The Inside Story on Clinical Research Billing

Presented by:
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AGENDA

- The ins and outs of a compliant research billing operation: practical strategies to making it work
- Integrating current research billing compliance programs with the revised CMS policy
- Centralizing research compliance for a successful research billing program
Research Billing Compliance

- Billing patients or third party payers for products and services provided to patients enrolled in clinical trials in accordance with applicable laws and regulations include:
  - Federal health care program requirements e.g., Medicare Part A, B & C
    - National and Local Coverage Policies
    - Final National Coverage Determination (NCD) 9/2000
    - Coding requirements and guidelines

PRACTICAL IMPLICATION: Sites developing their own standards for reviewing billing compliance in research. For example, how do you apply compliance based on Medicare coverage regulations for expenses to be billed to Industry rather than Medicare. We use Medicare regulations as the “Gold Standard” for review of all billable projects
Why Is Research Billing Compliance So Important?

- The government’s current and proposed enforcement agenda

- **Qui Tam:** A lawsuit brought under the False Claims Act by a private plaintiff on behalf of the Federal or State Government (rather than by the Government itself) AKA Whistleblower lawsuits

- Inadvertent or non-meditated research billing transactions with potential for false claims rather than intended fraudulent billing: still considered filing a false claim and carries penalties.

- Large dollar volume processes

- Adverse public relations
Identifying the High Risk Areas

Billing Medicare (or the patient) for items or services that are otherwise reimbursable or free to the hospital through federal or private grant funds – a.k.a. “double billing” or “double dipping”

- Billing Medicare for experimental procedures or devices (unless covered specifically by an IDE)
- Charging for an investigational drug in a clinical trial under an investigational new drug application without approval of the FDA
- Waiving Medicare co-payments and deductible obligations for study participants
- Receiving remuneration from sponsors that could be viewed by Medicare as kickbacks. Fair market value on reimbursements.
- Coding and billing for non-covered items or services as a covered benefit by an insurer
- Billing for items solely to satisfy data needs or trial eligibility
- Inadequate medical record documentation for items or services billed

Use of Advance Beneficiary Notices

- Where assigned physician claims (i.e., claims submitted by and paid to a physician on behalf of the beneficiary) are denied for lack of medical necessity, Medicare will pay for the services as long as neither the beneficiary nor the physician knew the services would not be covered. However, where the physician knew or, because of published carrier policies, prior denials or otherwise, had reason to know that the services would likely not be covered and did not notify the beneficiary, Medicare will not make payment. Unless the physician has followed the ABN rules, he may not then seek payment from the beneficiary.
Benefits of a Compliant Billing Operation

- Reduces legal consequences of non-compliance
- Enhances the sensible, straightforward identification of possible compliance problems
- Improves public relations
- Provides a process to address compliance issues internally
- Demonstrates an enhanced internal control of our research environment
- Protects the assets of your Institution or practice
What’s the Importance of a Compliant Research Billing Office?

- To help in establishing appropriate patient care budgets for clinical research. This is the initial step in determining compliant billing practices.

- To ensure funding provisions per study agreement for billing of patient clinical research and ensure financial remuneration for adverse events.

- To establish a process ensuring accurate patient care billing for clinical research.

- To perform audits ensuring billing compliance with federal regulations and Medicare regulations.

- To develop standardized tools supporting a patient billing compliance program and controls for clinical research billing before its externally imposed.
Imagine The Surprise: Medicare Doesn’t Cover Everything!

Rush University voluntarily disclosed the existence of billing errors related to research in 2003. The Rush settlement will pay the United States and the State of Illinois approximately $1 million to settle the matter on the cancer clinical trials overpayments that covers a six year period. This includes approximately $278,000 of the payment representing a 50 percent penalty.

- The settlement also prompted significant overhaul and development of clinical research billing practices at Rush and set up a model for a functional, centralized office to coordinate, implement, and perform billing compliance review.

Source: http://www.rush.edu/webapps/MEDREL/servlet/NewsRelease?id=716
Rush University Medical Center officials admitted the hospital filed false Medicare and Medicaid claims during a six-year period but maintain it was done inadvertently. This mistake will cost them more than $1 million.

- This is one of the first settlements of overpayments related solely to the National Coverage Decision (NCD) on Clinical Trials that in September 2000 defined how Medicare would reimburse providers for services to patients in a clinical trial, or research study."
Medicare Doesn’t Cover Everything

- The Medicare National Coverage Decision for Clinical Trials 2000, now the Clinical Research Policy, specifically excludes from coverage “items or services customarily provided by the research sponsor free of charge for any enrollee in the trial.” Therefore, if the sponsor provides the item or service free of charge for any enrollee, that item or service is not covered by Medicare.

- If the beneficiary has no legal obligation to pay for the item or service then Medicare and other insurance plans don’t cover it. The beneficiary has no legal obligation to pay for the item or service if the sponsor agrees to pay (after denial) so the patient will not have that obligation.

