

NCURA Region II Conference

Trial by Fire: How to Navigate Clinical Trial Billing Compliance

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Session Topics

- Overview of CMS Regulations on Clinical Trial Billing
- Potential Approaches to Compliant Clinical Trial Billing
- Case Study: West Penn Allegheny Health System
- Questions

Overview of CMS Regulations on Clinical Trial Billing

Why Is This Important?

- Growing focus of attention from regulators and investigators on the topic
- RUMC settlement with OIG reached in December 2005
- Integrity of research
- Trust of sponsors and research participants
- Attention to accurate budgeting to ensure appropriate use of research dollars
- Assurance that all research dollars are captured (under-billing is as, or more, common than over-billing)

Timeline of CMS Regulations Related to Clinical Trials and/or Research Billing

- Regulations addressing Category B IDE device trials, September 1995
- NCD for Clinical Trials mentions devices, September 2000
- Passage of the Medicare Modernization Act that permits coverage of routine care items in Category A device trials, December 2003
- Regulation permitting payment for routine care services provided in an FDA covered Category A clinical trial for a life threatening condition, but the device itself remains uncovered, November 2004
- Announcement of the initiation of the reconsideration of the clinical trial policy (“First Reconsideration”) – July 2006
- The Proposed Decision Memorandum (First Reconsideration) – April 2007
- Clinical Trial Policy Final Decision (First Reconsideration) – July 2007
- Proposed Decision Memorandum for Second Reconsideration of Clinical Trial Policy, Renamed Clinical Research Policy. Clarifies its inapplicability to IDEs and keeps HDE coverage within the purview of the contractors, July 2007
- Decision Memo on Second Reconsideration to Maintain Status Quo – October 17, 2007

What Is Covered In the Clinical Trial Policy?

“Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.”

Is It A Qualifying Clinical Trial?

Any clinical trial receiving Medicare coverage must meet the following four requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage.
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed diseases rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
- The clinical trial must meet the seven desirable characteristics.

The Seven Desirable Characteristics

What are the Seven Desirable Characteristics?

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

The Seven Desirable Characteristics

How do I prove that my trial meets the seven desirable characteristics?

Medicare will cover the routine costs of qualifying trials that either have been:

- Deemed to be automatically qualified;
- Self-certified that they meet the qualifying criteria; or
- Are required through the Coverage with Evidence Development process

Unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Self-Certification

- CMS will convene a federal panel of representatives from DHHS, NIH, CDC, FDA, DOD, and VA to develop qualifying criteria that will indicate a strong probability that a trial exhibits these characteristics.
- The panel will not review and approve individual trials.
- The panel will meet periodically to review and evaluate the program and recommend changes to CMS.
- PI will certify that the trial meets the criteria.

The panel met once. This self-certification process was never implemented.

What About The “Deemed” Status?

The following trials are deemed to automatically meet the 7 desirable characteristics:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA;
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place and;
- Trials required through the Coverage with Evidence Development (CED) process.

Additional Items Of Note

- This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies, local coverage determinations, or the regulations on investigational device exemptions (IDE).
- For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care.
- Medicare regulations require Medicare + Choice (M+C) organizations to follow CMS's national coverage decisions. M+C organizations, therefore, must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

Which Device Trials are Covered?

- **Device trials that may be covered under Medicare include the following categories:**
 - Devices approved by the FDA through the Pre-Market Approval (PMA) process;
 - Devices cleared by the FDA through the 510(k) process;
 - FDA-approved Investigational Device Exemption (IDE) Category B devices;
 - FDA-approved IDE Category A devices in an immediately life-threatening situation, disease, or condition (the device itself is not covered, but related services are);
 - Hospital Institutional Review Board (IRB) approved IDE devices.

