Clinical Trials Billing Fundamentals

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BWPO/BWH Billing Compliance Office

REV: 2014Q4TS
Objectives

1. To provide a common understanding of clinical trials
2. To give details of key billing concepts
3. To explain patient care charges
4. To supply the elements of trial budget development
5. To clarify what it means to be a ‘qualifying’ clinical trial
6. To describe overview of future state – Partners eCare and Epic functionality for research

Primary Focus: Corporate sponsored clinical trials
Why getting Research billing ‘right’ is important

- Medicare ‘double billing’ has been a focus and the subject of numerous OIG/DOJ investigations/settlements
- The 2009 OIG Work plan included Clinical Trial Billing in its top compliance initiatives
- Not managing clinical research billing risks may lead to:
  - Billing for services already paid for by the sponsor
  - Billing for services promised free in the informed consent
  - Billing for services that are for research only that are not allowable to bill under the CMS Clinical Trial Policy (CTP)
What is a clinical trial?

‘Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. … Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.’

http://clinicaltrials.gov/ct2/info/understand#types
The Goal - Sort through all components, figure out what’s billable to insurance, determine a budget, then ensure that charges/cost get to the right place (insurance or study fund).
Patient care and charges within the trial

Every clinical service provided to a patient/subject has a patient care charge:

- Each must be accounted for by billing to insurance or by charging to the study fund
- These charges are defined in the institution’s rate book or charge master
- Most services have a hospital (technical) component and a physician (professional) component

Sometimes referred to as ‘patient care costs’ with regard to research, since ‘charging’ the study fund becomes an ‘expense’.
Preparation for budget development:

Each PI should carefully review the protocol and define for the patient population to be treated in the clinical trial:

- what is ‘usual and customary care’?
- what are ‘research specific’ services?

This will support and inform the MCA and budget work.
Technical vs. Professional charges

For clinical services provided in a hospital there are typically two bills/claims for each service:

- The hospital ‘technical’ or facility component
- The physician ‘professional’ component
More on charges …

For industry sponsored clinical trials:

The budget incorporates both technical and professional charges.

For federal sponsored clinical trials:

Professional charges cannot be charged to a study fund where investigator has effort assigned, but technical charges should be captured appropriately.
What is a Medicare Coverage Analysis?

- A study-specific billing summary that lists all items and services to be provided as part of a qualifying clinical trial with notations of what should be billed to the research sponsor and what can be billed to Medicare.

- A Partners requirement since January, 2008 (BWH, Faulkner, Spaulding, and MGH).

- Required by the IRB before protocol activation will be completed.

- Required for both industry sponsored and federal/foundation sponsored qualifying clinical trials.
Why an MCA is important…

- Informs the PI / study staff of how to direct the patient care charges.
- Becomes a tool for research billing compliance.
- Helps to avoid the risks of non-compliance.
  - Billing for services paid for by the sponsor >> fraud
  - Billing for services promised free in the informed consent >> fraud
  - Billing for services that are specific to the research protocol, but not medically necessary >> fraud
Medicare requirement for patient care billing

The Centers for Medicare and Medicaid Services (CMS) Clinical Trial Policy (CTP) says that the study must meet these criteria in order to bill Medicare for patient care services related to a clinical trial:

1. The study must meet the ‘qualifying’ requirement
2. The services must meet the definition of ‘routine cost’
3. Medicare must typically pay for those services when provided outside of the context of the clinical trial
## Sample Draft MCA