  *Watch contractual terms with sponsors closely on this issue. Sponsors might not always understand Medicare reimbursement rules. Sponsors are not billing Medicare and 3rd party insurers so there is questionable liability on the part of Sponsors. Institutions should not rely on Sponsors for correct reimbursement/billing advice when it comes to Medicare.*
Investigational Devices

- Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a body member.

- Investigational Devices are categorized as either Category A (Experimental) or Category B (investigational) and are assigned an Investigational Device Exemption number (IDE). All Category A and B devices need to have a Local Coverage Determination for possibility of coverage. Each Carrier and Fiscal Intermediary will have their own submission requirements to provide LCD’s.

- Medicare Carriers Manual §2303.1
In July 2007....
Non-Device Trials

This applies only to a qualifying trial, evaluating a Medicare benefit, has therapeutic intent, and enrolls diagnosed beneficiaries.

- The Medicare statute precludes payment when “payment can reasonably be expected to be made under a liability insurance policy or plan (including a self-insured plan).” Medicare guidance on this point states that when the language described above is present in a clinical trial agreement, Medicare interprets the language as creating a plan or policy of insurance under which payment can reasonably be expected to be made by the sponsor, so that Medicare considers its payment obligation to be secondary to that of the sponsor.
Deemed Trials – What Medicare Won’t Cover

- Investigational item or service itself
- Items/services not normally covered as a Medicare benefit
- Services furnished solely for data collection
- Services normally provided by the sponsor free of charge
What’s the Big Deal?

- If you know or have reason to know that a patient encounter should not be billed to a federal third party payer and the charge goes through anyway, you may be filing a False Claim.

- A False Claim may be punishable by criminal and money penalties, so please be careful!
The Challenges in Clinical Trial Billing
And Why You should Centralize a Billing Program

- Most billing systems were not constructed with research in mind.
  - Some institutions with billing compliance programs have developed their own “home-grown” systems to compensate and use a combination of registration functionality and manual reviewing of claims.

- Research organizations are typically separate from clinical billing departments, thus requiring a strong systems link or strong communication.
  - Financial personnel typically do not understand clinical research language/concepts and vice versa.
The Challenges in Clinical Trial Billing And Why You should Centralize a Billing Program (con’t)

- Research is decentralized and Investigators/Coordinators often find “workarounds”
  - Without a standardized process backed by policy, it becomes increasingly difficult to audit and make institutional corrections.

- Clinical trials patients are not always identified institutionally
  - Doing an operational systems process review continually identifies “holes” where research subjects might not imprint into the billing system properly and increases the chances for inappropriate billing practices.
What Can You Do?
Tracking Costs is....

Detective Work!
Billing Compliance

- Develop a Clinical Trial Patient Tracking system (CTPT) to ensure that you are following the federal guidelines for charging billing and collection
- Note your Conventional/Routine care costs vs. Grant related charges and bill accordingly
- Know FDA & Medicare rules for Devices and Drugs
- Know federal, state, sponsor and institutional rules regarding residual balances
What is Clinical Trial Patient Tracker? (CTPT)

- A clinical trials patient management system designed to be secure, accurate and acts as an independent record of study procedures billed to the clinical trial
- Assures that proper bills are discharged to third party payers including Medicare
- Provides statistical information on finance of studies to the investigative team
What does a CTPT Provide?

- Improves collections and revenue and helps to meet budget projections
- Prevents mis-charging of procedures to the subject’s insurance or to the clinical trial
- Authorizes procedures for each subject based on the study they are enrolled on
- Provides template of procedures, once loaded for each patient enrolled
- Confirms what should be billed to the account prior to it being billed
Example of success using a CTPT

- 18 month increase of 8.2 million in revenue after initiating CTPT
- Better compliance with federal guidelines
- Less hassle for investigative team to review each patient’s research bills and provides useful information concerning status of the trial to date
## Sample Tracking System

### Budget Tab

<table>
<thead>
<tr>
<th></th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Visit 6</th>
<th>Visit 7</th>
<th>Visit 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1,525.96</td>
<td>934.84</td>
<td>934.83</td>
<td>934.83</td>
<td>1,238.05</td>
<td>934.81</td>
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</tbody>
</table>

### Unit

<table>
<thead>
<tr>
<th>Outside Billable Items</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnds with ICF Changes</td>
<td>$750.00</td>
</tr>
<tr>
<td>Amnds without ICF Changes</td>
<td>$500.00</td>
</tr>
<tr>
<td>SAE (Local)</td>
<td>$150.00</td>
</tr>
<tr>
<td>SAE (Non-Local)</td>
<td>$50.00</td>
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</table>
# Tracking System Milestone Grid

<table>
<thead>
<tr>
<th>Sponsor ID #</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4 Week 3</th>
<th>Visit 5 Week 4</th>
<th>Visit 6 Week 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Week 1</td>
<td>Week 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PLEASE ENTER DATE OF SERVICE FOR EACH VISIT**

