University of California Compliance & Audit Symposium

Accuracy in Research Billing

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Goals & Topics

1. Brief review of:
   - CMS Clinical Trial Policy (NCD 310.1)
   - California SB37
2. The role of a Coverage Analysis
3. Special CRB rules and challenges
4. CRB auditing

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Themes

- CRB audits are very different from most billing compliance audits because there are usually many documents that need to be pulled together and they are often not centrally housed
- The "pieces of information" are often in many different places!
- There may be different "payors" for different services during the same research visit

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Themes

- Who impacts research billing?
  - Principal Investigator
  - Clinical Research Coordinator
  - IRB process
  - Budget negotiators
  - Clinical Trial Agreement negotiators
  - Grant administration
  - Information Technology
  - Health Information Management
  - Registration/Scheduling
  - Medical center billing and coding
  - Physician professional fee billing and coding
  - Study fund managers
  - Managed care contract negotiators
  - ….and others!

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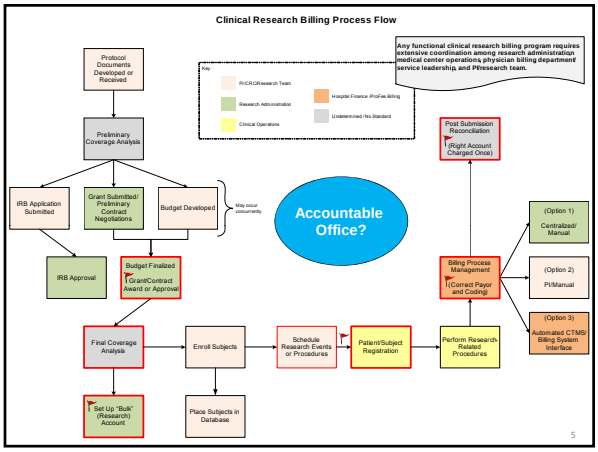

Important CRB Terms to Know

- **Clinical Research Billing (CRB):**
  - Billing payors or studies/grants for clinical services during a research study
  - Note: This involves all clinical research studies, even if there is no experimental or investigational item
- **Research Informed Consent Form (ICF):**
  - Document approved by an IRB and signed by the patient (who is known as the "subject")
  - CRB compliance begins when the patient signs an ICF
- **Protocol:** The scientific document which sets out the goals and design of the research study

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Important CRB Terms to Know

- **Schedule of Events (SOE):**
  - All of the services that must be performed during the study and when they must be performed
  - Often looks like a spreadsheet
- **Clinical Trial Agreement (CTA):**
  - Contract between UC and the sponsor of the study
  - Sets out what the sponsor is paying for during the study (the "budget")
- **Coverage Analysis:**
  - A document that brings together information about the study in light of billing rules and provides direction as to whether the service should be billed to the payor or the study

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Principal CRB Risks

- Ignoring clinical research billing rules can lead to:

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
5. Billing a Medicare Advantage Plan when Palmetto (MAC) should be billed

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Health Insurance & CRB

- Third-party payors have individual rules on what they will pay during clinical research studies
- However, many follow Medicare rules or have CRB rules which closely mirror Medicare
- California has a special law (SB37) which requires commercial insurers to pay for "routine patient care costs" during *cancer* clinical research studies (SB 37 closely mirrors the Medicare rule)
- Practical approaches to CRB utilize Medicare rules

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CMS CRB Rules

- Medicare requires a three-part process for clinical research services coverage:
  1. Does the study "qualify" for coverage?
  2. What items and services are "routine costs"?
  3. Do Medicare rules allow coverage of specific "routine costs" within a research study?
- Plus:
  1. What is paid for by the sponsor?
  2. What is promised free in informed consent?

Slide 10

What is a Qualifying Clinical Trial?

- A qualifying clinical trial (QCT) depends on what is being studied:
  - Devices – use the device trial rules
  - Non-device studies – use the CMS Clinical Trial Policy

Generally:

- Drug studies that are under an IND application or are IND exempt
- Studies funded by certain HHS agencies, DOD, or VA
- IDE Category B devices
- IDE Category A devices addressing life-threatening conditions

- Note: there are multiple criteria for each type of qualifying study

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What is a Qualifying Clinical Trial?