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Screening</th>
<th>2 wks</th>
<th>3 mo</th>
<th>6 mo</th>
<th>9 mo</th>
<th>12 mo</th>
<th>15 mo</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
<tr>
<td>Inclusion / Exclusion</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
<tr>
<td>Vitals</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is bundled with the physical exam and not separately billable.</td>
</tr>
<tr>
<td>Randomization</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
<tr>
<td>Physical exam</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>Given the patient's condition, a physical examination appears reasonable and necessary at work-up to address signs and symptoms. A physical examination in follow-up and during unscheduled visits appears appropriate to monitor and detect for complications related to the investigational item.</td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>TTE</td>
<td>M</td>
<td>M</td>
<td></td>
<td>M</td>
<td>M</td>
<td></td>
<td></td>
<td>We assume that given the patient's presenting symptoms and procedure performed that a transthoracic echocardiogram is reasonable and necessary at this frequency to initially diagnose and then monitor patient's condition. Coverage supported by Massachusetts Medicare Part A LCD L441.</td>
</tr>
<tr>
<td>Study drug</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>Study drug promised free of charge in informed consent.</td>
</tr>
<tr>
<td>Study drug administration</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>IV administration of the investigational drug is a covered service under NCD 310.1.</td>
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<tr>
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<td>F</td>
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<td>F</td>
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<td>This involves filling out a form and this activity is not separately billable to Medicare.</td>
</tr>
<tr>
<td>Concomitant meds</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>This involves filling out a form and this activity is not separately billable to Medicare.</td>
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<td>NB</td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
<tr>
<td>Procedure</td>
<td>Screening</td>
<td>2 wks</td>
<td>3 mo</td>
<td>6 mo</td>
<td>9 mo</td>
<td>12 mo</td>
<td>15 mo</td>
<td>Comments</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is research only and not billable to Medicare.</td>
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<tr>
<td>Vitals</td>
<td>n/a</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is bundled with the physical exam and not separately billable.</td>
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<tr>
<td>Randomization</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
<tr>
<td>Physical exam</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>Given the patient's condition, a physical examination appears reasonable and necessary at work-up to address signs and symptoms. A physical examination in follow-up and during unscheduled visits appears appropriate to monitor and detect for complications.</td>
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<tr>
<td>Pregnancy test</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>TTE</td>
<td>M</td>
<td></td>
<td>NB</td>
<td></td>
<td></td>
<td>M</td>
<td>NB</td>
<td>We assume that given the patient’s presenting symptoms and procedure performed that a transthoracic echocardiogram is reasonable and necessary at this frequency to initially diagnose and then monitor patient's condition. Coverage supported by Massachusset PI has indicated 3 and 15 mo are not usual and customary care at BWH.</td>
</tr>
<tr>
<td>Study drug</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>ICF</td>
<td>Study drug promised free of charge in informed consent.</td>
</tr>
<tr>
<td>Study drug administration</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>IV administration of the investigational drug is a covered service under NCD 310. 1.</td>
</tr>
<tr>
<td>Adverse events</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>This involves filling out a form and this activity is not separately billable to Medicare.</td>
</tr>
<tr>
<td>Concomitant meds</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>F</td>
<td>This involves filling out a form and this activity is not separately billable to Medicare.</td>
</tr>
<tr>
<td>SF 36</td>
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<td>NB</td>
<td>NB</td>
<td>NB</td>
<td>NB</td>
<td>This service is research only and not billable to Medicare.</td>
</tr>
</tbody>
</table>
Charges/costs not allowable to bill to Medicare:

- Paid for by the research sponsor (double billing)
- Promised free in the informed consent
- Not ordinarily covered by Medicare
- Solely to determine trial eligibility or for data collection/analysis
What an MCA is not...

- Not a reimbursement analysis
- Not quantitative (does not detail actual billing codes)
- Not a definition of coverage by private payers
Non-qualifying trials

If the clinical trial is determined to be non-qualifying under Medicare’s CTP – then: typically the study does not meet the requirement for therapeutic intent and/or is primarily observational in nature.

- A billing grid is not required to be created by PCRO.
- The IRB is informed that the MCA requirement for this study has been completed.
- Research-only procedures associated with the study may not be billed to Medicare.
- Usual and customary care items or services provided around and during the trial may be billed to Medicare in the usual manner.

You should have a research service grid, in order to guide charge processing.
The clinical trial budget...

Comprised of administrative activities and clinical services as defined by the protocol.

Administrative activities (to be supported by the sponsor):
- Informed consent
- Assessing eligibility criteria
- Capturing data required by the protocol
- Performing Partners IRB requirements
  Typically ‘priced’ for budget purposes based on time estimates for salary and fringe

