

LSUHSC ORS PRESENTS:



# Research Billing in EPIC

May 1, 2024

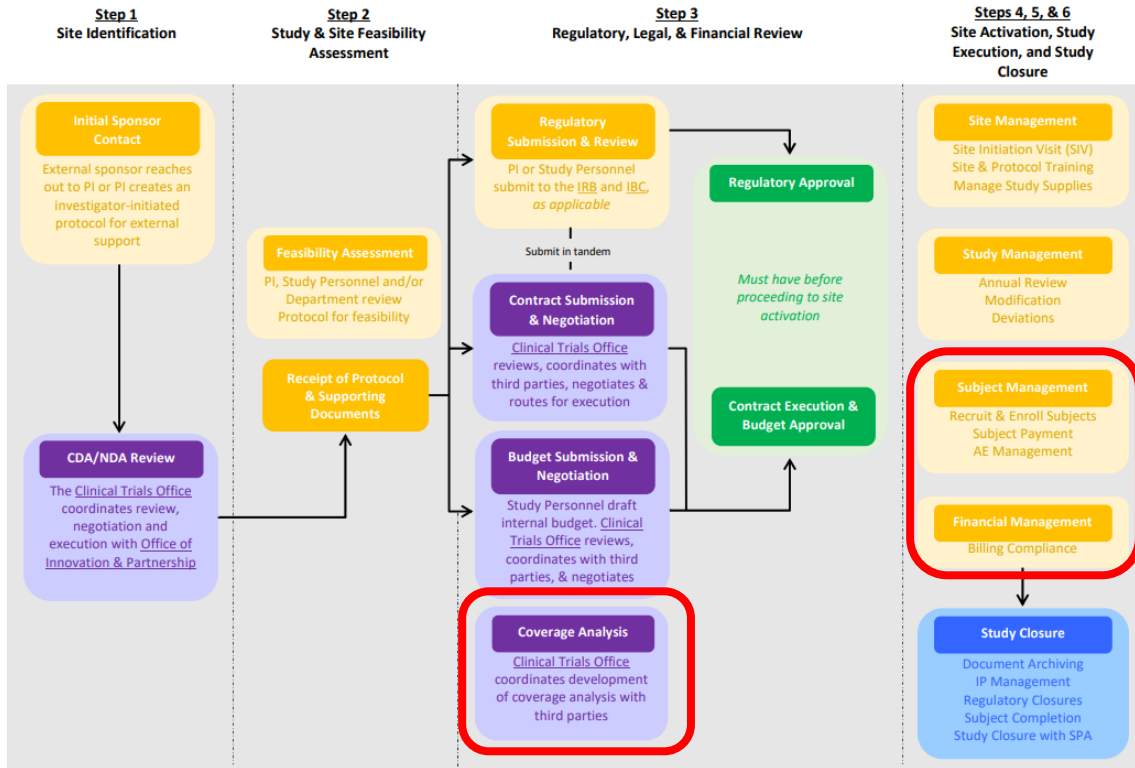
**Brianne Voros, MS, CCRP**

Email: [bvoros@lsuhsc.edu](mailto: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



