LSUHSC ORS PRESENTS:

LUNCH & LEARN

Research Billing in EPIC
May 1, 2024

Brianne Voros, MS, CCRP
Email: bvoros@lsuhsc.edu
Objectives

- Discuss the importance of the MCA in the context of Research Billing Compliance
- Review Linking to Research Studies in Epic
- Describe the process for Research Billing Review in Epic
Lifecycle of a Clinical Trial

Step 1: Site Identification
- Initial Sponsor Contact
  - External sponsor reaches out to PI or PI creates an investigator-initiated protocol for external support

Step 2: Study & Site Feasibility Assessment
- Feasibility Assessment
  - PI, Study Personnel, and/or Department review Protocol for feasibility
- Receipt of Protocol & Supporting Documents

Step 3: Regulatory, Legal, & Financial Review
- Regulatory Submission & Review
  - PI or Study Personnel submit to the IRB and IRC, as applicable
- Contract Submission & Negotiation
  - Clinical Trials Office reviews, coordinates with third parties, negotiates & routes for execution
- Budget Submission & Negotiation
  - Study Personnel draft internal budget, Clinical Trials Office reviews, coordinates with third parties, & negotiates
- Coverage Analysis
  - Clinical Trials Office coordinates development of coverage analysis with third parties

Steps 4, 5, & 6: Site Activation, Study Execution, and Study Closure
- Site Management
  - Site Initiation Visit (SIV), Site & Protocol Training, Manage Study Supplies
- Study Management
  - Annual Review, Modification, Deviations
- Subject Management
  - Recruit & Enroll Subjects, Subject Payment, AE Management
- Financial Management
  - Billing Compliance
- Study Closure
  - Document Archiving, IP Management, Regulatory Closures, Subject Completion, Study Closure with SPA
Components of Research Billing in EPIC

1. Medicare Coverage Analysis (MCA)
2. Standard of Care Processes that affect Research Billing Compliance
3. Linking to Research Study in EPIC
4. Research Billing Review
What is a Medicare Coverage Analysis?

Analysis required for all clinical trials involving tests, procedures, and interventions associated with a clinical trial that are invoiced to third party payers (i.e., Sponsors) to determine what costs, if any, can be covered by Medicare.

The MCA is one of the most useful documents for building a clinical trial budget and ensuring clinical trial billing compliance.
• The Principal Investigator (PI) has the ultimate responsibility for achieving research billing compliance..... but the full support of the study team is needed to do so successfully.

• The PI has primary responsibility to understand and comply with rules for billing Medicare, Medicaid and third-party payors for services, drugs, devices, tests and procedures rendered in the clinical research context.

• Other site personnel (including patient service representatives, billers, coders, clinic administrators, etc.) are responsible for working with the Principal Investigator and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and documented appropriately.
Risks Associated with Research Billing Non-Compliance

1. Billing for services that are already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial and do not qualify for coverage
Federal False Claims Act

- Federal False Claims Act (FCA) establishes liability for anyone who submits a false claim for payment to the government
  
  *Specific intent not required*

- False Claims Act applies to clinical research activities and failure to comply with the rules may lead to fines and penalties

- Under the False Claims Act, those who knowingly submit, or cause another person or entity to submit false claims for payment of government funds, are liable for three times the government’s damages plus civil penalties of $10,781 to $21,563 per false claim.

- Study documents and MCA must be aligned to assure compliance with clinical trial billing rules and the regulations that protect human subjects
For Immediate Release....
Research Billing Non-Compliance in the Headlines

**PRESS RELEASE**

Florida Research Hospital Agrees to Pay More than $19.5 Million to Resolve Liability Relating to Self-Disclosure of Improper Billing for Clinical Trial Costs

Thursday, January 4, 2024

**PRESS RELEASE**

The Scripps Research Institute To Pay $10 Million To Settle False Claims Act Allegations Related To Mischarging NIH-Sponsored Research Grants

