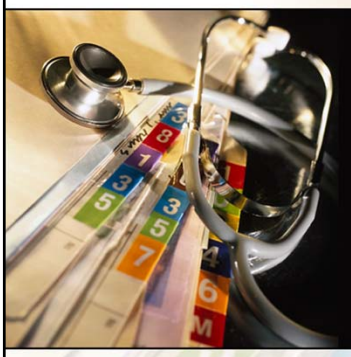

Clinical Research Billing Compliance

Diana Salinas & Eve Sakran
Jackson Health System
Ruth Krueger
Sanford Health System

Presenters

Diana Salinas, Esq., CHC
Chief Compliance Officer
Jackson Health System
Miami, Florida DSalinas@jhsmiami.org

Eve Sakran MS, CHRC
Corporate Director Research and Grants
Jackson Health System
Miami, Florida ESakran@jhsmiami.org

Ruth Krueger MS, RRT, CHC
Regional Director of Corporate Compliance
Sanford Health
Sioux Falls, South Dakota Ruth.Krueger@sanfordhealth.org

Objectives

- Provide a general overview of the government's perspective on clinical trials billing
- Identify CMS billing requirements, associated risks, Medicare coverage analysis and contract transparency
- Discuss electronic systems, audit tools, & outcomes

General Overview

- Growing focus on Research by many federal regulators:

HHS-Health and Human Services

DOJ-Department of Justice

ORI-Office of Research Integrity

CDC-Centers for Disease Control

FDA-Food and Drug Administration

NIH-National Institutes of Health

OIG-Office of the Inspector General

OHRP-Office for Human Research Protections

CMS-Centers for Medicare and Medicaid Services

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General Overview

- Prior to 2000, generally, Medicare beneficiaries were not enrolled in clinical trials
- In 2000, President Bill Clinton issued a mandate requiring the CMS program to extend research to beneficiaries by including routine costs of certain “qualifying” clinical trials
- Emergence of the Clinical Trials National Coverage Determination (NCD)
- NCD provides Medicare coverage for certain “routine costs” that are generally covered by Medicare when there is not a clinical trial

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General Overview

- The settlement agreement between Rush University Medical Center and the federal government certainly served as a model for Provider Compliance when billing for Medicare patients in research studies

General Overview – Rush Discussion

- In 2003 Rush discovered that it had inadvertently billed Medicare for services provided during cancer therapy research studies that were not reimbursable under the NCD on Clinical Trials. Rush officials self-disclosed the matter to the U.S. Attorney's Office within 30 days of identifying the issue and implemented comprehensive measures to minimize the chances of further overpayments for cancer clinical trials. This included implementing a bill hold on cancer research charges within 10 days of of discovering the issue, voluntarily expanding its internal investigation and subsequent corrective action to cover all clinical trials at Rush and developing a new billing process flow with a strong commitment to audit the new billing approach.

General Overview

- In 2006, while under a Corporate Integrity Agreement (CIA) Jackson Health System (JHS) discovers potential noncompliant research practices:
  - Limited and decentralized infrastructure surrounding research
  - Due to lack of awareness and education as it related to research practices at JHS
  - With minimal transparency or processes between institutions
- The hospital was unable to determine the scope and impact of research being conducted within its four walls – non compliance…what to do?

General Overview

- JHS Corrective Actions
  - Established new system's Research policy and centralized Clinical Trials Office for JHS
  - Established clear lines of responsibility for JHS as to research compliance and administration
  - Through the centralized office developed operational changes to ensure research compliance
  - Disclosure???
  - Six years later, where we are

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JHS Lessons

- The driving force for creating a centralized model in the hospital surrounding research at JHS was noncompliance issues in billing.
- What we discovered was a general lack of education in research compliance, limited infrastructure to drive development of compliant processes, and a lack of transparency between institutions.
- The hospital was unable to determine the scope and impact of the research being conducted within its four walls given the documentation and knowledge it had on hand.