# 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.**

# Understanding the MCA ...and Why It Is IMPORTANT

- 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

For Immediate 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

For Immediate Release

PRESS RELEASE

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

Wednesday, August 28, 2013

For Immediate Release

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



## Department of Justice

FOR IMMEDIATE RELEASE  
THURSDAY, APRIL 14, 2005  
WWW.USDOJ.GOV

CIV  
(202) 514-2007  
TDD (202) 514-1888

UNIVERSITY OF ALABAMA-BIRMINGHAM WILL PAY U.S. \$3.39 MILLION  
TO RESOLVE FALSE BILLING ALLEGATIONS

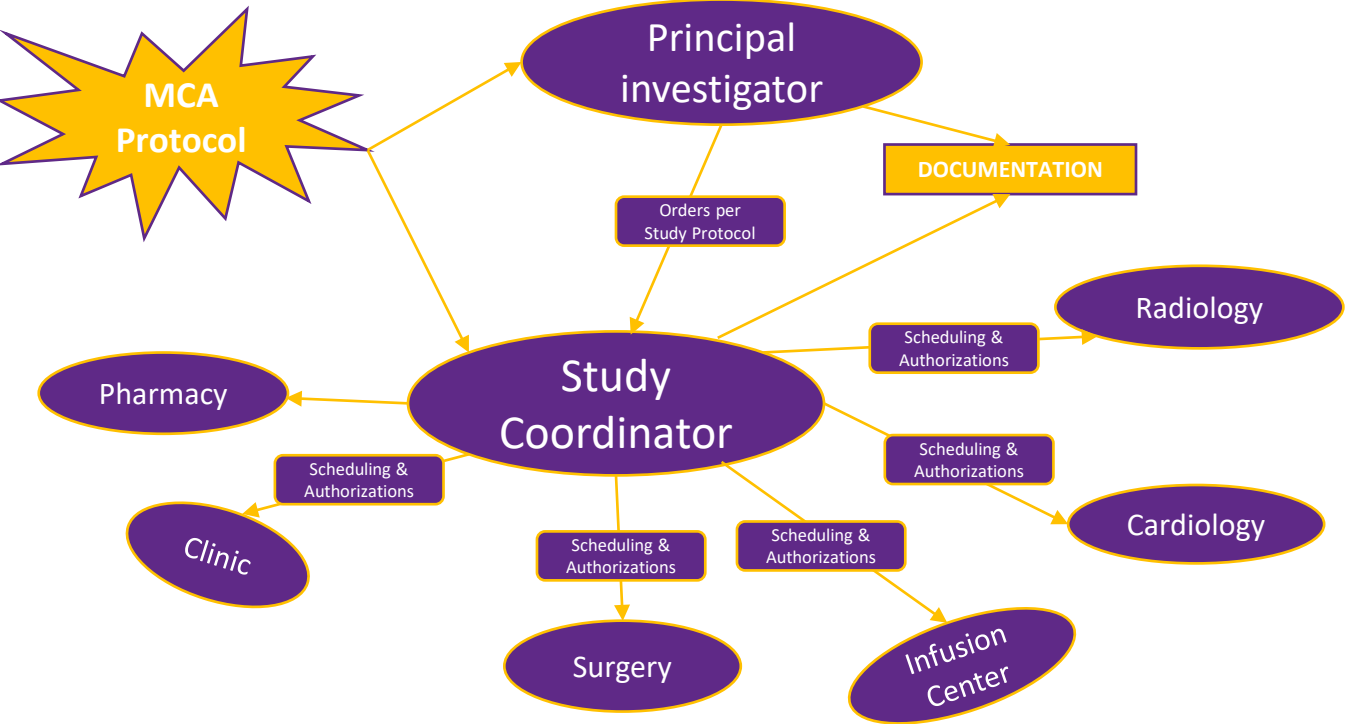
# The 3 C's of Research Billing Compliance

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



# The MCA is our cheat sheet to WHO pays WHAT

## 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.



# ...or MCAs can be very complex

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# 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?

# Linking Patient to the Research Study

The screenshot shows a software interface with a top navigation bar containing various icons and labels such as 'Maintenance', 'Patient Station', 'Patient Lists', 'My Reports', 'Appts', 'Snapboard', 'Research Billing Review', 'Telephone Call', 'Encounter', 'ED Track Board', 'Media M', and 'Research Studies'. Below this is a main toolbar with buttons for 'SnapShot', 'Chart Review', 'Order Inquiry', 'Review Flowsheets', 'Results Review', 'Allergies', 'History', 'Problem List', 'Demographics', 'Letters', and 'Research Studies'. The 'Research Studies' button is highlighted with a red circle and the number 1. Below the main toolbar, the 'Research Studies' section is active, showing a search field with 'Tulane Asthma Study' and a '+ Add' button. The '+ Add' button is highlighted with a red circle and the number 3. A dropdown menu is open under the '+ Add' button, showing a search result for 'Tulane Asthma Study [10012]'.

