

Medicare Billing and Reimbursement Essentials for Research

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Agenda

Why is Medicare Billing Compliance Important?

What are the Reimbursement Essentials?

National Coverage Decision (Trials Specific)

Process Flow for Medicare Reimbursement

What is your Institutional Approach?

Implementing a Process

Key Operating Strategies

What are the Common Pitfalls?

Conclusion

Why is Medicare Billing Compliance Important?



- Federal scrutiny of research
- Federal auditors' perspective on clinical trials billing

Federal Government's Scrutiny of Research

- Actions and outcomes that impact institutions conducting research
 - PATH audits
 - DOJ and OIG's audits on experimental drug trial billing practices
 - FDA and OHRP audits
 - Settlements, fines and research suspension
- The DHHS Office of the Inspector General ("OIG") 2000 Work Plan
 - Increased enforcement activity has resulted in increased criminal and civil sanctions in the area of provider billing.
 - OIG and DOJ share in proceeds from settlements

Federal Audit Perspective on Billing

- OIG's *assumption* on reviewing Medicare billing of research grant and clinical trials
 - Experimental treatment is generally **not covered** by Medicare
 - Physicians have an incentive **not to charge** cost to their grants
 - There is a significant risk of “**double billing**”
- Institutions have **not developed an infrastructure** (policies, procedures and systems) that would support accurate coding of charges.

