An Overview of Clinical Trials Billing

Objectives

1. Understand key research billing concepts
2. Identify different billing options in clinical research
3. Direct charges appropriately
4. Clarify study fund management/PI responsibilities
5. Inform on correction process

Billing compliance matters

Incorrect billing might be considered **fraud** or a **false claim**	• "Double billing" charges subject/insurance & study sponsor • Protocol-required items/services billed to insurance that are not eligible for CMS* coverage
Ethical **obligation** & Informed Consent agreement to **bill accurately**	• Breach of subject's privacy; could adversely impact their life in material ways • Patient could end up in Collections; credit affected
Institutional **reputation** to promote **research excellence**	• Subjects volunteer their time for research • Prospective clinical research cannot be done without research subjects and their trust in the process

**Centers for Medicare and Medicaid Services*

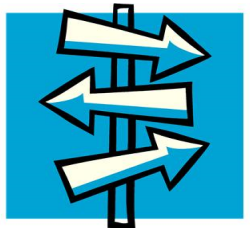
EPIC charge definition

1. Usual and customary care, which will occur in parallel with clinical research, and which will not be related to, or required by, a study protocol
   OUTCOME: encounters are billed as usual to patient or patient's insurance and may require billing review in Epic

2. Usual and customary care that may be required by the protocol
   OUTCOME: special billing requirements may apply, need Medicare Coverage Analysis determination and billing review

3. Protocol-related, clinical-research-only procedures: if not billed to insurance, must be charged to study fund
   OUTCOME: cannot bill to insurance, study must pay, need billing review

Medicare Coverage Analysis (MCA)

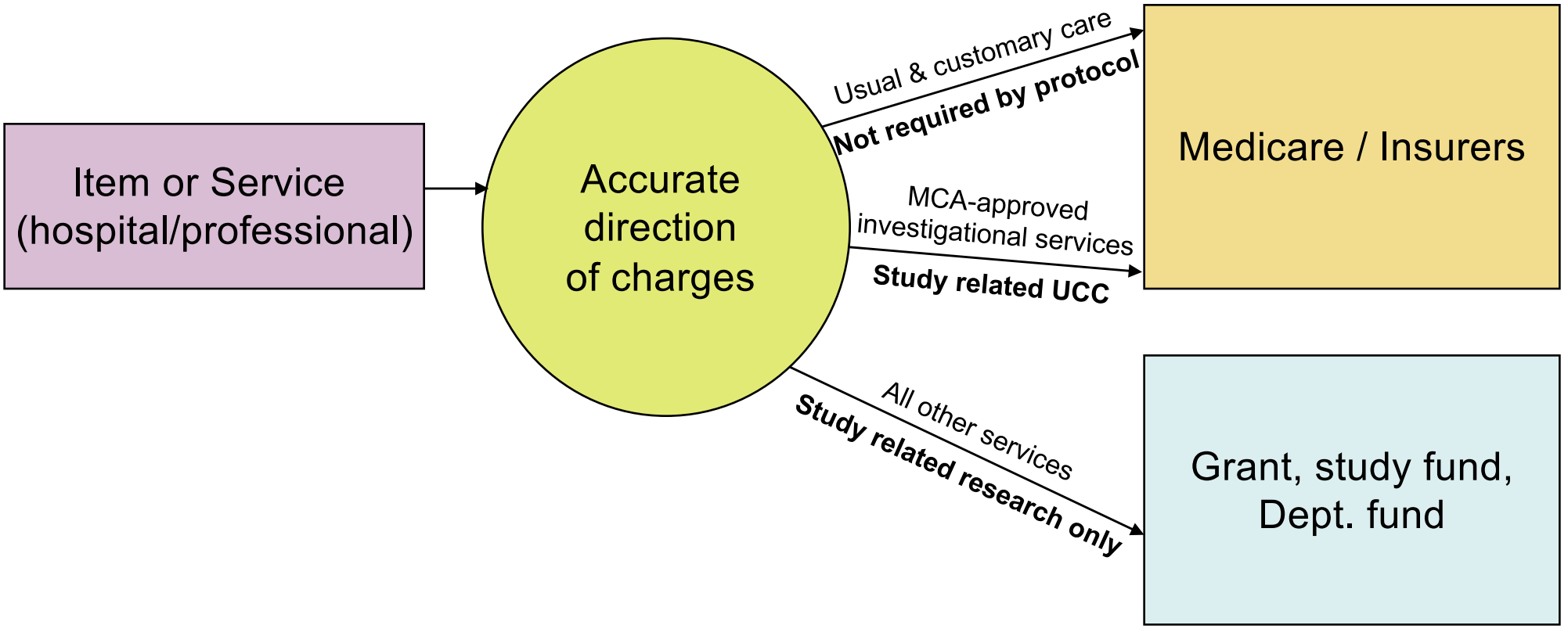


Partners Clinical Trials Office (CTO):

- Is notified, through the Partners initial IRB process, to determine if a study meets the Medicare criteria for a Qualifying Clinical Trial and requires an MCA
  - May contact the PI to obtain routine billing practice information for MCA determination or finalization
  - Develops billing calendar for Qualifying Clinical Trials that details protocol items/services and charge direction
  - For Qualifying Clinical Trials, some research-only procedures may be billable to insurance and will be discussed with PI
- Sends letter to the PI of the protocol informing PI whether study is a Qualifying Clinical Trial or a non-qualifying study
- If the protocol is non-qualifying, then the study fund must cover all protocol-required items/services that are performed solely for research
- **PI of the protocol** and **PI of the fund** (if not the same) are **equally responsible** to monitor **study**-related **charges**

Billable Research Services

Study team should confirm: **billing calendar**, IRB **Informed Consent** and **internal** budget and/or **external** funding agreement/**contract** are consistent; front-end understanding and setup results in increased billing accuracy



Who should be billed for *Usual and Customary Care Services?*

- ***Usual and customary clinical care*** (a.k.a. "standard of care"): the standard treatment a patient would normally receive in the course of medically necessary care
- Services that are usual and customary care may be billed to insurers like Medicare, Blue Cross Blue Shield, etc. -- even if it is given as part of a research study – or may be paid for by a study sponsor.