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.

# Linking Patient to the Research Study

Research Studies ?

[View Study List](#)

## Tulane Asthma Study

### Participant Details

Status  Status Effective Date  **4**

Active Start Date  Active End Date

Participant ID  **5**

Patient-Specific Coordinators

Comments

**6**

### Study Details

Study Type  Study Code  IRB#  NCT#

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 x-5555.

**Md Investigator Research, MD**  
Principal Investigator

Patient-Facing Area of Research  
**Lungs & Breathing**

Links  
[Clinical Trial Info](#)

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.

# Research Association Status Definitions

## 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*

# Linking Patient to the Research Study

The screenshot displays a medical software interface for a patient named Monique-RC Bell. The patient's details include gender (Female), age (43 y.o.), date of birth (1/17/1981), MRN (20032978), and language (English). A red banner labeled "Research Participant" with a circled number 7 is visible. The interface shows the "Tulane Asthma Study" with a "Participant Details" section containing status (Enrolled: Other), start/end dates (1/18/2024), and participant ID (1234567). A "Study Calendar" section indicates "No study visits". On the right, "Study Details" include study type (Interventional), study code (10012), IRB# (102), and NCT# (00704495). The description states the study is about asthma treatment efficacy. A principal investigator, Md Investigator Research, MD, is listed. The interface also shows navigation tabs like Snapshot, Chart Review, and Research Studies, and a bottom section for Documentation with links for Adverse Events, Data Capture, and Tasks.

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

# Link Encounter to Study When in an Encounter

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.

The screenshot displays the 'Research Studies' section of a medical software interface. At the top, a navigation bar includes buttons for 'Chart Review', 'Synopsis', 'Rooming', 'Screenings', 'Plan', 'MAR', 'Wrap-Up', and 'Research Studies' (which is highlighted with a red circle and the number 3). Below this, a search bar contains the text 'dd study' and an '+ Add' button. To the right, there is a 'Show:' checkbox for 'Pre-Consen'. The main content area is titled 'Active on My Studies' and features a card for the 'Tulane Asthma Study'. The card includes a 'Link encounter' button (circled in red with the number 4), a 'MR' icon, and the name 'Md Investigator Research, MD' with the title 'Principal Investigator'. Below the card, there are links for 'Adverse Events', 'Data Capture', and 'Tasks'. A description of the study is provided, along with contact information for the study team and information about the next study visit.

Research Studies 3

search Studies

dd study + Add Show:  Pre-Consen

Active on My Studies

Tulane Asthma Study 4 Link encounter

MR Md Investigator Research, MD  
Principal Investigator

Links  
[Clinical Trial Info](#)

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

[Adverse Events](#)    [Data Capture](#)    [Tasks](#)

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

# Link Upcoming Visits to Studies via Appointment Desk

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

**Appointment Desk**

**Patient Summary (Edit)**

**Alas, Nate-RC (68 yrs)**

DOB: 4/17/1955  
SSN: 159-24-1237  
Legal Name: Alas, Nate-RC

Registration Status: Ver  
Preferred Language: English  
Needs Interpreter?: No

Mobile: 608-555-7972  
Home: 608-555-7972  
Work: [Redacted]

E-mail: [Redacted]

**Preventive Care**

**Guarantor Accounts**

Account Name	Acct Ver	Stat	Serv Area	Type	Fin Class	Balance	Acct Status
Alas, Nate-RC	New		SBO	P/F	SELF	0.00	

**Account Name**   **Acct Ver**   **Stat**

Account Name	Acct Ver	Stat	Provider	Appointment Department	Appt Notes	ORD	R..	R#	Procedure
CSN			IT	Nurse Family Medicine [E400000]	UMCNO MED CLN ACB	annual exam			

**Future**   **Past**

CSN	Encounter Date	Time
3005836	1/9/2024 Tue	9:00

**Link Research Study** 4



# Reports for Linking Upcoming Visits to Studies



## LCMC ES Appt Search for Research Coordinators

Workbench Template 100935

### Description

Reports created from this template search for appointments matching the criteria specified. For example, it may be used to find all appointments for patients enrolled in a particular research study.