Which Device Trials are Covered? (continued)

- **Device language from the Proposed (but not implemented) CRP:**
 - Investigational Device Exemption (IDE). This policy is not applicable to, and does not change Medicare coverage according to the regulations on category A and category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406.
 - Humanitarian Device Exemptions. Since humanitarian use devices (HUDs) with an FDA approved humanitarian device exemption (HDE) are not addressed in this policy, local contractors may continue to make determinations about the coverage of HUDs.

What is the Approval Process for Device Trial?

- Carriers and Fiscal Intermediaries are responsible for making the coverage determinations on all FDA-approved IDE devices.
- Consistent with the rules of the local carrier and/or fiscal intermediary, the provider participating in the clinical trial must furnish all necessary information concerning the device, the clinical trial and participating Medicare beneficiaries needed for a coverage determination and claims processing. **You should check with your local carrier / fiscal intermediary to determine which documents should be submitted and to whom.**
- A coverage determination for the device should be obtained by the provider prior to conducting/finalizing the Medicare Coverage Analysis of the device study.

How Do You Apply These Criteria To Individual Protocols?

Conduct a Medicare Coverage Analysis (MCA)

- An MCA is a systematic review of research-related documents to determine the Medicare qualifying status of the study itself and the Medicare billing status of the items and services provided to the research subjects over the course of the research.
- Many create a billing grid that summarizes the items and services related to the protocol with the supporting information to justify billing, because:
 - Medicare rules tend to set the trend for the payer industry.
 - Double billing or mis-billing Medicare can result in fines, sanctions, or suspension.

Use the MCA to segregate research charges

What are the Challenges to Compliant Research Billing?

- Many institutions lack the ability to identify and track research patients
- Billing is an automated process with little opportunity to intervene once services are provided
- Clear channels of communication between research teams and Patient Financial Services may not exist
- Research contracts are confidential, and infrequently shared with billers

Potential Approaches to Compliance

Models for Addressing Clinical Research Billing Compliance

- Create a research registration process by:
 - Dual registration (e.g. research registration and non-research registration)
 - One registration, two insurance provider codes
 - Flag research patient in registration system
- Identify and segregate research versus non-research appointments via:
 - Different color paper / online forms
 - Pre-populate paper / online form with items and services of each study
 - Research check boxes on the paper / online forms
 - Integrate with a clinical research management system
- Modify appointment requests / scheduling
 - Research flag utilized for procedures in scheduling system
 - Separately schedule research and non-research

Models for Addressing Clinical Research Billing Compliance (continued)

- At the point of Charge Entry:
 - Flag research or non-research when coding encounter forms
 - Modify Charge Description Master (CDM) to include research-specific codes
- During Charge Capture:
 - Review Physician Order Entry / appointment request against Medicare coverage analysis
 - Automate processes above via clinical research management system interface
- Prior to the generation of a bill, implement:
 - Manual back-end bill review and charge scrubbing; or
 - Modified IT systems to accommodate above suggestions

Models for Addressing Clinical Research Billing Compliance (continued)

- Common Short-Term Solutions:
 - Patient-level research flag
 - Visit-level research flag
 - Edit checks via patient registry / Clinical Research Management System
 - Dual registration

Potential Work Plan

- Examine existing infrastructure
- Document process flow for existing operations
- Solicit support of key players to provide technical expertise and project support
- Create a Steering Committee to determine evaluation criteria and guiding principles for process development
- Develop an Interim and Long Term clinical trial billing process
- Develop training materials and process flow documents for the interim and long-term processes
- Pilot the process and schedule roll-out of the interim and long-term processes

**Case Study:
West Penn Allegheny
Health System**

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Settlement Agreement with The Office of Inspector General (OIG), Department of Health and Human Services.

Allegations were that . . .

- Cardiology Investigational Devices were not “reasonable and necessary” and thus not reimbursable under Medicare.
- “Knowingly” submitted false claims for payment to Medicare for experimental procedures and/or procedures utilizing investigational devices.

Settlement was reached without admission of guilt or wrongdoing to avoid the uncertainty and expense of further litigation.