Friday, September 11, 2020

**PRESS RELEASE**

Emory University To Pay $1.5 Million To Settle False Claims Act Investigation

Wednesday, August 28, 2013

**PRESS RELEASE**

Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct

Monday, March 25, 2019

**FOR IMMEDIATE RELEASE**

THURSDAY, APRIL 14, 2005

WWW.USDOJ.GOV

**CIV**

(202) 514-2007

TDD (202) 514-1888

**FOR IMMEDIATE RELEASE**

UNIVERSITY OF ALABAMA-BIRMINGHAM WILL PAY U.S. $3.39 MILLION TO RESOLVE FALSE BILLING ALLEGATIONS
The 3 C’s of Research Billing Compliance

1. Coordination of study information across multiple study documents

2. Communication of relevant study information to the billing process

3. Cooperation among departments and offices that may not usually work together
The 3 C’s of Research Billing Compliance

1. Information that must be coordinated and communicated to minimize compliance risks
   • What is billable and not billable
   • Who is enrolled in a research study
   • Which services are required by the protocol

2. Within an academic medical setting, many different parties are involved in developing study documents that have important information for billing:
   • University/Campus
   • School of Medicine
   • Medical Center
   • Physician Offices
   • Sub-contractors/Private Physician Groups
The PI and SC should be the Protocol EXPERTS for Non-Study Staff
Research Billing Terms & Definitions

- **Study related**: A service/procedure that must happen for a research study and occurs after the subject has signed the research consent.
  - Study-related services may bill to insurance (designated as **M** on the MCA).

- **Routine Care Costs aka Standard of Care**: A study-related service that also happens as part of a subject’s standard medical care and is not promised free from the sponsor is designated as **M** on the MCA. **M services bill to insurance**.
  - These costs may include doctor visits, hospital stays, and lab and imaging tests.

- **Research Sponsored (S)**: A study-related service that only happens for research, or is promised free from the sponsor (even if it is part of a subject’s standard medical care) will be designated as **S** on the MCA. **S services must bill to the sponsor**.
  - These costs may include the investigational intervention (such as the drug being tested), extra doctor visits, electrocardiograms or blood draws, certain lab and imaging tests, and questionnaires performed solely for research purposes.
MCAs can be simple and easy to understand ....
...or MCAs can be very complex

<table>
<thead>
<tr>
<th>Screening Evaluation</th>
<th>Treatment Goals</th>
<th>Follow up</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenoma Excision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Evaluation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics and Baseline Disease Characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior and Treatment Underway</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor Location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor Measurement</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Physical Examination**
- Adenoma, Adenocarcinoma, or Prostate
- Rectal, Pelvic, Abdominal, or Upper Extremities
- Other

**Bloodwork**
- Hemoglobin
- White Blood Cell Count
- Platelet Count
- Creatinine
- Lipid panel
- Electrolytes
- Thyroid stimulating hormone
- TSH

**Imaging**
- Endoscopy
- Colonoscopy
- Ultrasound
- CT Scan
- MRI
- PET Scan

**Billing Designations**
- M: Bill to Patient/Insurance
- N: Bill to Sponsor
- NB: Not Billable

**Supporting Designations**
- AN: As Needed Procedure
- IN: Informed Consent
- IP: Inpatient
- NIA: Non-Adherent
- NR: Not Part of the Research Study
- SR: Send Out

**Charges**
- Send Out: This is an non billable item and cannot generate a charge

*This is not available in the current protocol.*

*A physical exam appears reasonable and necessary at this frequency for the clinical management of the patient to assess the patient's disease status, as well as to detect, monitor, and treat side effects of [drug name]. Additional, regular exams of the recurrent tumor are not recommended.*

*According to the NCCN Guidelines for Prostatic Cancer, every 3-6 months, a physical examination is recommended.*

*If any abnormal findings are noted, the patient should return to the office for further evaluation.*

*Send Out: This is an non billable item and cannot generate a charge.*

*This is a non-reimbursable item and should be used only for research purposes.*

*This is a non-reimbursable item and should be used only for research purposes.*

*This is a non-reimbursable item and should be used only for research purposes.*
Lessons Learned

Never assume that RESEARCH means that everything required by the protocol is FREE

Let the normal processes that are currently in place for non-research patients continue to function for your research patients (i.e. prior authorizations, scheduling, etc.)

Utilize the current workflows of the clinic/hospital/support staff to implement the clinical trial.
How do we IDENTIFY Patients in EPIC as Enrolled in Research?
1. Click on the Research Studies button in the main toolbar.