Example:

A patient has Inflammatory Bowel Disease, and is scheduled for a clinically indicated colonoscopy. Pre-procedure, the patient was consented for a research study looking for markers of inflammation from biopsies taken during a clinically indicated colonoscopy. No additional biopsy samples were collected for research. The research team is using the data from the procedures and biopsies.

- ***Question***: Can the colonoscopy be billed to insurance?
- ***Answer***: The colonoscopy procedure may be billed to insurance because it is usual and customary care for Inflammatory Bowel Disease. Biopsies collected for clinical care are billable to insurance. The study team can use the data from the procedures and biopsies but the study fund should not be billed.

Who Should be Billed for *Research Specific Services?*

- ***Research-specific patient care:*** specific to the research study, not a part of the usual and customary treatment plan for the patient
- Research-specific patient care typically may not be billed to insurance and must be charged to the grant or a department fund

Example:

A patient was diagnosed, via colonoscopy, with Inflammatory Bowel Disease two-months prior, and recently enrolled in a study looking for markers of inflammation from colon biopsies. The study requires two colonoscopies over one year, one may be data collection within three months of date of consent, and one for study sample processing. This patient population normally receives one colonoscopy year.

- ***Question***: Should the second colonoscopy and biopsy be billed to insurance?
- ***Answer***: No.
  - Colonoscopies and biopsies collected for research purposes only must be billed to a study fund.
  - The first colonoscopy and biopsies taken for standard clinical purposes should be billed to the subject's insurance (even if the data are also being used for research purposes).

Who Should be Billed for

Research Services in Qualifying Clinical Trials

- Medicare may cover Investigational items or services if:
  - The study is a Qualifying Clinical Trial
    AND
  - The Investigational or Research Item or Service would typically be covered by Medicare for research

- Other insurers are under no obligation to follow Medicare's determination; they may do so at their own discretion

Example:

A qualifying clinical trial investigates a new type of artificial knee.

- ***Question***: Would the surgery to place the artificial knee be covered by Medicare?
- ***Answer***: Typically Medicare would cover the expense of the surgery if the trial is approved by CMS* and the sponsor is not providing reimbursement for the procedure. A Medicare Coverage Analysis (MCA) would be conducted prior to the start of the trial. The study team would bill based on the MCA determination.

**Centers for Medicare and Medicaid Services*

Charge direction in Epic

- Active study code required in Epic (auto-populated from Insight)
- Enroll subject to applicable study code
- Link research encounters/orders/admissions to study
- Run Epic's "Research Billing Review Report" for accurate charge review
  - review charges within 7 days of posting in Epic
  - check Research Billing review report 2-3 times per week
  - delinquent charge review could result in leadership email escalations

Accurate charge allocation is **YOUR** responsibility!

Managing the Study Fund
Study team responsibilities

The PI and/or delegated study team member(s) must:

1. Ensure the fiscal health of his/her study fund

2. Develop a budget prior to the start of the study that encompasses all activities related to the research; use this list of activities to track if items are being billed appropriately

   – Industry sponsored trials: Partners Clinical Trials Office negotiates contract and budget

   – All other funding sources: work within study team and departmental resources

3. Link the IRB protocol, with patient care charges, to the research fund(s) that will be used to cover patient care costs

4. Define roles and responsibilities and ensure all study staff are trained on ordering, charge direction, and monitoring of study services and associated charges

Managing the Study Fund
Study team responsibilities, cont.

5. Contact Department Administrator monthly to monitor study funds in a timely manner

6. Promptly submit and monitor Patient Care Correction request in Insight's Agreements module if charges are:

   - missing that should be billed to the fund (could have gone to patient's insurance)
   - appearing and should be billed to insurance/patient
   - needing to be transferred to a different fund

Study team is accountable for protecting the research participants and the institution from incorrect billing.

Quiz

1.) *True or False:* Incorrect billing may be considered insurance fraud, or a false claim for payment from the Federal Government. **(True)**

2.) A Patient receives a CT scan as part of their regular medical care, you later use that CT for research purposes. The CT scan should be billed to: **(C)**

A.) the study fund

B.) a sundry account

C.) the patient's insurance

D.) an unrelated study fund

3.) *True or False:* In a non-qualifying trial, all research specific charges must be charged to the study fund**.** **(True)**

Quiz

4.) The Medicare Coverage Analysis determination is completed by: **(A)**

A.) Partners Clinical Trials Office (CTO)

B.) IRB

C.) your post award grants administrator

5.) If you discover that a patient or their insurance was billed for research services that should be billed to the study fund you should: **(D)**

A.) Use the Insight Patient Care Correction module to submit a correction request

B.) Make certain the charge correction includes both technical/hospital and professional fees if applicable

C.) Monitor the status of the correction request in Insight

D.) All of the above