Clinical services/procedures (may be billable to third party payer or supported by sponsor):
- Labs
- Radiology services
- Other tests/procedures/surgery/bed charges
## Draft Budget (typical industry)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Screening</th>
<th>2 weeks</th>
<th>3 mo</th>
<th>6 mo</th>
<th>9 mo</th>
<th>12 mo</th>
<th>15 mo</th>
<th>Total</th>
</tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Vitals</td>
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<tr>
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<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>0</td>
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<td>Adverse events</td>
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<td>50</td>
<td>50</td>
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<td>50</td>
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<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
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<td>40</td>
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<td>Coordinator - crf completion, scheduling, administrative mgmt</td>
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<td>125</td>
<td>125</td>
<td>125</td>
<td>125</td>
<td>150</td>
<td>925</td>
</tr>
<tr>
<td>PI - crf signoff, study oversight, clinical mgmt of patients study related</td>
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<td>1,270</td>
<td>4,925</td>
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<tr>
<td>Overhead @ 25%</td>
<td>164</td>
<td>123</td>
<td>298</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td>318</td>
<td>1,231</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>819</strong></td>
<td><strong>613</strong></td>
<td><strong>1,488</strong></td>
<td><strong>550</strong></td>
<td><strong>550</strong></td>
<td><strong>550</strong></td>
<td><strong>1,588</strong></td>
<td><strong>6,156</strong></td>
</tr>
</tbody>
</table>
Patient care charges flow in a clinical trial

Sponsor Payments

Per contract terms

Submit invoice to Sponsor

Receive payment from Sponsor

Patient Care Charges (Costs)

Study Fund

Medicare/Insurance

Research - clinical services:
> Outside of usual care/ ‘standard of care’ practice

Research – administrative activities
> Informed consent
> Validating eligibility criteria
> CRF data entry
> Tracking visits

Routine - clinical services:
> Usual / conventional care
> Administration of investigational item/service (per MCA)
> Detection, prevention and treatment of complications (related to the investigational item/service)
To budget patient care effectively

- Understand the protocol
- Identify all the services in the protocol
- Determine what is usual care vs. a service required only for the protocol
- Identify ‘where’ (physical location) services are being provided
- Price all clinical services using the CPT codes (rate book, Budget Builder)
- Apply the institutional research discounts

Keep in mind - some services are combinations of CPT codes (‘bundled’)

Charging to the study fund

- All patient care services provided specific to the research study protocol that will be charged to the study fund must be identified or ordered via the use of an F number (Financial Medical Record Number).

- This number ‘defines’ the charge as research and provides a means to direct the charge to the Special Accounting Department, where the research fund is expensed.

- An F number needs to be in place before any patient care services are ordered for a research subject.
The **Post Award** Grant Administrator within the Grants & Contracts Department in Research Management will initiate the F number setup process through Special Accounts. This will only occur if the IRB approval for the protocol is in place.

Once the F number has been assigned, Special Accounts will notify you and the Principal Investigator via email.

After the account is set-up you will receive an embossed orange F number card.

This card should be in the possession of the Study Coordinator or Principal Investigator only, and never given to the research subject.
Directing charges correctly

When ordering or scheduling services it must be clear which services will be billed to insurance and which services will be charged to the study fund.

You should use the services grid or MCA as your guide. If there is no MCA, meaning the trial is non-qualifying, then all research clinical services/charges should be directed to the study fund.
Ordering research services to charge to the study fund:

- Paper requisitions should include the F number for the services to be directed to the study fund.

- Service Order Systems (i.e. Percipio) must include PI/Protocol/MRN/F number in the designated fields (per instruction document).
Review

Billing to Medicare/3rd party payers

- If your trial is qualifying, PCRO will complete a Medicare coverage analysis.

- If your trial is non-qualifying, you should have a documented study services grid to assist with directing charges.

- Services billed to insurance still require documentation for medical necessity.

- Services not billed to insurance - to be charged to the study fund are routed to the study fund by ‘tagging’ them with an F number.
Research Core Services have been created and are organized to provide services to researchers, which help to facilitate research activity.

- Review your protocol services requirements, then evaluate if a core service may be a more efficient delivery manner.

- Services have associated ‘user’ fees.

- Fees are invoiced to investigators monthly, then cross-charged to study funds.

http://www.partners.org/researchcores/home.asp

www.bwhbri.partners.org

Quick Links: How do I…
Find a Core Facility?
CMS requirements for billing to Medicare:
- ICD-9-CM Diagnosis Code V70.7
- NCT number (added during claims creation)

Indicates participation in a qualifying clinical trial.

The V70.7 should always be a secondary diagnosis noted on the subject’s encounters.
CMS requires modifiers on outpatient claims for qualifying clinical trials. If outpatient claims have the V70.7, Finance will be identifying, in order to assign the appropriate modifiers.

