop your workgroup
- Have a budget!
- Hire consulting or technical resources if necessary
- Develop process workflows and roles/responsibilities
- Set up system to track clinical trials patients
- Pilot the new process
- In-service staff
- Rollout

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Questions/Comments?

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