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Settlement Terms

- Required re-payment of prior claims billed.
- Required written policies and procedures addressing billing for investigational devices and procedures consistent with applicable law and regulations.
- Required distribution of these policies and procedures to all individuals whose job functions are related to those policies and procedures.
- Required review of those policies and procedures annually for a period of five years.

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Settlement Terms (cont'd)

- Required distribution of policies and procedures to new employees as they are hired through orientation.
- Required a training program on an annual basis for a period of five years to all relevant individuals involved in billing for any patient care involving investigational devices or procedures.
- Required annual reports to the OIG on the policies and procedures in place, how they were distributed, the training provided including attendees, schedule of training and attendance.

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Relevant Individuals Requiring Training

- Institutional Review Board (IRB)
- Department Chairs
- Principal Investigators
- Study Coordinators
- Research Administrative & Ancillary Personnel
- Medical Records
- Patient Financial Services

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Policy Statement

- The Department Chair or Institute/Center Director is responsible for ensuring that the Director, Office of Sponsored Research is advised in writing of the intended investigational use of any drug, biological, medical device or services covered by this policy in his/her area of clinical responsibility.
- Notification must occur before care is provided to the patient with sufficient time to obtain clarification of the applicable payer's position on reimbursement.
- The approval process can be lengthy, therefore this notice should be submitted to the Director, Office of Sponsored Research as soon as it is known that a study is being planned and prior to submission of the study protocol to the Institutional Review Board (IRB).
- In the case of a medical emergency, the notification must be provided to the Director, Office of Sponsored Research and the IRB, and must occur as soon as possible after the service is provided.

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Responsibilities of Relevant Individuals

Department Chair/Institute Director

The Department Chair or Center Director is responsible for ensuring compliance with the research billing policy by:

1. Ensuring that all physicians and staff in the department or institute are informed of the requirements of this policy.
2. Ensuring that the Director, Office of Sponsored Research is notified of the intent to provide research services as required by this policy.

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Responsibilities of Relevant Individuals

Investigators for Research (Medical Staff)

- Members of the Medical Staff are responsible for informing their Chair/Director and Operations Vice President of the intent to use any investigational drug, biological or medical device, or provide services covered by this policy.
- Responsible to complete the Investigational Device and Drug Reimbursement Verification Form and submit it to the Director, Office of Sponsored Research as soon as it is known that a study is being planned and prior to submission of the study protocol to the IRB.
- The principal investigator is responsible to ensure that the Clinical Trial Billing Procedure is followed for each participant throughout the trial.

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Responsibilities of Relevant Individuals

Office of Sponsored Research/Operations Vice Presidents

- The Operations Vice President and the Office of Sponsored Research are responsible for working with the Department Chair/Institute Director to ensure that this policy is effectively communicated and implemented.
- The Office of Sponsored Research is responsible for reviewing billing forms for accuracy and obtaining the signature of the attending physician prior to submitting billing forms to Hospital/Profee Billing.
- Office of Sponsored Research will forward the Investigational Device and Drug Reimbursement Verification Form to Patient Financial Services (PFS) for coverage determination.
- The Office of Sponsored Research will notify the principal Investigator, the Chair/Director and the Operations Vice President in writing of the outcome of the coverage review by PFS.

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Responsibilities of Relevant Individuals