☆		LCMC ES Appt Search for Research Coordinators
☆		Upcoming Appointments
★		Upcoming Appointments (ALPHAMEDIX)
★		Upcoming Appointments (CAMURUS)
★		Upcoming Appointments (CRINETICS)
★		Upcoming Appointments (FUSE)
★		Upcoming Appointments (Neulasta)
★		Upcoming Appointments (REFINE)

Upcoming Appointments (ALPHAMEDIX)

Expand Appts Research Studies Encounter Link to Research Study

Detail List Explore

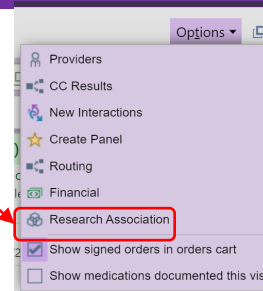
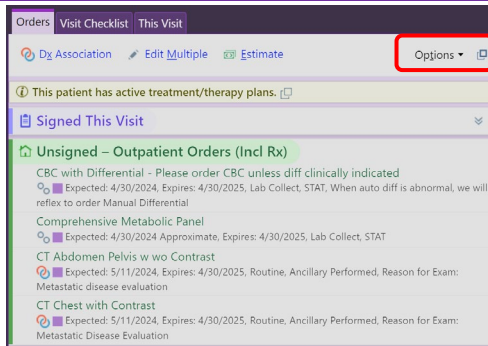
Filter

Linked Participant ID	Visit Date Time	Has Link Appt	Department	Prov/Res	Appt Status	Visit Type	Linked Study Code	Linked Start Date
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, CHAIR 3	Sch	INFUSION TX		
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, FAST TRACK CHAIR 2	Sch	INFUSION TX		
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, FAST TRACK CHAIR 1	Sch	ONCOLOGY LAB		
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, FAST TRACK CHAIR 2	Sch	INFUSION TX		
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, INFUSION BED 2	Sch	CALCULATED INFUSION 1	ALPHAMEDIX-02	11/08/23
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, INFUSION BED 1	Sch	CALCULATED INFUSION 1	ALPHAMEDIX-02	01/08/24
			EJGH OP ONCOLOGY	EJGH OP ONCOLOGY, INFUSION BED 2	Sch	CALCULATED INFUSION 1	ALPHAMEDIX-02	01/22/24

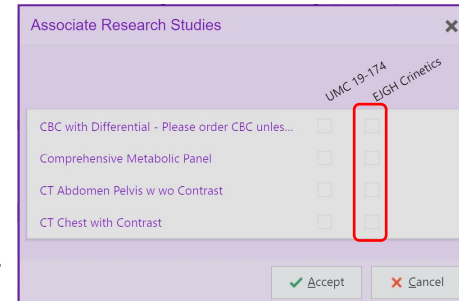
- Search in Reporting Workbench for **LCMC ES Appt Search for Research Coordinators**.
- Modify report with Study Code and Save Report as Favorite.
- Select visits to be linked and Click Link to Research Study.
- Can be used to link Past or Upcoming Appointments

*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.



