RECOVERY AUDIT CONTRACTORS

RAC ROUND-UP SUBSCRIPTION SERVICE

"Being Proactive"

Kyphoplasty, CMS Clarifies "Effective" and "Implementation" Dates & Changes to Carotid Artery Stenting Coverage

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RAC Round-Up Subscription Service: Webinar Overview

- "RACs: Being Proactive"
  - Second Tuesday of each month
  - Discuss one or two high-risk areas for RAC review
  - Review ideas on how to proactively audit
  - Propose operational safeguards

- "RACs: What are We Learning"
  - Fourth Tuesday of each month
  - Keep subscribers up-to-date on RAC developments
    - Discuss RAC updates
    - Analyze publicly available decisions involving RACs
  - Pool questions from subscribers

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RAC Round-Up Subscription Service: Webinar Overview

- Regularly scheduled Webinars will be supplemented, as necessary, with special “emergency” sessions

- <u>Administrative Matters</u>
  - Each session will be 60-75 minutes in duration, including a question and answer session
  - Each session will begin at 12:00 PM CT
  - If you are unable to participate in the live discussion, each session will be recorded and made available in MP3 format

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Goals

- The goals of the RAC Round-Up Webinars:
  - Teaching/knowledge transfer
  - Practical points
  - Assist organizations to develop in-house methods of managing
  - Please share your thoughts, suggestions (and criticisms)

- Our Perspective—
  - *Defend your claims*: Appeals process is critical
  - *Manage your compliance risks*: Compliance implications to a RAC review must be addressed – the RAC process is not just about RAC recovery
  - *Be proactive*…and preemptive

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Today's Topics and Agenda

- Kyphoplasty Settlements
- CMS clarifies definitions
- Carotid Artery Stenting Changes

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Kyphoplasty FCA Settlements

- In May, 2008, DOJ announced a FCA settlement with Medtronic Spine, LLC (f/k/a Kyphon, Inc.)
  - Medtronic agreed to pay the US $75 million to settle allegations that it caused the submission of false claims to Medicare
  - Kyphoplasty Procedure = a “minimally-invasive” surgical procedure used to treat compression fractures of the spine caused by osteoporosis, cancer or benign lesions
  - US alleged that Kyphon engaged in a multi-year marketing plan that resulted in certain hospitals billing Medicare for certain kyphoplasties performed on an inpatient basis that should have been performed on an outpatient basis

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Kyphoplasty FCA Settlements

- In May, 2008, DOJ announced a FCA settlement with Medtronic Spine, LLC (f/k/a Kyphon, Inc.)
  - US did not question the medical necessity of the procedure, but rather the setting in which the procedure was performed
  - Qui tam complaint filed by two whistleblowers (former Kyphon employees)
  - Medtronic also agreed to enter into a CIA with the OIG

- But, the $75 million settlement with Medtronic was not the end of the story

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Hospital Settlements

- In June, 2009, three hospitals in Minnesota agreed to pay $2.28 million to settle FCA allegations relating to kyphoplasty claims

- In September, 2009, six more hospitals (3 in Alabama and 3 in Indiana) agreed to pay $8.36 million (in the aggregate) to settle kyphoplasty claims

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Hospital Settlements

- In May 2010, DOJ settled with nine other hospitals (located in Alabama, Indiana, Florida, Michigan, South Carolina, New York and Minnesota) for kyphoplasty related claims. The hospitals agreed to pay more than $9.4 million

- On January 4, 2011, DOJ announced another FCA settlement with seven more hospitals (located in Florida, Mississippi, Texas, South Carolina, North Carolina). The hospitals agreed to pay more than $6.3 million (in the aggregate) to settle the FCA allegations

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What to Do?

- Not all of the hospitals that have settled were named as defendants in the qui tam complaint filed by the relators

- If your hospital performed inpatient kyphoplasty procedures, what should you do?

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Audit Issues

- Operative Medicare rules and regulations do not preclude Medicare coverage for inpatient kyphoplasty procedures

- NGS, for example, has an LCD for Vertebroplasty and Vertebral Augmentation (Percutaneous) (L26439) that specifically allows for inpatient coverage of kyphoplasty procedures

- Milliman Care Guidelines specify clinical indications for admission to inpatient care (e.g., progressive or severe neurologic deficit, spine fracture with significant damage to vertebral column or spinal cord)

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Audit Resolution

- Consider adding kyphoplasty to your compliance auditing plan and conduct a probe sample of your hospital's inpatient kyphoplasty procedures within the past 6 years
- Do the records support the medical necessity of an inpatient admission?
- If not, is further examination warranted.
- If audit results indicate that not all inpatient admissions were appropriate, self-disclosure may be warranted
  - If disclose to local US Attorney, case will likely be referred to DOJ Civil Division for coordination with US Attorney's Office in Western District of NY (qui tam complaint was filed in Western District of NY) and OIG

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CMS Clarifies Definitions on Transmittals

- When CMS issues changes to its manuals or to the scopes of work for contractors or instructions to providers, there are often three dates associated with the transmittal:
  - Release Date
  - Effective Date
  - Implementation Date
- Real example from transmittal discussed later:
  - Effective date: October 22, 2010
  - Release Date: December 10, 2010
  - Implementation Date: January 12, 2011
- What in the world do these dates mean and when are providers expected to comply?

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CMS Clarifies Definitions on Transmittals

- CMS issued Change Request 6592/Transmittal 66 on January 7, 2010 to establish consistent terms and set out definitions.
  - Issue Date;
  - Implementation Date;
  - Effective Date; and
  - Date of Service

- Note: the Effective Date and Implementation Date for the Transmittal is February 8, 2011

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CMS Clarifies Definitions on Transmittals

- The changes are additions to the
  - General Information, Eligibility, and Entitlement Manual
  - Chapter 7 “Contractor Administrator Requirements”

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CMS Clarifies Definitions on Transmittals

- Issue Date:

  The date the Centers for Medicare and Medicaid Services (CMS) publishes a change request (CR).

  When a CR has passed through all phases of the change management process, it is then ready for publication; that is, the CMS is ready to make the instructions contained in the CR available to contractors, maintainers, providers, beneficiaries and/or any group or organization that may be affected, as appropriate. The CMS publishes CRs by posting them, as Transmittals, on the CMS Web site.

  Note: The issue date is named “Date” on the Transmittal form, One-Time Notification, Recurring Update Notification, and the Standard CR forms. It is sometimes referred to as the “transmittal date.”

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CMS Clarifies Definitions on Transmittals

- Implementation Date:

  The implementation date identified in a change request (CR) is the date by which Medicare fee-for-service contractors and shared system maintainers shall apply all changes detailed in the business requirements, unless otherwise specified. It is the date when all necessary updates to infrastructure, business processes and/or supporting technology changes shall be completed and operational in order to execute new/modified policy and procedure.

  Unless otherwise stated, the implementation date is the same for all business requirements listed within a specific CR. In some instances, a separate implementation date(s) may be given for a particular business requirement(s) within a CR.

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CMS Clarifies Definitions on Transmittals

- Effective Date:

  The effective date identified in a change request (CR) is the date on which any new rules, laws, processes and/or policies become active.

  Beginning on this date, Medicare contractors shall apply the new rules to process Medicare claims according to their updated business processes and supporting technology.

  The effective date is normally a mandated date resulting from legislation or a regulation. In the case of National Coverage Determinations (NCDs), the effective date is the first day the item or service that is the subject of the NCD is covered nationally under the Medicare Program.

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CMS Clarifies Definitions on Transmittals

- Effective Date (more):

  Effective dates are not always future dates; sometimes, they are in the past. When this happens, the Centers for Medicare and Medicaid Services (CMS) instructs contractors, using business requirements, how to process claims for the period between the effective date and the implementation date. Typically, the effective date is the first day of any given fiscal year quarter or the first day of the month.

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CMS Clarifies Definitions on Transmittals

- Implementation Date (jumping back for more):

  Implementation and effective dates are frequently not the same. The list below contains the scenarios for the differences:

  – The effective date and implementation date are different because the first day of the quarter is not a Monday;

  – The effective date and the implementation date are different because the effective date occurs after the implementation date;

  – The effective date and the implementation date are different because the effective date occurs before the implementation date, but both dates are in the future; or

  – The effective date and the implementation date are different because the effective date occurs before the implementation date, and the effective date is in the past, while the implementation date is in the future.

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CMS Clarifies Definitions on Transmittals

- So…..what does this mean for the example:
  - Effective date: October 22, 2010
  - Release (Issue) Date: December 10, 2010
  - Implementation Date: January 12, 2011

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (MM/CR7249)

- On December 10, 2010, CMS released a new rule regarding contractor approval for billing for embolic protection devices during carotid artery stenting (CAS) if:
  - The device has been “510k-cleared” by the FDA
  - The patient is enrolled in a post-approval extension study
- Parallels rules for billing for CAS procedures during “full clearance” post-approval studies
- The CAS post-approval studies are becoming increasingly common at hospitals – and they often do not look like research studies because the device is approved by the FDA

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting

- The basics on CAS post-approval studies:
  - Providers must receive approval for billing CAS services during post-approval studies.
  - Post-approval studies are similar to registry studies in which the manufacturer is collecting additional data on the device's safety and effectiveness.
  - Sometimes the FDA requires the continued collection of information as a condition for approval.
  - In 2004 & 2006, CMS updated the Claims Processing Manual to require providers to seek approval for billing from the local Medicare Contractor Medical Director.
  - At the same time, CMS issued a directive to the Medicare Contractor that approval was not discretionary.
  - When billing, the provider is to use a special code that begins with P.

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting

- What was/is this all about?
  - Difficult to know!
  - Most likely, data collection and possibly a suspicion by CMS of how the devices were approved
  - Odd circumstances in which CMS nationally approves coverage to the manufacturer, but providers need to submit requests for billing to the contractor, and the contractor does not have discretion to disapprove (the contractor must approve)

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting

- New Rule:
  - Extends this same CAS process to “510k-cleared” “extension studies” which involve embolic protection devices
  - “Extension studies” are optional studies the manufacturer may undertake after the device has gone through “510k-clearance.” They collect additional data on the device’s use.
  - CMS is extending the CAS “post-approval studies” rule to include 510k-cleared extension studies which use embolic protection devices

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting

- Mechanics:
  - Seek approval from Medicare Contractor Medical Director using same process as approval for IDE device studies
    - FDA acknowledgement letter
    - CMS national letter
    - Any other materials Contractor requests
  - When billing, use the special FDA number assigned to the device, an "I" in front of the code
  - CMS's example:
    - "For example, the FREEDOM study, examining 510k-cleared Gore Flow Reversal System was assigned I090962, and must be identified as such on all claims."

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510k-Cleared Embolic Protection Devices during Carotid Artery Stenting

- What is this all about?
  - Directive to Medicare Contractors:
    - "Upon receiving the FDA acknowledgement letter and CMS coverage letter, contractors shall issue a letter to the provider assigning an effective date for participation in the 510k post-approval extension study." (emphasis added)
    - Arguably non-discretionary for contractors to grant approval
  - Further statement by CMS:
    - "You should be aware that your contractor is not required to mass-adjust claims for dates of service between the October 22, 2010, effective date and this CR's implementation date, but they may adjust claims that you bring to their attention."

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Follow-Up

- Questions?

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- Next Lecture:

Tuesday, January 25, 2011

12pm CT/1pm ET

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