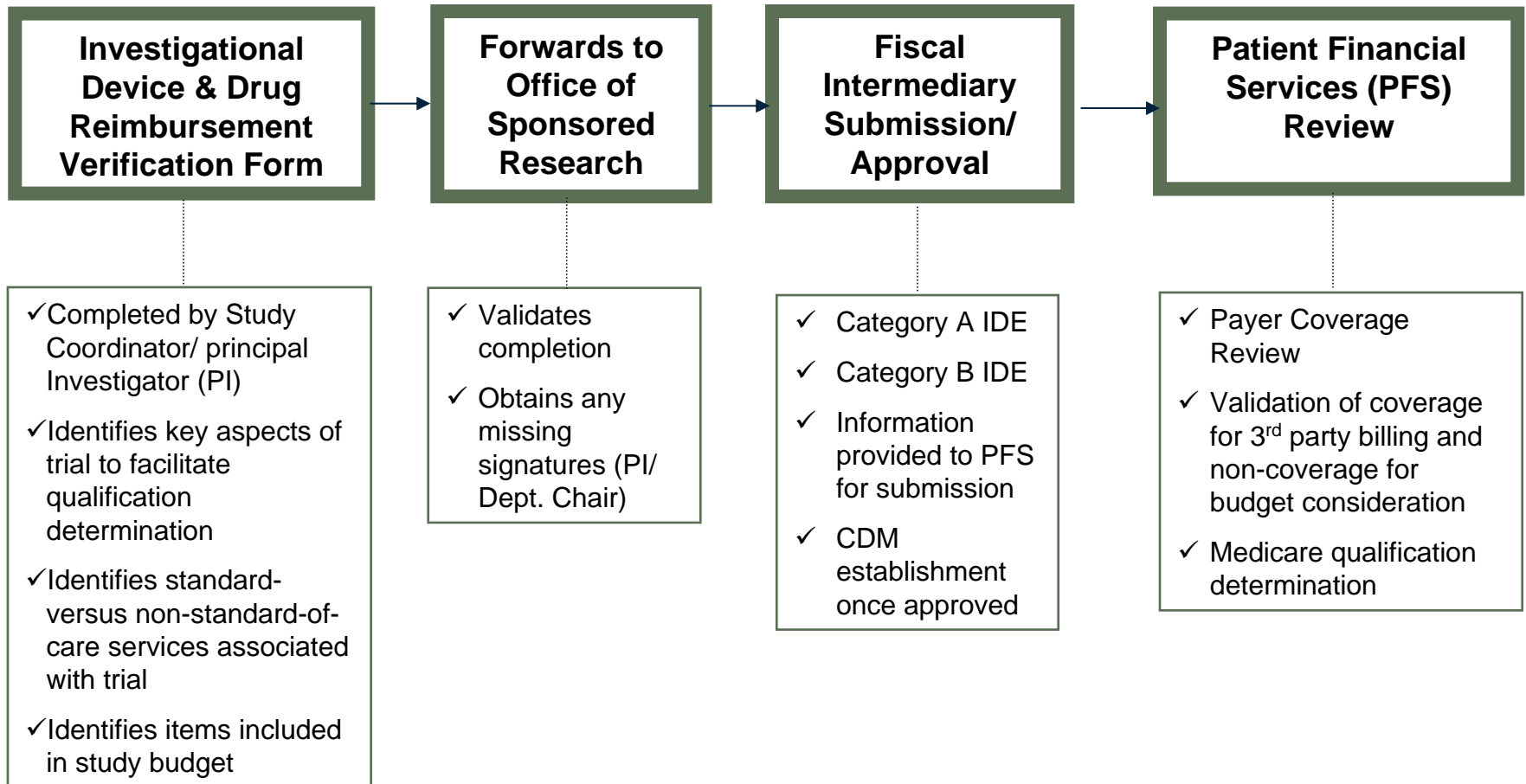
Patient Financial Services

- The Patient Financial Services Department is responsible for obtaining written clarification of the applicable payor's position on reimbursement for any investigational drug, biological, medical device or services covered by this policy and for notifying the Office of Sponsored Research in writing of the outcome of this review.
- For Category B and certain Category A Investigational Device Trials, this involves communication and coordination with the local Medicare Fiscal Intermediary to obtain approvals for coverage of services in the clinical trial budget prior to subject enrollment.