- For IDE device studies, the MAC (Palmetto) must approve the study before billing for "routine costs"
- For non-device studies, the qualifying status should be documented through an internal process
  - The "QCT Analysis"

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What are "Routine Costs"?

- In qualifying clinical trials, Medicare covers items and services scheduled by the protocol that are considered "routine costs"
- Routine costs are:
  - Conventional care items and services
  - Detection, prevention and treatment of complications
  - Administration of investigational item

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What are Routine Costs?

- Note that "routine cost" does not necessarily mean what the physician routinely does
- "Routine costs" does not equate to "standard of care"
- Sometimes "routine costs" allows more than standard of care, such as the administration of a study drug
- It is important to document why the organization determined the protocol service is a "routine cost"

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SB37: Cancer Studies in California

- Covered: Phase I, II, III, and IV clinical trials with a therapeutic intent for patients with cancer. Trial must either involve an IND exempt drug or be approved by one of the following:
  - National Institutes of Health (NIH)
  - U.S. Food and Drug Administration
  - U.S. Department of Defense
  - U.S. Department of Veterans Affairs
- Who is required to pay? All California insurers, including the state's Medicaid program and other medical assistance programs.
- What does it pay for? "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program
- Note: SB37 is slightly broader than the Medicare rules

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The Role of a Coverage Analysis

	Code	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Comment
Physical Exam	99201-99215		M	M	M	M	
EKG	93000	M	M	M			
Drug 123	J0123	S	S				
Infusion	96500	M	M				
Urinalysis	81000		S	S			
Ultrasound	93990			ICF			
Patient Diary	N/A		NB	NB	NB	NB	

M=Medicare
S=Sponsor
ICF=Free in Informed Consent
NB=Not Billable

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The Role of a Coverage Analysis

- Coordinates relevant study information
- Facilitates and strengthens the budgeting process
- Standardized tool available to all involved in the billing process
- Provides a financial and compliance auditing platform

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The Role of the Coverage Analysis

- Who develops the Coverage Analysis?
  - Every institution has developed its own process
- Where is the Coverage Analysis?
  - Find out!

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Special Rules for CRB

- CRB Coding
- Medicare Advantage (Medicare Part C)

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CRB Coding

- Medicare requires certain codes and modifiers to be used for claims submitted for routine costs during
- January 18, 2008 Transmittals
  - Q0/Q1 Modifiers (Transmittal 310)
  - Clinical Trial Number Option (Transmittal 1418)
- Status:
  - V70.7 code: required
  - Modifiers: required in outpatient setting
  - Clinical Trial Number: optional

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V70.7 Code

- V70.7 is a diagnosis code which means "examination of participant in clinical trial"
- The V70.7 is required for all Medicare claims which contain "routine costs"
- The V70.7 is the provider's attestation that the claim contains routine costs during qualifying clinical trials
- For billing "routine costs," the V70.7 is listed as the secondary diagnosis
- If the V70.7 is listed as the primary diagnosis, then the claim will be denied

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Condition Code 30

- Institutional Inpatient Claims:

  "Institutional providers billing clinical trial service(s) must report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer) and a condition code 30 regardless of whether all services are related to the clinical trial or not."

- Outpatient Claims:

  "On all outpatient clinical trial claims, providers need to do the following:
  - Report condition code 30,
  - Report a diagnosis code of V70.7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer)"

Medicare Claims Processing Manual, Ch. 32, Sec 69.6

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Clinical Research Modifiers

- Medicare CRB Modifiers:
  - Q0: "investigational clinical service"
  - Q1: "routine clinical service"
- Applied to hospital outpatient and physician professional fee claim forms per CPT code

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A note on the medical record