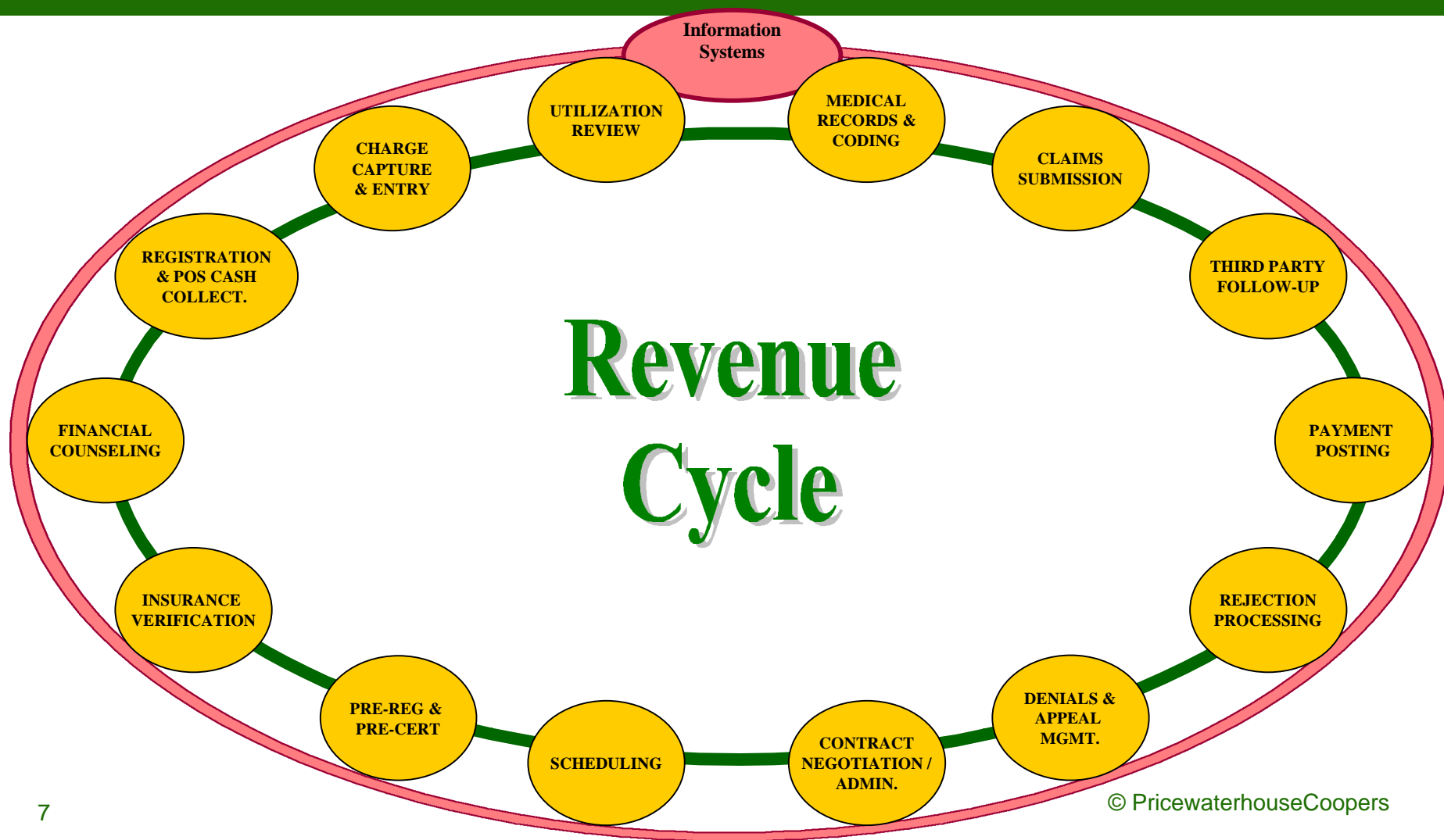
Reimbursement Essentials



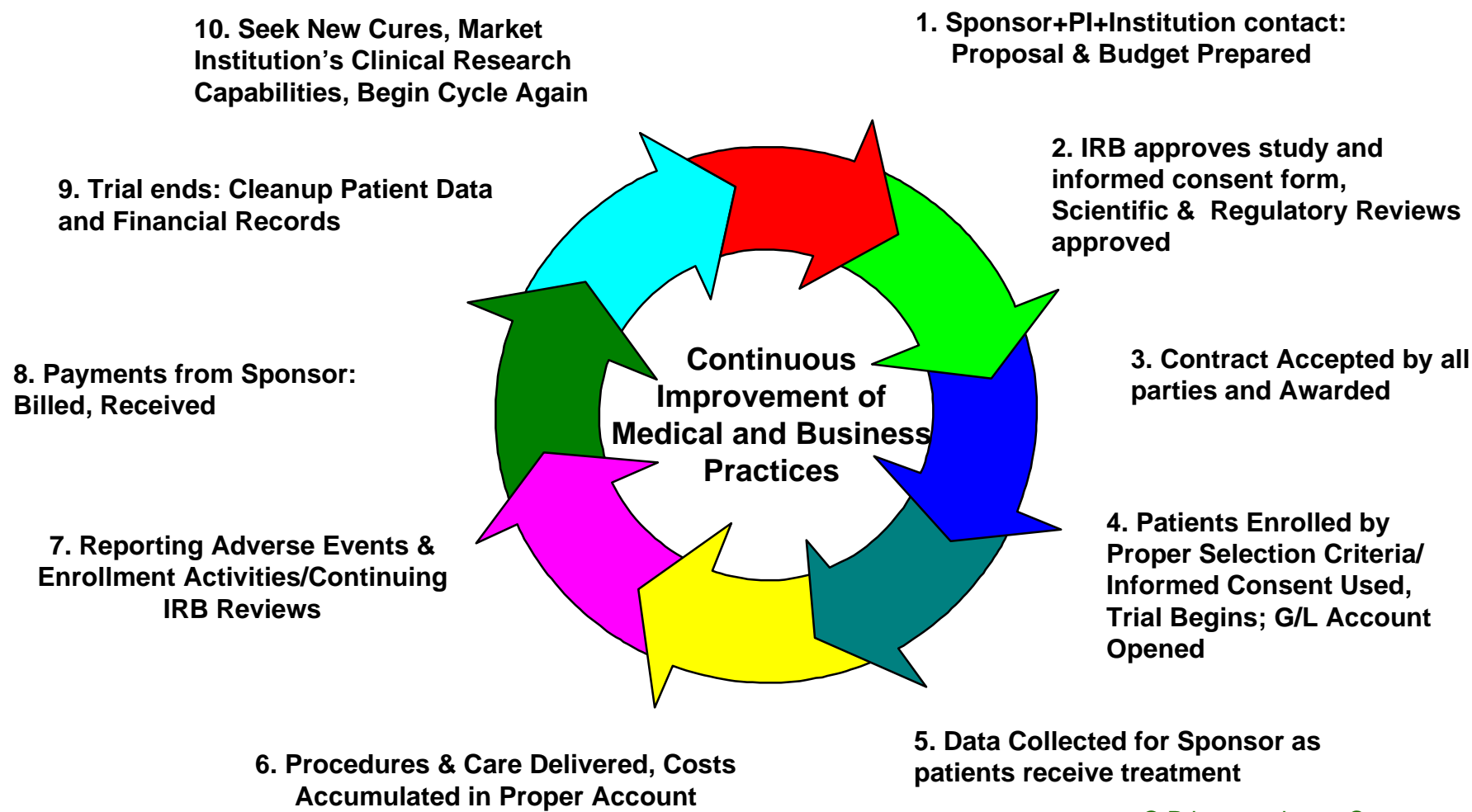
- Revenue Cycle
- Clinical Trial Business Cycle
 - Why is it so difficult?
 - What is your organization doing?
- National Coverage Decision - Trial specific questions
- Process Flow for Medicare reimbursement