Integration Techniques

- Establish clear lines of responsibility for research compliance and administration
  - Can't be left to the doctor doing the research
- Seek input on operational changes from research
- Billing compliance and research compliance must have open communication
- Notify research compliance or administration of complaints regarding doctors involved in research

Challenges in developing Clinical Research Billing Systems

- Multiple and disparate systems, i.e. Front end & back end systems, Pathology, Radiology
- Lack of understanding of clinical research or implementation objectives by interface team
- Training issues with the development teams and users
- Multiple points of entry for patient registration using research provider accounts
- Multiple user options resulting in high user error; ***More clicks, More errors***
- Restrictions in user access based on job classifications
- Failure to understand the impact of historical data or changes in the various hospital information systems to the research interface
  - Historical data coming over that confused the user, i.e. old insurance company information

Pitfall #1Multiple Clinical Billing Applications

- Front End system is the Cerner system. All clinical information, progress notes, physician's orders, and appointments are made in Cerner.
- Back end or patient accounting system is the Siemens System. All clinical content is interfaced to the Siemens system for proper and compliant billing. ***Interface testing required*.**
- Other departments have their preferred "Best of Breeds" applications, i.e. SunQuest for pathology. ***Another interface test***
- 3M application utilized to assign codes by coders in Medical Records ***And another interface test***
- Front end systems did not inform coders that patient was enrolled in study.
- Records may have been 'thinned' and critical information removed, i.e. Informed Consent

Pitfall #2 Fragmented information

- Identification of patient as a clinical research participant in the information system was challenging.
- First visit where patient is actually consented, along with screening and eligibility testing, can be easily lost, resulting in tests being billed to insurance instead of sponsor.
- The study coordinators who had the knowledge were not necessarily the ones inputting the patient information.
- No effective communication between the research team and the clinical staff- not necessarily the same people

Pitfall #3 Process Not Transparent

- How do you know when a research trial patient comes in for the first visit or the 3rd visit?
- What visits/tests/procedures:
  - Are being paid for by the sponsor?
  - Are routine care but contained in the protocol?
  - Have nothing at all to do with the trial?

Responsibility & Solutions

Ultimately Provider responsible for dropping a clean bill

Team Created

1. Medicare coverage analyses (MCA): to establish study related procedures being paid for by sponsor vs. routine care to be billed to insurance companies. This was used internally to scrub bills.
2. Encounter Form: to be used by the study coordinators and submitted to the JHS CTO same day.
3. Bill HOLD: Senior Management in the revenue cycle did not like the bill hold option but this solution provided the necessary time to scrub the bill with the study-calendar in hand and add the necessary CMS required modifiers

Hospital Process & Responsibility

- CTO staff reviews the documentation available in the IRB electronic system, including the signed JHS CTO application, the FDA letter identifying IND #, complete study calendar, etc.
- The study is considered incomplete if documentation is not accounted for and the PI is prompted to provide all documentation before review is possible

Why is the timeliness of receiving patient consents so important?

The Centers for Medicare & Medicaid Services (CMS) requires that patients enrolled in a clinical trial (inpatient or outpatient) have:

1. V70.7(Examination of participant in a clinical trial) Diagnosis Code listed as a secondary Dx. Code on each patient visit/service.
2. Device studies require the IDE # assigned by the FDA to be placed on each patient's claim submitted.
3. The ClinicalTrials.gov identifier number remains optional.