2. Search for and select your patient to open their chart.

3. Within the Research Studies activity, search for the study in the Add study search field.
4. Search for and select an active association status, such as In Screening, Consented, or one of the Enrolled options. Once selected, the Status Effective Date will auto populate with today’s date. If you need to back chart (chart for events that happened in the past), change the Status Effective Date and the Active Start Date will automatically adjust.

5. Enter a participant ID if the patient’s name is not used in the study and only an ID number.

6. Click Accept to save your changes.
Pre-Consent

• **Identified** subject is identified as meeting prescreening criteria but has not been approached

• **Interested** subject has been approached to participate but has not signed consent form

• **Declined** subject is not interested in participating

After Consent

• **In Screening** subject has consented to participate but has not completed screening phase

• **Consented** subject has consented to participate but has not started treatment

• **Enrolled – Treatment Phase** subject is on active treatment

• **Enrolled – Follow Up Phase** subject is still on trial but has completed treatment phase and in follow up

• **Withdrawn**

• **Completed** subject has completed all study visits and is no longer enrolled in trial
7. Notice a Research Participant banner will appear on the Storyboard. This will alert every provider that views the chart of the patient’s participation in a research study.

8. You will be able to click on Participant Details hyperlink to view the study report, which will display study details, linked encounters and linked orders.
1. Click on the Research Studies button in the main toolbar.
2. Search for and select your patient to open their chart.
3. Within the Research Studies activity, search for the study in the Add study search field.

![Image of Research Studies interface]

- **Tulane Asthma Study**
  - **Enrolled: Other**
  - **Status Effective Date:** 1/10/2024
  - **Active Start Date:** 1/10/2024
  - **Study Type:** Interventional
  - **Study Code:** 10012
  - **IRB#:** 102

Description:
Tulane Medical Center is participating in a study of the efficacy of asthma treatment and control in patients currently being treated with a leukotriene modulator and/or sympathomimetic agents but are not using inhaled steroids. Patients in this study may be receiving a study medication or a placebo.

If you have any patient care concerns potentially related to study, please contact the study team at x5-5555.

Next Study Visit
No upcoming study visits
1. Click **Appts** on your main toolbar.

2. Look up your patient and click **Accept**.

3. Right-click the upcoming appointment.

4. Select **Link to Research Study** to confirm association or to link the appointment to the research study.

5. Click ✗ Close when all updates for the encounter are complete.
Link Upcoming Visits to Studies via Appointment Desk
Search in Reporting Workbench for **LCMC ES Appt Search for Research Coordinators**.

- Modify report with Study Code and Save Report as Favorite.
- Select visits to be linked and Click Link to Research Study.
- Can be used to link Past or Upcoming Appointments.

*Reach out to me if you need additional guidance on setting these up.*
Linking Orders to Research Study When in an Encounter

1. At the top of the Orders Panel, select Options.
2. Then Click Research Association.
3. In pop up, Select the check box next to the Order to Associate under the applicable study.
Once linking begins, you will be able to click on the **Participant Details** hyperlink to view the study report, which will display study details, linked encounters and linked orders in the Study Calendar.
Currently, Professional Billing Charges are billed outside of Epic through ACS (in most cases).

Therefore, these charges are not captured in Epic. Because these charges may be reimbursed by the sponsor, some important safeguards are required to flag research patients when the billing report is sent to ACS.

This can be accomplished with the diagnosis code

`Z00.6: Examination of participant in clinical trial`

This will FLAG the patient as enrolled in a clinical trial and prompt ACS to reach out to the Study Coordinator.
CMS requires that the following diagnosis code be used on Medicare research claims to identify Medicare patients who are participating in a Qualifying Trial:

- Diagnosis code **Z00.6: Examination of participant in clinical trial**

In addition, the claims must include one of the following modifiers to differentiate between routine and investigational clinical services:

- **Q0** – Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

- **Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study.
Coding Office Visits with Modifiers

- **Q0** – *Investigational clinical service provided in a clinical research study that is in an approved clinical research study.*
- **Q1** – *Routine clinical service provided in a clinical research study that is in an approved clinical research study.*
DID YOU ADD Z00.6 TO YOUR VISIT DIAGNOSES?