- Section 69.3 of Ch. 32 also contains the following:
  - "The billing provider must include in the beneficiary's medical record the following information:
    - trial name,
    - sponsor, and
    - sponsor-assigned protocol number.
  - This information does not need to be submitted with the claim but must be provided if requested for medical review." (emphasis added)

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Medicare Advantage

- There is a special CRB rule for claims processing for Medicare patients in Medicare Advantage Plans (Medicare Part C)
- Any routine costs during non-device studies must be billed to Palmetto as the MAC and not to the Medicare Advantage Plan.
- Split-billing sometimes needs to be turned into "triple split-billed" when the Medicare patient is a Medicare Advantage patient. There may be charges for the same visit which are billed to:
  - The study fund (bulk account) [services paid for by sponsor]
  - Medicare Advantage [services not related to the study]
  - Medicare Administrative Contractor ["routine costs" for the study]

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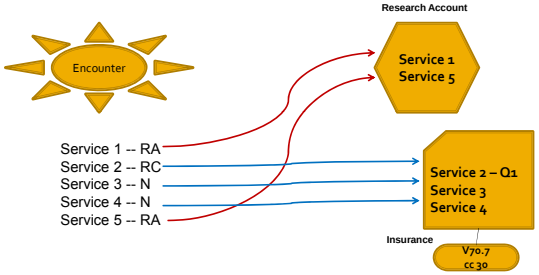
Charge Direction



RA= research account
RC= routine cost
N= normal/not part of study

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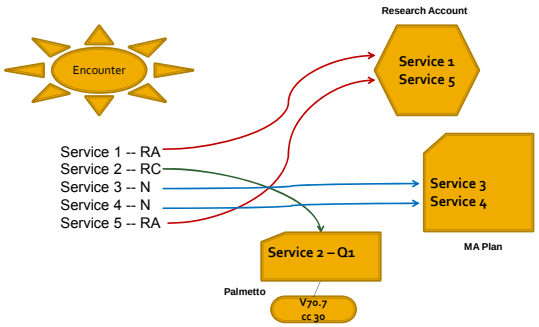
Charge Direction: Medicare Advantage



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CRB Auditing

- Principal challenges for CRB auditing:
  - Gathering documents
  - Selecting patients
  - Choosing the claims to audit

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CRB Auditing

- Document gathering:
  - Protocol
  - CTA & funding documents
  - ICF
  - Approval letter from MAC for device studies
  - Coverage Analysis (is there one?)
  - Study calendar (is there one?)
  - Medical record
  - Claims

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CRB Auditing

- Patient selection
  - Patients on research studies generally receive the same services within the study, but not all patients stay in the study the same length of time
  - Some patients enrolled in a study are "screen fails," meaning they sign the ICF but don't meet inclusion criteria so they never receive the research treatment
  - In auditing, decide whether your audit will:
    - (1) take a completely random selection of patients or
    - (2) select patients who have received some threshold number of research visits

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CRB Auditing

- Patient selection:
  - Who are the patients?
  - Do you know where to get the information?
  - Is there a central database?
  - Do you need to ask for patient enrollment information from individual departments or physicians?

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CRB Auditing

- Claims selection:
  - A general approach for CRB auditing is to audit a series of research visits for a patient and not just one visit
  - In order to "get it right," CRB requires communication across many departments and one random visit often doesn't provide enough information to make confident findings
    - Note: This will be a facts and circumstances determination

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CRB Auditing

- Claims selection:
  - Visits that are not research-related – and there may be many! – are not relevant to CRB auditing
  - The "study calendar" is a key document
  - The study calendar identifies the dates the patient received study-required visits
  - Where is the study calendar?
    - Is there a clinical trials management system with centralized information?
    - If not, then the study calendars usually need to be obtained from the physician's research coordinator

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Take-away Points

- CRB auditing requires considerable document gathering
- Understand what systems and databases are in place before undertaking it
- Plan for a long process – it won't happen overnight
- Make sure you have a good grasp of key points on the rules
- Conducting interrater reliability testing at the beginning is a wise course due to the complex nature of the materials being reviewed

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- Questions/Discussion

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