Outpatient Claims

Outpatient Claims Only:

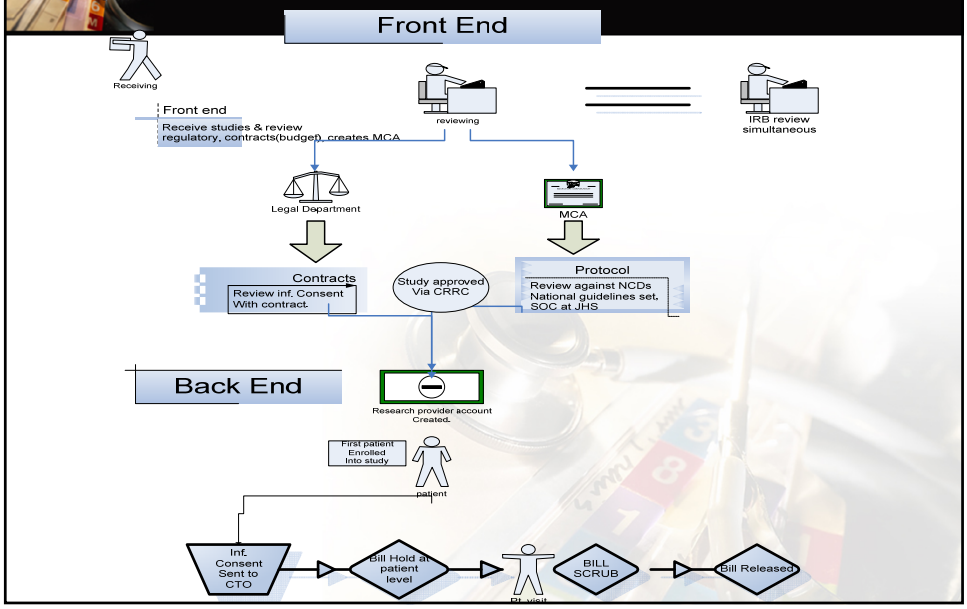
1. Healthcare Common Procedure Coding System (HCPCS). Affectionately know by coders as *hicspics* codes.

2. Modifiers: Q0 and Q1 are required by CMS on the outpatient claim of patients enrolled in a trial.
   - Q0 Identifies all lines that contain an investigational item/service with this HCPCS modifier.
   - Q1 identifies all lines that contain a routine service with a HCPCS modifier.

3. Condition Code 30 is a field also required on these outpatient claims.

4. JHS may not bill outpatient clinical trial services and non-clinical services on the same claim for Medicare beneficiaries enrolled in a managed care plan. Created encounter ticket April 2010.

Centralizing the hospital process



Questions to Determine an Effective CT Billing Process

Qualifying Trial	Routine Costs	Billing for Services
1. What was the qualification process? 2. How was this documented?	1. How were the routine costs determined? 2. How were these documented?	1. How were the routine cost determinations communicated? 2. How were the charges captured? 3. Was there a UB/HCFA review prior to billing? 4. How were the services documented?

Sample Coverage Analysis #1

Medicare Coverage Analysis (MCA) - *Example only - we make no representation that the codes and references are correct*

Study name		<28 days prior to		Weekly During RT		3 week Toxicity		Last week of RT		6 weeks following RT		Observation: 12 and 24		
	CPT	Research	Insurance	Research	Insurance	Research	Insurance	Research	Insurance	Research	Insurance	Research	Insurance	Resource to support routine care. Include LCD, NCD, IOM, Practice guideline, or Principal Investigator if no other
Physical exam	99211-99215		X											Physical exam supported by NCCN guidelines (version 3.2012)
urine hcg-WOCBP	81025		X											QCT-Reproductive risks listed in the consent/protocol
CBC	85025		X		X2									Routine treatment for disease management
CMP	80053		X			X3		X3						Research provided for subsequent draws

X2 - If clinically indicated X3- Reimbursed at the end of study

PI Signature_____ Date _____

Sample Coverage Analysis #2

RC = routine care(bill to insurance) R = research paid (*Example only - we make no representation that the codes and references are correct)*