<table>
<thead>
<tr>
<th>1001</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1002</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1003</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Tracking System

### Deposit/Invoice Log

<table>
<thead>
<tr>
<th>Date Invoiced</th>
<th>Invoice Number</th>
<th>Amount Invoiced</th>
<th>Date Issued</th>
<th>Check Number</th>
<th>Amount Received</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$13,750.00</td>
<td>8/5/2004</td>
<td>5886589</td>
<td>$13,750.00</td>
<td>Paid in Full</td>
<td></td>
</tr>
</tbody>
</table>

## One Time Fee Payment Report

<table>
<thead>
<tr>
<th>Date Invoiced</th>
<th>Invoice Number</th>
<th>Amount Invoiced</th>
<th>Date Issued</th>
<th>Check Number</th>
<th>Amount Received</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$13,750.00</td>
<td></td>
</tr>
</tbody>
</table>

## Clinical Payment Report

<table>
<thead>
<tr>
<th>Date Invoiced</th>
<th>Invoice Number</th>
<th>Amount Invoiced</th>
<th>Date Issued</th>
<th>Check Number</th>
<th>Amount Received</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Tracking System
### Payment Report

<table>
<thead>
<tr>
<th>Date on Study</th>
<th>Patient initials</th>
<th>Sponsor ID #</th>
<th>Patient Care Costs Expended to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Jul</td>
<td>PT 1</td>
<td>1001</td>
<td>$0.00</td>
</tr>
<tr>
<td>25-Jul</td>
<td>PT 2</td>
<td>1002</td>
<td>$0.00</td>
</tr>
<tr>
<td>2-Aug</td>
<td>PT 3</td>
<td>1003</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
<tr>
<td>0-Jan</td>
<td>0</td>
<td>0</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

**Total Patient Care Costs Expended** $0.00

**Total Cost of Outside Billable Items** $0.00

**Total Reimbursed to Date** $0.00

**Total Reimbursement Due** $0.00
# Tracking System Invoice Log

<table>
<thead>
<tr>
<th>DATE:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>INVOICE NO:</td>
<td></td>
</tr>
<tr>
<td>PI:</td>
<td>John Doe, MD</td>
</tr>
<tr>
<td>SPONSOR:</td>
<td>SPONSOR</td>
</tr>
<tr>
<td>TO:</td>
<td></td>
</tr>
<tr>
<td>PROTOCOL NO:</td>
<td>2004-BIDMC</td>
</tr>
<tr>
<td>TITLE:</td>
<td>A Randomized Double Blind Phase II Study to Evaluate STUDY DRUG Treatment versus Placebo in Patients with Carcinoma and High Risk of Recurrence</td>
</tr>
<tr>
<td>STUDY PERIOD:</td>
<td>6/20/04 - 9/19/06</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Payment</td>
<td>$0.00</td>
</tr>
<tr>
<td>(See Payment Worksheet)</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL** $0.00

Payment due within 30 days of date of invoice
Verifying Payment

You want this... not this!
Auditing a Study Before Closing

- Compare the total amount received from the Sponsor to what was budgeted, if there are deviations, determine the reason and bill or correct as needed.
- Compare the list of subjects enrolled on the trial with the milestone grid for missing or additional subjects.
- Using the total enrolled subjects, determine the correct amount of salaries (all personnel) that should have billed to the grant.
## Close-out Audit: Sponsor Account Summary Report

<table>
<thead>
<tr>
<th>Pmt Name</th>
<th>Visit</th>
<th>Date</th>
<th>Monitored</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7/1/2004</td>
<td>8/1/2006</td>
<td>1,525.96</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7/15/2004</td>
<td>8/1/2006</td>
<td>934.84</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7/22/2004</td>
<td>8/1/2006</td>
<td>934.83</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>7/29/2004</td>
<td>8/1/2006</td>
<td>934.83</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>8/5/2004</td>
<td>8/1/2006</td>
<td>1,238.05</td>
<td></td>
</tr>
</tbody>
</table>
Why Is There Such A Priority in Regards to Our Billing Compliance?

- Medicare “double billing” has been the subject of numerous OIG/DOJ investigations/settlements.
- OIG 2004 Work plan includes Clinical Trial Billing in its top “compliance” initiatives.
- From a research and business perspective, it is important to track clinical care/standard of care v. “research only”.
- Medicare billing fraud carries serious penalties.
Billing Compliance

In Summary

- Whether your compliance program is new or well established, it is important to periodically evaluate the revenue stream through compliance.
- Risk assessment is not a one-time event; ongoing identification and monitoring of risk areas is mission critical.
- Do not underestimate the importance of increasing awareness of risk areas.
- Best practices may not exist; the right solutions depend on several factors and you may have to discover them as you go.
- Review bills for research-related services to ensure compliance with grant or other funding requirements.
Questions?

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