Q0 Modifier – A CMS outpatient modifier created to identify trial related investigational items (devices and drugs) and their administration in a qualifying trial.

Q1 Modifier – A CMS outpatient modifier created to identify routine trial related services in a qualifying trial.
Inpatient and Outpatient Documentation in LMR:

When a research service is provided during or with a ‘usual care’ stay or visit, an authenticated physician’s note is required which documents:

“Patient participating in a qualifying clinical trial.”

This will support the addition of the NCT#.
IRB/QI Tools

Responsibility Log
➢ Include tasks specific to management/oversight of research billing

Subject Enrollment Log
➢ Include details of subject visits/services

http://www.partners.org/phsqi/ToolsPage.htm
### Subject Enrollment Log
Enhanced for Visit Tracking

<table>
<thead>
<tr>
<th>Visit Tracking</th>
<th>Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHRC Protocol #:</td>
</tr>
<tr>
<td></td>
<td>Study Title:</td>
</tr>
<tr>
<td></td>
<td>IRB-Approved Enrollment Target:</td>
</tr>
<tr>
<td></td>
<td>Per PHRC policy, a subject is considered enrolled once s/he signs the written informed consent form, OR (with IRB approval) provides verbal or implied consent by completing a questionnaire or participating in a focus group.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N</th>
<th>Subject ID</th>
<th>MRN</th>
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<td></td>
<td></td>
<td>Visit 1</td>
<td>Visit 2</td>
<td>Visit 3</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>Visit 4</td>
<td>Visit 5</td>
<td>Visit 6</td>
</tr>
<tr>
<td>3</td>
<td></td>
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<td>Visit 7</td>
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<td>Visit 9</td>
</tr>
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<td>4</td>
<td></td>
<td></td>
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<td>Visit 11</td>
<td>Visit 12</td>
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<td>5</td>
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Review and Reconciliation of the Study Fund

Although current systems impose some challenges, it is essential to monitor and reconcile the study fund on a regular basis. This is covered in the study coordinator orientation and training.

- Track services ordered specific to research
- Review statements from Finance and Insight fund statements

The fiscal ‘health’ of the study fund is the PI’s responsibility.
Clinical Trial Process Flow / Life Cycle

**START**

- Initiation
  - Idea/sponsor discussion
- Contracting
- Execution

**Pre-Award**

**Post-Award**

**END**

- Study Close
  - Scientific
  - Financial

**Epic functionality**

- Identify research subject
- Identify research clinical service(s)
- Identify research study

**Identify research subject**

- compare to protocol
- confirm charge direction

**Billing process**

- billing validation
- bill to insurance or fund

**Charge reconciliation**

- report to investigator
- review fund expenses

**Epic patient care charge flow**
Background of Research Functionality

- **Research Model**
  - Research Study Record
  - Research Enrollment Record
  - Manage Study Recruitment

- **Cadence & Prelude**
  - Appointment Scheduling
  - Admission Scheduling

- **Hospital Billing & Professional Billing**
  - Research Billing Calendars
  - Charge Routing & Review

- **EpicCare Ambulatory, EpicCare Inpatient & Analytics Registries**
  - Ambulatory and Inpatient Documentation and Ordering
  - Patient Identification for Studies
Epic Research Workflow

1. Study Approved
   - Epic needs to know about the STUDY
     (Study Administrative Record)
     - Which PATIENTS are associated with the study
2. Place Release Restriction on Research Patient Records
3. Which ENCOUNTERS are associated with the study
4. Which ORDERS are associated with the study
5. Visit charges generated from clinical activity and/or manual charge entry
   - Which CHARGES should be routed to which account
7. Research Billing Review
8. Charges Billed Appropriately
Summary

Improvements

✓ Supports recruitment
✓ Includes linking patient/subject clinical services to study
✓ Allows for identification of research study, research subject and research clinical services (from clinical order entry or financial charge entry)
✓ Allows ability to compare to protocol and validate charges
✓ Allows for reporting to investigators and charge/fund reconciliation
✓ **Supports billing compliance**
If you experience any discrepancies in your research fund due to improper assignment of patient care charges, or if your research subject’s insurance carrier has been charged for services covered under the study protocol, please contact us and we will provide instruction and/or assistance in how you should request the correction:

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