Revenue Cycle

Slide Courtesy of PwC's Revenue Cycle Team



Clinical Trials Business Cycle



Why is clinical trials billing so difficult?

- The rules for billing standard care to research patients are subject to ***varying interpretations***
- For many trials, it is difficult to ***distinguish research from standard care***
- The clinical trials business cycle involves ***many departments and people***
- ***Operational and information systems are geared to patient care***, not research
- Errors create ***publicity as well as financial risk***
- The government is ***paying attention***

What are typical organizations doing?

Processes

- Creating “workarounds” to handle financial interactions with different hospital/practice ancillary departments.
- Process - heavily paper driven (memorandums to departments and personnel)

Staff

- Knowledge of processes vary by research staff member
- Research staff feels the need to “jump through hoops” to get things accomplished

Financial

- 10 • Clinical trial account balances - using the residual funds as a “rainy day” cost center

Medicare Billing Guidelines

- 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.
- *i.e. “Double dip”: Billing of thirds party payors for cost that are reimbursed through clinical trials; or billing twice for the same service.*

National Coverage Decision (NCD)

Trial Specific Questions

Qualifying Trial

- Does the service/item evaluate a benefit category?
- Does the study have a therapeutic objective?
- Does the study enroll diagnosed Medicare beneficiaries
- Does the study have desirable characteristics?

Routine Cost

- Would the items/services be provided in the absence of the trial?
- Are the items or services required for the provision of the study item/service?
- Are the items/services required for appropriate monitoring or to prevent complications?
- Are the items/services medically necessary for the diagnosis or treatment of complications arising from the provision of the study item/service?

Process Flow for Medicare Reimbursement

General Issues

Qualifying Trial

- What was the qualification process?
- How was this documented?

Routine Cost

- Who/How were routine costs determined?
- How were these documented?

Billing for Services

- How were the routine cost determinations communicated?
- How were the charges captured?
- Was there a UB-92/HCFA 1500 review?
- How were the services documented?