Clinical Trial Billing Procedures

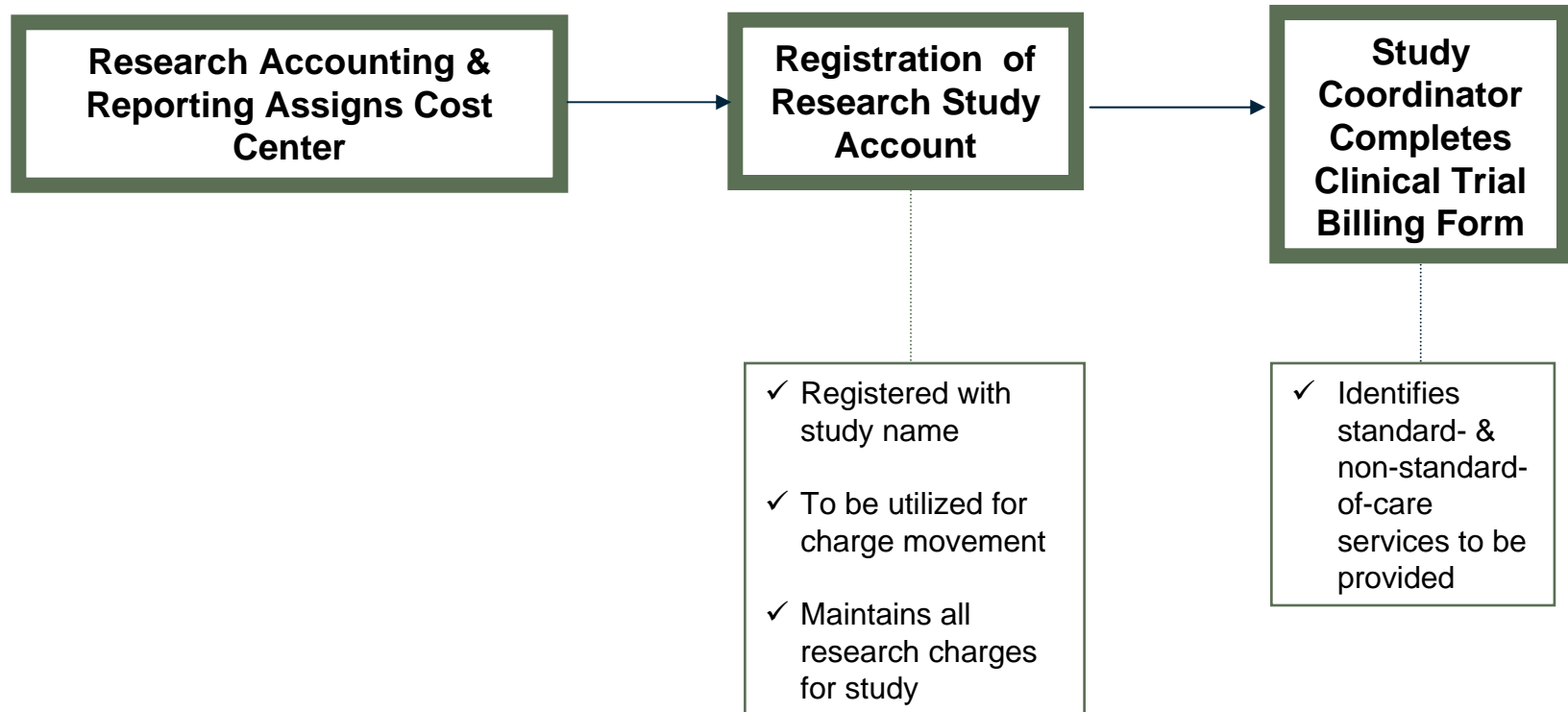
Initial Approval Process

(Prior to IRB Review)