# Linking Patient to the Research Study

Research Studies

[View Study List](#)

EJGH ALPHAMEDIX-02



**Participant Details** 8 [Additional Info](#) [Past Updates](#)

Status Status Effective Date  
**Enrolled: Treatment Phase** 11/14/2023

Active Start Date Active End Date  
11/9/2023 —









Participant ID  
[REDACTED]

Patient-Specific Coordinators

 Connie Romaine, RN  Brienne Voros

Comments  
[REDACTED]

**Study Calendar**  Hide Past

Date	Encounter Type	Dept	Provider
Past			
11/10/2023	 <a href="#">HOV - HOV - Completed</a>	EJGH OP ULTRASOUND	EJGH US OP 3
11/10/2023	 <a href="#">HOV - HOV - Completed</a>	EJGH CARD TESTING	LCMC CV EJGH CARD TEST ECG
11/13/2023	 <a href="#">CT CHEST WITH CONTRAST Visit - Canceled</a>	EJGH OP CT SCAN	EJGH CT OP 1
11/13/2023	 <a href="#">CT ABDOMEN PELVIS WO<del>U</del> CONTRAST Visit - Canceled</a>	EJGH OP CT SCAN	EJGH CT OP 1
11/13/2023	 <a href="#">Rare Cancer Established Patient Visit - Completed</a>	ZZZEJGH YEN RARE CANCER	Mary Alice Hobbs-Maluccio, MD
11/13/2023	 <a href="#">HOV - HOV - Completed</a>	EJGH MRI	EJGH MRI 3T
11/14/2023	 <a href="#">Research Initial Evaluation Visit - Completed</a>	ZZZEJGH YEN RARE CANCER	Mary Alice Hobbs-Maluccio, MD
11/14/2023	 <a href="#">Infusion, 90 Minutes Visit - Completed</a>	EJGH OP ONCOLOGY	Sherry Sherwood, RN

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.

# Professional Billing Charges

- 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 – Z00.6 and Q0/Q1 Modifiers

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

Wrap-Up

Images Benefits Inquiry Dictations Open Orders Care Teams Links Preview/Print AVS FC Checklist More

Patient Instructions Follow-up Communications Review Visit Diagnoses LOS Charge Capture

Level of Service

NEW1	NEW2	NEW3	NEW4	NEW5
RET1	RET2	RET3	RET4	RET5
IPREV18-...	IPREV40-...	IPREV65+	PPREV18...	PPREV40...
PPREV65+	TCM 14 Day	TCM 7 Day	No Fee	

LOS: PR OFFICE OUTPATIENT NEW 45 MINUTES [99204]

Modifiers: +

Additional E/M codes: [Click to Add](#)

Billing area:

- ***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.***

# Best Practice

## BestPractice Advisory -

### ! 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

✓ Accept

# Putting it ALL together



# Research Billing Review Process

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

## Calculated Infusion 1 Visit

04/30/24

Study-Related

Radiation/Oncology Series | DNB (DNB

Error)  
BLUE CROSS - BLUE CROSS POS

Mark as Reviewed

Charges Encounters

Account Activities

Research Correct

Group by: Revenue Code CPT®/HCPCS Code Svc Date Encounter Review Status Protocol Day **None** Other

### Study-Related - Bill to Study

Research Correct All Select All Deselect All

Study R...	Svc Date	Post Date	Code	Procedure	Study Src	Rsh Amount	Qty	Amount
<input type="checkbox"/>	04/30/2024	04/30/2024	36415	30000030-HC VENIPUNCTURE		29.50	1	59.00
<input type="checkbox"/>	04/30/2024	04/30/2024	86316	30280015-HC LABCORP IMMUNOASSAY TUMOR ANTIGEN QUANT...		89.50	1	179.00

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

Research Correct All Select All Deselect All

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

### Non-Study Charges

Research Correct All Select All Deselect All

Study R...	Svc Date	Post Date	Code	Procedure	Study Src	Qty	Amount
<input type="checkbox"/>	04/30/2024	04/30/2024	96375	26000010-HC INJECTION INTRAVENOUS THERAPEUTIC/PROPHYLA...		2	500.00
<input type="checkbox"/>	04/30/2024	04/30/2024	96365	26000014-HC INTRAVENOUS INFUSION THERAPEUTIC/PROPHYLA...		1	666.00
<input type="checkbox"/>	04/30/2024	04/30/2024	96366	26000004-HC INTRAVENOUS INFUSION THERAPEUTIC/PROPHYLA...		4	652.00

# 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](#)



# QUESTIONS