This patient is enrolled in a clinical trial.

Please consider:
1. Linking patient to research study
2. Ensuring that all orders are linked to the research study before signing visit.

Click HERE to provide feedback on this BPA

Remove the following orders?

Remove Keep

Check with your Study Coordinator 😊

Expires: 5/9/2020, Routine, Lab Collect

Acknowledge Reason

See comments
Putting it ALL together
All charges linked to patients enrolled in a research study in Epic are flagged and reviewed to make sure they're billed appropriately through the Research Billing Review Process.

Each charge associated with a research patient falls into one of three buckets:

- **Non-research related.** These charges are billed to the patient or their insurance.
- **Research-related, bill to the study.** These are research charges that will be billed to the study or study sponsor.
- **Research-related, bill to the patient.** These are research-related charges that are billed to and paid by the patient or their insurance.
## Research Billing Review Process

### Study-Related - Bill to Study

<table>
<thead>
<tr>
<th>Study R.</th>
<th>Svc Date</th>
<th>Post Date</th>
<th>Code</th>
<th>Procedure</th>
<th>Study Src</th>
<th>Rsh Amount</th>
<th>Qty</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>36415</td>
<td>30000030-HC VENIPUNCTURE</td>
<td></td>
<td>29.50</td>
<td>1</td>
<td>59.00</td>
</tr>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>86316</td>
<td>30280015-HC LABCORP IMMUNOASSAY TUMOR ANTIGEN QUANT...</td>
<td></td>
<td>89.50</td>
<td>1</td>
<td>179.00</td>
</tr>
</tbody>
</table>

### Study-Related - Bill to Insurance/Patient

<table>
<thead>
<tr>
<th>Study R.</th>
<th>Svc Date</th>
<th>Post Date</th>
<th>Code</th>
<th>Procedure</th>
<th>Study Src</th>
<th>Qty</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>2500000</td>
<td>ONDANSETRON HCL (PF) 4 MG/2 ML SOLN</td>
<td></td>
<td>16</td>
<td>14.75</td>
</tr>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>2500002</td>
<td>DEXAMETHASONE SODIUM PHOS 10 MG/ML SOLN</td>
<td></td>
<td>10</td>
<td>8.75</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pending</td>
<td>2500003</td>
<td>arginine-lysine-sterile water 25-25 mg/mL Soln</td>
<td></td>
<td>1</td>
<td>1,489.75</td>
</tr>
</tbody>
</table>

### Non-Study Charges

<table>
<thead>
<tr>
<th>Study R.</th>
<th>Svc Date</th>
<th>Post Date</th>
<th>Code</th>
<th>Procedure</th>
<th>Study Src</th>
<th>Qty</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>96375</td>
<td>26000010-HC INJECTION INTRAVENOUS THERAPEUTIC/PROPHYLAX...</td>
<td></td>
<td>2</td>
<td>500.00</td>
</tr>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>96365</td>
<td>26000014-HC INTRAVENOUS INFUSION THERAPEUTIC/PROPHYLAX...</td>
<td></td>
<td>1</td>
<td>666.00</td>
</tr>
<tr>
<td></td>
<td>04/30/2024</td>
<td>04/30/2024</td>
<td>96366</td>
<td>26000004-HC INTRAVENOUS INFUSION THERAPEUTIC/PROPHYLAX...</td>
<td></td>
<td>4</td>
<td>652.00</td>
</tr>
</tbody>
</table>
Important Takeaways

1. Understanding the MCA is the foundation of ensuring compliant research billing

2. Linking Patients, Orders, and Encounters on the front end saves a headache on the backend

3. Communication with all involved is KEY

4. Add Z00.6 diagnosis code with Q0/Q1 modifiers

5. Research Billing Non-Compliance jeopardizes our ability to continue doing research. We must work together to ensure that it is done correctly!
Resources

- LSUHSC CTO Training - Medicare Coverage Analysis for Clinical Research
- CITI Training - Clinical Trial Billing Compliance
- CMS.gov National Coverage Determination (NCD) - Routine Costs in Clinical Trials
- HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies