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## **Medicare Advantage & Clinical Research Billing**

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## Structure of CRB Webinars

- Session 1: Opportunities & Challenges
- Session 2: CRB: A Team Effort
- Session 3: Clinical Trial Agreements
- Session 4: Informed Consents
- Session 5: Study Budgets & CRB Billing Rules
- **Session 6: Medicare Advantage & CRB**
- Session 7: Specific Issues in Billing & Coding

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## Objectives

- Review the Medicare Advantage (Part C) clinical research billing rules and CMS's "split-billing" instructions
- Explain importance of identifying and correctly coding all covered services for Medicare Advantage enrollees
- Discuss how to identify which covered charges during an encounter are billed to the Medicare Advantage Plan and which are split-billed to the Original Medicare MAC (Palmetto)
- Examine the Medicare Advantage rules in the context of hospital inpatient, hospital outpatient and physician professional billing

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## First things first:

### What is Medicare Advantage?

- Medicare Advantage is an optional program for seniors that provides the same benefits as Medicare Part A (inpatient insurance) & Part B (outpatient and physician insurance) but may include lower co-insurance, lower or no deductible, and additional benefits for either the same premium as Part B or slightly higher
- Medicare Advantage is "Part C" of Title XVIII of the Social Security Act
- Medicare Advantage is formerly known as:
  - Medicare + Choice
  - Medicare Managed Care

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## Medicare Advantage

- CMS contracts with private insurance companies to administer Medicare Advantage benefits; these are referred to as Medicare Advantage Plans (MAPs)
- The MAPs compete for seniors to enroll in the same way Part D Prescription Drug Plans compete for enrollment
- Medicare Advantage enrollment varies around the country
- 35% of seniors in California are enrolled in a MAP

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## Medicare Advantage & CRB: General Rule

- Clinical research study-related services are covered for Medicare Advantage enrollees, but where the claims are sent follows different rules for non-device studies
- Device trials: Research-related services during device trials are billed to MAP in the same way (Medicare Managed Care Manual, Ch. 8, Sec. 40.4.4)
- Non-device trials: Research-related services are billed to the provider's "Original Medicare" contractor (i.e., the same contractor where Part A & Part B claims are sent) (Medicare Managed Care Manual, Ch. 8, Sec. 40.4.3)
- Impact: Not only must all research patients be flagged in the CRB process, but the billing system must direct all research-related claims for Medicare Advantage patients to the Original Medicare contractor (Palmetto)

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## Basic Rule

Medicare Claims Processing Manual, Ch. 32, Sec. 69.9:

- “For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans.”
- “Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.”

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## Device Trials are not impacted by the special MA clinical trials rule

Medicare Managed Care Manual, Sh. 8, Sec. 40.4.4:

- “Medicare Advantage organizations should not confuse clinical trial coverage under the September 2000 NCD with Medicare's policy on IDE (Investigational Device Exemption) coverage. Category B IDE trials have been covered, at contractor discretion (within CMS's rules and guidelines), since November 1, 1995, under 42 CFR 405.201 to 405.215. Category B IDE costs are included in the Medicare Advantage (MA) payment rates. Therefore, these claims are not paid on a fee-for-service basis by fiscal intermediaries and carriers. The MA organizations can apply plan rules, including prior authorization rules, when determining whether to cover an enrollee's participation in a Category B IDE trial.”

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## Medicare Advantage & CRB: Patient Implications

- Patient out-of-pocket implications:
  - Deductible is allowed to be waived
  - Sending claim to Original Medicare generates Part B co-insurance (co-pay)
  - Part B co-insurance is not allowed to be waived
  - Co-insurance for Part B is 20% of Medicare rate
- Impact:
  - Medicare Advantage patients enrolled in clinical trials generally have higher co-pays for the covered services
  - CMS recognizes this and is contemplating a rule change for 2011 in which the MAP will be required to reimburse the patient for the difference between the MAP co-pay and the Original Medicare co-pay
  - However, 2011 proposed “fix” does not change the provider’s obligation to re-direct the claims to the Original Medicare contractor

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## Medicare Advantage & CRB: Compliance Implications

- Billing a MAP when the Original Medicare contractor should have been billed could create an overpayment situation
- MAPs are contractors for the Medicare Program
- MAPs negotiate a rate with CMS for each senior who enrolls in the MAP
- Billing a MAP when a provider should not involves a MAP paying funds which it should not
- The U.S. False Claims Act was amended in 2009 to include “contractors” of the United States government

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## Do patients know about this rule?

- CMS would say they do
- FAQ from Medicare beneficiary information booklet about clinical trials (March 2010):
  - **I'm in a Medicare health plan. Can I still be in a clinical research study?**
  - Yes. If you're in a Medicare Advantage Plan (like an HMO or PPO) or other Medicare health plan, you can get the same coverage for clinical research studies as a person in Original Medicare, as described in the previous section. Once you join a Medicare-covered clinical research study, Medicare will pay for your covered services as if you were in Original Medicare. This means that your Medicare health plan can't keep you from joining a clinical research study. However, you should tell your plan before you start a study. That way, the plan can still keep track of your health care services and explain what you will have to pay for copayments, coinsurance, and deductibles.

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## Which services are billed to Original Medicare?

- Services that are "related to the clinical trial" are billed to Original Medicare
- Services that are "unrelated to the clinical trial" are billed to the MAP
- CMS does not provide clear guidance as to when something is "related to" or "unrelated to" a clinical trial
  - Organizations should establish a consistent approach that uses good faith interpretations
  - Common approach:
    - "related to" refers services scheduled by the protocol and services to treat complications;
    - "unrelated" refers to unscheduled services that are not the result of being enrolled in the study

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## Which services are billed to Original Medicare?

- Practical approach: Use the MCA as a guide
- Possible scenarios:
  - If the service is on the MCA (because it is scheduled by the study), then the service should be billed to Original Medicare
    - Example: protocol scheduled drug infusion
  - If the service has nothing to do with the study and is not scheduled by the protocol, then bill to the MAP
    - Example: patient complaint of back pain requires imaging services
  - If the service is to treat a complication related to the investigational item, then the service should be billed to Original Medicare
    - Clinical research coordinators should inform the CRB process of when treatment of complication occurs

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## Split-billing on “mixed” days

- If the encounter includes some services which are related to the research study and some which are not related to the research study, then charges for the encounter must be “split”
- Split billing usually refers to directing charges from the same day to different payors
- It is important to split bill for “mixed” research days because if the entire claim is directed to the Original Medicare contractor, then the MAP inappropriately benefits (by not having to pay) and the patient must pay unnecessary co-pays
- The CRB process must know:
  - Which encounters include protocol-related services
  - Which charges are related to the research study (the MCA shows this)

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## Medicare Claims Processing Manual

- Medicare Claims Processing Manual, Ch. 32, Sec. 69.9
  - “[F]or beneficiaries enrolled in a managed care plan, institutional providers must not bill outpatient clinical trial services and non-clinical trial services on the same claims. **If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that ONLY the clinical trial services are contained on a single claim and billed as fee-for service...** Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.” (emphasis in original)

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## Review of Provider Settings

- Hospital outpatient setting: Encounters including research-related services must be reviewed for potential split-billing
- Physician professional fees: Encounters including research-related services must be reviewed for potential split-billing
- Inpatient care: CMS is not clear on the impact for split-billing. An inpatient claim cannot be “split.” The CMS split-billing references are for outpatient services.
  - Options:
    - If the reason the patient is admitted is unrelated to the study, then send claim to MAP
    - Keep “routine cost” charges off the UB claim form for MAP patients or place in non-covered column
    - Pre-authorize with MAP
    - Use v70.7 code

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## Likely changes in 2011 could increase audits/reviews

- CMS has not released a final rule, but in April 2010 the agency announced that it would likely require MAPs to pay the co-pay differential
- This will make the patient “whole” and the patient will not have additional out-of-pocket expenses for enrolling in a research study
- Likely effect: MAPs will be paying more under this new arrangement and the MAPs will likely be watching carefully what services during a clinical trial are being billed to Original Medicare to ensure that the MAP is only paying legitimate co-pay differentials
- In other words, it would not be surprising to find more CRB reviews being conducted by MAPs

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## Operational Suggestions

- Determine method to inform CRB process that a patient is enrolled in a research study
- Identify to CRB process which services occurred which contained services related to the research study
- Use the MCA as a means to identify which services are related or unrelated to the research study
- Require clinical research coordinators to inform CRB process whenever services occur to treat complication that are related to the research study
- Develop process to split bill
- Be prepared for the 2011 co-payment changes

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## Take-away Points

- Establish a process to identify subjects enrolled in Medicare Advantage Plans
- If no automated process, then hold MAP research subjects for split billing process
- Use an MCA to identify which items and services during an encounter are split and sent to Original Medicare and which items and services are sent to the MAP
- Use consistent approach for determining what is or is not related to the research study
- Adopt process to inform CRB process of when research-related unscheduled events occur

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## References for further reading

CMS National Coverage Determination 3101 ("Routine Costs in Clinical Trials")

CMS Claims Processing Manual, Ch. 32, Sec. 69.9

Medicare Managed Care Manual, Ch. 8, Sec. 40.4.3 & 40.4.3


"Medicare Advantage Fact Sheet." (July 2010) Kaiser Family Foundation

CMS Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 5, 2010)

Editors. (2009) "Medicare Advantage: Reforms Needed to Ensure Access to Clinical Trials." NCD 310.1 ("Routine Costs in Clinical Trials") J of Oncol Prac May 2009 vol. 5 no. 3 144-145

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- Questions

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