Task/Procedures	Code (CPT and/or CDM)	Infusion Day 1	Infusion Day 2	2 weeks	12 weeks	24 weeks	References
Obtaining Informed Consent	N/A	PI					Obtained by study coord or PI
Physical Exam	99201		RC	RC	RC	RC	Per the National Kidney Foundation clinical practice guidelines for vascular access: update 2006
EKG	93000	RC	RC	RC			Per the National Kidney Foundation clinical practice guidelines for vascular access: update 2006
Investigational Drug	N/A	Free	Free				Provided by study sponsor
Infusion	96400	RC	RC				Per the American Society of Diagnostic and Interventional Nephrology - Professional Association Association for Vascular Access - Professional Association, 2008
Urinalysis	81000		R	R			Bill to research
Ultrasound	93990			RC			Per National Kidney Foundation clinical practice guidelines for vascular access: update 2006
Patient Questionnaire	N/A		X	X	X	X	Obtained by study coord or PI

PI Signature Date

Example Billing Grid

Protocol Name: Phase II Study of Drug ABCD

Procedure/Evaluations	Screen	Study Plan									
Study Week	**0**	**1**	**2**	**3**	**4**	**8**	**12**	**16**	**20**	**24**	**End of Study**
Physical Exam	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Pregnancy Test	SOC										
Hematology (CBC)	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Chemistry (BUN,creatinine,electrolytes, AST, ALT, alkaline phosphatase, total bilirubin)	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
CT Scan Of Chest, Abdomen & Pelvis	SOC				RS	SOC		SOC		SOC	SOC
EKG	SOC	RS	RS	RS	RS						SOC
MUGA Scan	SOC				RS		RS		RS		SOC
Thyroid Stimulating Hormone (TSH)	RS		SOC		SOC		SOC				RS
Vitamin D	RS				RS			RS			RS

KEY
SOC = Standard of Care (Cost Can be Billed to a Third Party Payer)
RS = Research Sponsored (Cost Covered by Internal Study/Grant #)

Protocol Contact
Name / Email / Phone # of Responsible CRC

Medicare National Coverage Policy generally only covers TSH up to 2 times per year for patients with thyroid disease. Should re-negotiate with sponsor.

How Does a False Claim Occur ?

- Double billing - Charging more than once for the same goods or services.
- Charging for items promised for free in the informed consent document.
- Being over-paid by the government for a service, and then not reporting that overpayment.

Challenges for Billing Correctly

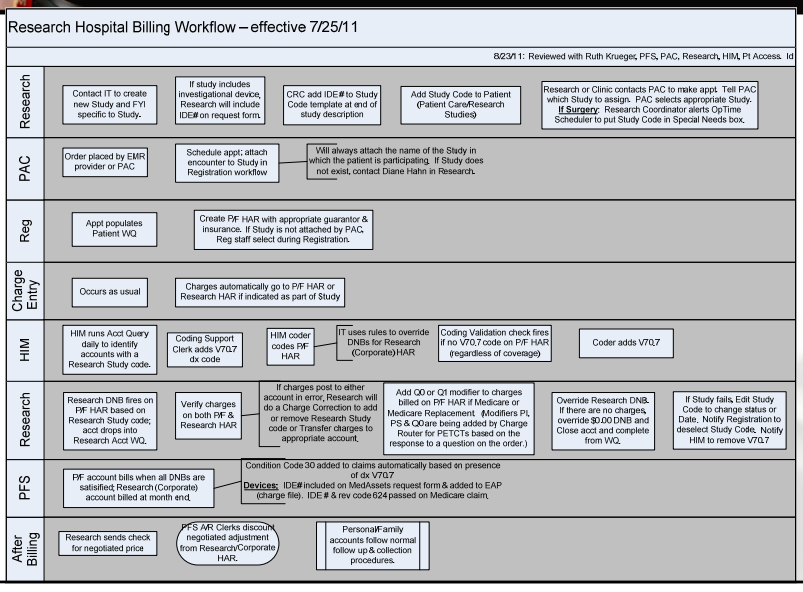
- No standard process for determining whether a study is qualified or for identifying covered services
- Inability to identify and track research patients throughout the system
- Automated billing processes that allow little opportunity to intervene once services are provided
- Lack of clear channels of communication between research teams and billing services
- Research contracts are in one department, but billing occurs elsewhere