Process Points

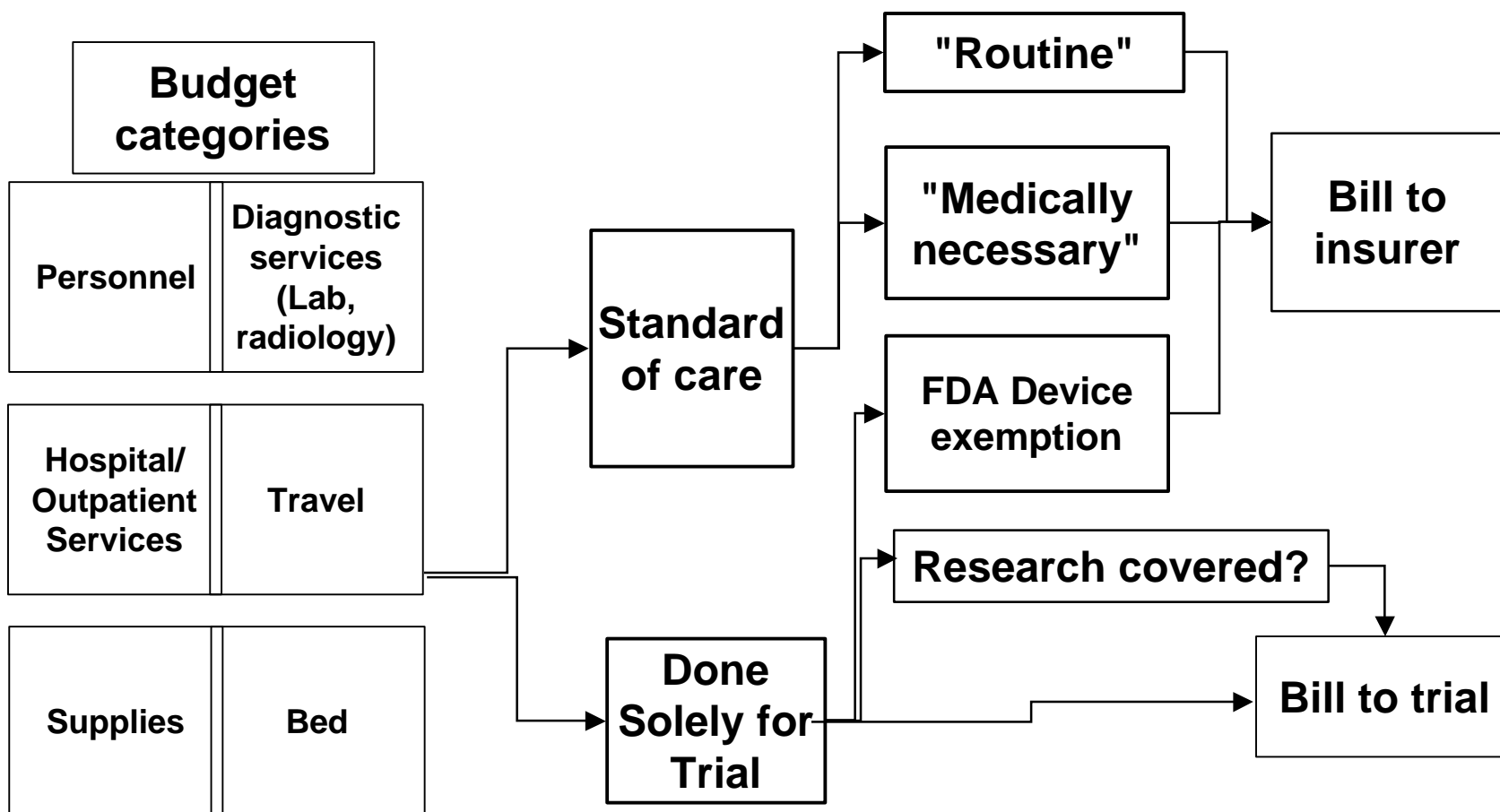


- Budgeting
- Registration
- Billing

Important Process Points

- Clinical Trials Budgeting
 - Services/items reimbursement payments
 - Knowing which services/items are “routine”
- Routine Cost Communication Flow
 - Ensuring provider communication of appropriate “QV” procedural code modifiers to charge entry personnel
- Proper Registration
 - Ensuring entry of the appropriate secondary or tertiary “V70.5” diagnosis code
- UB-92 and HCFA 1500 Review
 - Ensuring coding and document review prior to claim submission
 - Internal, on-going audit

For each trial, PI must decide which services (professional, hospital, lab services) are standard of care versus trial specific.