Clinical Trial Billing Procedures

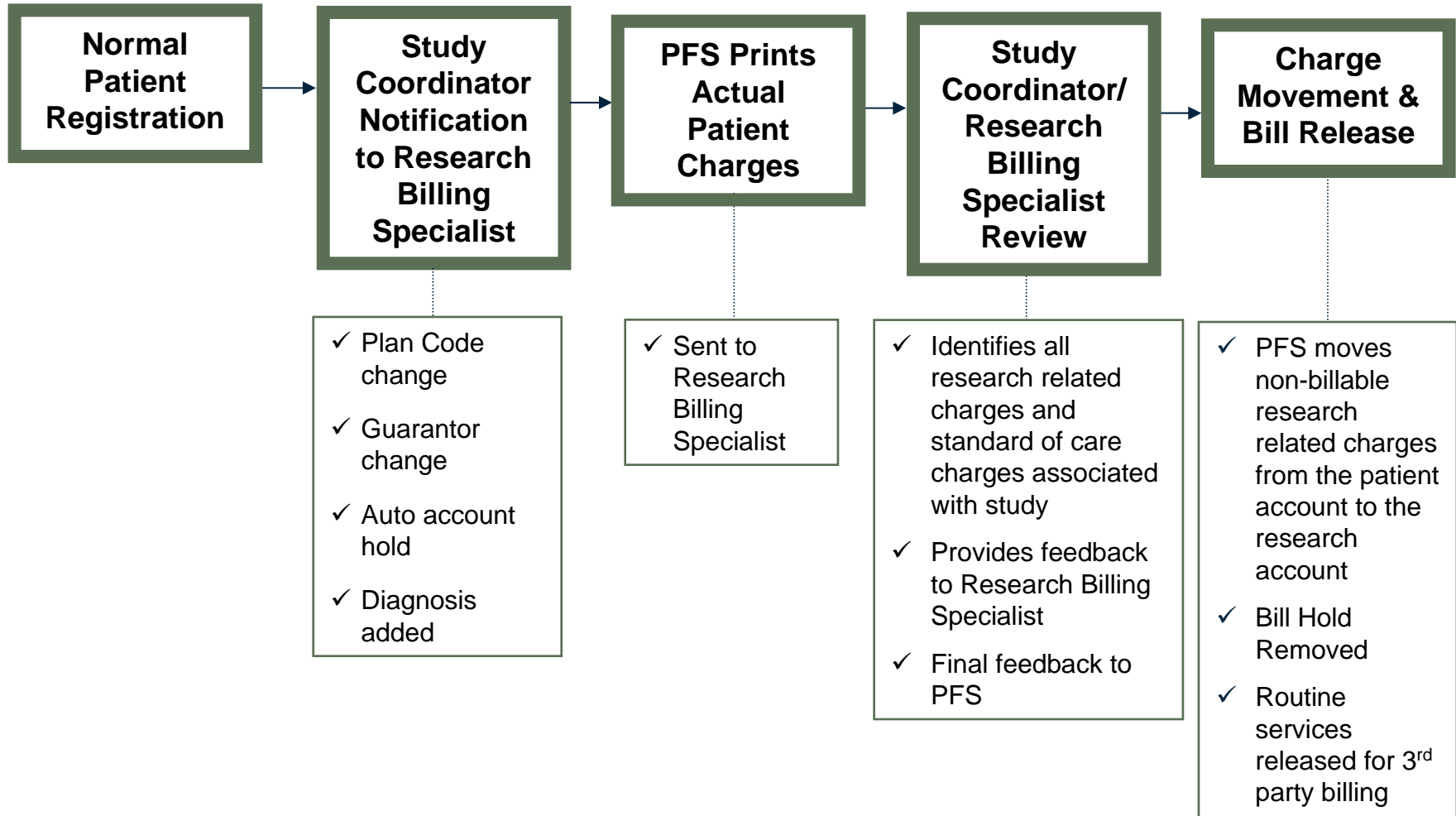
Research Account Establishment



Clinical Trial Billing Procedures

Ongoing Identification and Reconciliation Process

(Completed for each Research Subject)



Questions?