Federal Audit Perspective on Billing

- OIG's assumption when reviewing Medicare billing of research grant and clinical trials
  - Experimental treatment is generally not covered
  - Physicians have an incentive to not charge cost to their grants
  - There is a significant risk of "double billing"
- Institutions have not developed an infrastructure that would support accurate coding of charges

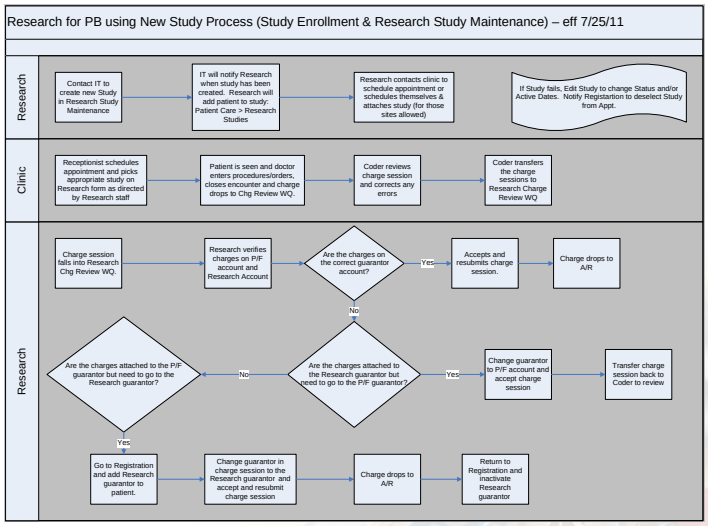
EPIC Hospital Research Billing Workflow

Sanford Health



EPIC Clinic Research Billing Workflow

(Sanford Health)



EPIC Hardwiring Example

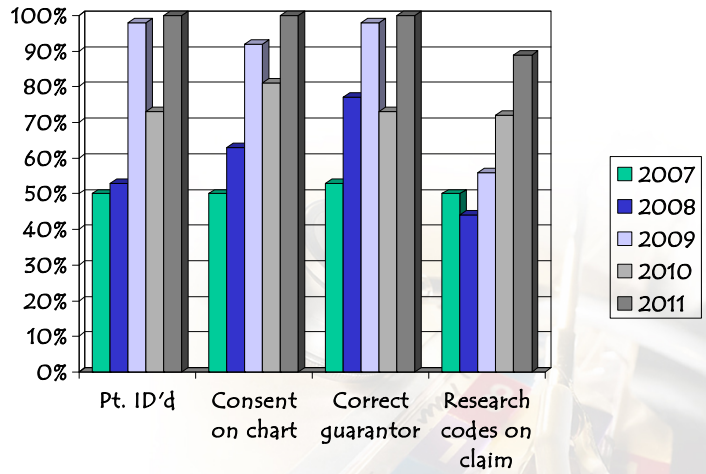
Research Billing Module

- Patient level identification – shows in header
- EPIC specific research study code (RSC) at encounter level
- IDE # in CDM to claim with Rev Code 624
- V70.7 added from coding validation, drives CC 30
- RSC drives DNB WQ that drives Q modifier & charge review prior to claim drop

Audit Tool

- Account #
- Study Code/Flag Attached (EPIC term)
- Study Name
- DOS
- Rev Code 624 /IDE# (if appropriate)
- V70.7
- Condition code 30 (Facility only)
- Q Modifier (OP only)
- Billed to appropriate guarantor
- Consent on chart / language matches MCA

Research Billing Hardwire Outcomes



Open for Questions….

- Can you bill routine care for the services required in the protocol for a federally funded clinical trial?
- If the protocol requires a PET CT at the 8 year mark of the clinical trial, can you bill it as routine care?
- Can the consent say "…we will pay for services provided if denied payment by your insurer…"?

Closing Quip

"Research is formalized curiosity. It is poking and prying with a purpose."

Zora Neale Hurston

Once could say the same about Research Billing Compliance ;-)