Proper Budgeting

Compliance and Risk areas addressed

- Allows good financial management of research
 - Know the costs
 - Know the appropriate allocation of costs
- Supports reimbursement of charged services
- Addresses billing compliance issues
- Accounts for personnel expenditures (faculty and research staff)
 - Compensation and benefits
 - Related expenses (travel, education)

Benefits of Research Registration

- Decreased billing errors
- Improved billing accurate and research compliance
- Increased study patient satisfaction
- Improved collection of revenue attributed to clinical service areas (e.g. hospital, physician providers)
- Improved data capture for the research enterprise

Billing Process Development Needs

- Training
- Monitoring - Back-end
- Problem Resolution Process

Implementing a Process



- Key operating strategies
- Questions to consider
- Additional billing policies and procedures

Implementing a Process

Strategic Change Process

- Understand the clinical trials billing process (existing processes)
- Determine the risks of noncompliance
- Determine locus of control
 - Who is responsible for the process?
 - Who will champion the changes?
- Assemble a team
- Develop a solution/process for appropriate clinical trials billing

Implementing a Process

Key operating components process strategy

1. Centralize and coordinate process flow
2. Standardize the process and documents
 - Clearly defined roles and responsibilities
 - Written policies and procedures
3. Provide training and education for staff throughout the process
4. Monitor the effectiveness of process
 - Assign designated staff to monitor in the progress of trials
 - Intervene as needed to assure timely approval
5. Perform quality assurance review - ensure research charges are posted correctly to the clinical trial account

Questions to consider for process implementation?

- What is the best way to train departmental personnel in the application of such an institutional policy?
- How can you encourage frequent and active communication between the research coordinator(s), hospital labs, and other shared services to assure correct posting or charge capture of all charges on the study?
- Is a back-end review conducted to identify and remove inappropriate charges to third party payers?

Related Policies to be Considered

- Elements of clinical trials budgets
- Criteria and authorization requirements for conducting unfunded trials
- Unrelated business income tax (UBIT)
- Research discounts
- Information to be provided by departments to registrar, ancillary departments related to billing
- Compliance hotline and other feedback mechanisms
- Records, documentation requirements
- Quality assurance function
- Sponsor invoicing and maintaining research A/R
- Accounting for and reimbursement of the hospital, university for indirect costs
- Accounting for personnel charges (faculty and support) salaries
- Closeout of residual balances

Common Pitfalls



- Typical problems areas for billing compliance

Typical Problem Areas for Billing Compliance

- Budgeting - Budgetary capabilities often vary by support/admin staff.
 - No standard budget development or negotiation of terms with trial sponsors.
 - It is unclear whether anyone assesses the adequacy of the budget and identifies study v. non-study charges.
- Patient Registration - Often, information collected at the time of registration is insufficient to ensure the proper Medicare billing.
 - Clinical departments have created “work arounds” to handle financial interactions with hospital ancillary departments outside of the billing system.

Typical Problem Areas for Billing Compliance

- Patient Registration -
 - Patients are not identified as research patients nor given clear notice/counselling of their potential financial obligations.
 - Grant specific information is not captured accurately or completely.
- Outpatient Services - Too much reliance placed on hospital / clinic personnel
 - Providers/Technicians may not be aware that individual is a research subject.
 - Subjects arrive for service, yet not registered in the system.

Conclusion

- **Best practices for addressing clinical research billing issues do not exist. However, there are essentials for a comprehensive approach to implementing a research reimbursement plan.**
- **The right solution for an organization will depend on the mix of:**
 - Research portfolio
 - Organizational structure
 - Culture
 - Systems
 - Growth plans

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