Medicare: "Complex regulatory structure."

"Truth and enlightenment are on another peak. I do medicare explanations."
Objectives

- Medicare Provider-Based Rule Primer
  - Regulation Overview
- Section 603 of the Bipartisan Budget Act of 2015
  - Amendment to the Social Security Act
  - Impact on OPPS Coverage
  - Proposed Implementation for CY 2017
- 60-Day Rule
  - Duty to Refund Overpayments

Provider-Based: What Is It?

- Medicare rule (42 C.F.R. § 413.65) related to payment for hospital services
- Defines what operations are part of a Medicare-certified provider (vs. supplier)
- Determines what services can be billed under the Medicare provider number (CCN)
- Originally § 413.65 applied to ALL providers, but was amended in 2002 to effectively limit to hospitals/CAHs
Provider-Based: What Is It?

- **Key concept**: HOSPITAL billing
  - Facility fee on a CMS 1450/UB-04
  - Professional fee on CMS 1500 with correct POS code (unless CAH bills under Method II)
    - POS 22 – on-campus hospital outpatient department
    - POS 19 – off-campus hospital outpatient department
  - Just like traditional hospital-based doctors in ER, anesthesiology, etc.
  - Provider-based status NOT a special payment status – except for certain RHCs
  - Hospital CoPs and payment rules apply (ex. supervision)

Provider-Based: Requirements

Provider-based requirements are multi-faceted and include the following:

- **All facilities or organizations (on- and off-campus):**
  1. Common Licensure
  2. Financial Integration
  3. Clinical Integration (Clinical Oversight, Medical Records, Medical Staff)
  4. Public Awareness

- **Off-Campus** locations must also meet:
  1. Common Ownership
  2. Administration and Supervision
  3. Location
  4. Notice of Coinsurance
Provider-Based: Public Awareness

Public awareness – naming/branding/signage

- The Hospital name is required – a must!
- Multiple tag lines are fine
  - Community Hospital
  - Mayberry Clinic
  - Spectacular Medical Group
  - Spectacular Health System
- Hospital does not "need" to be first or biggest
- But, avoid fine print "Community Hospital"
- Not just signage: marketing materials, registration, phone listings, websites ... (CMS does check!)

Provider-Based: Requirements

Other Provider-Based Requirements Include:

- Meet all applicable Medicare hospital conditions of participation and payment
  - Life Safety Code
  - Supervision
- Subject to all terms of provider agreement and deficiencies at any site can jeopardize entire hospital provider status
- EMTALA obligations
- Implications for CAH location standards (new sites)
- If NOT met
  - Provider-based vs. freestanding payment differential
  - Loss of reimbursable distinction and 340B child site status
Provider-Based: POS Codes/Modifiers

- Services provided in off-campus HOPDs must be identified on claims
  - Hospital Claim: HCPCS Modifier "PO" on facility claims (UB) for services paid under OPPS
  - Physician Claim: New POS code on professional claims (1500)
    - POS 19 to identify services provided in an off-campus HOPD
    - Revised POS 22 to identify services provided in an on-campus HOPD and satellite/remote locations of hospital
  - Required reporting by January 1, 2016 (no impact on payment; data collection)

Definition of Campus

- What is "On Campus"?
  - "Campus means the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider’s campus."
  - Affects:
    - Ability to open new provider-based HOPD services given Budget Act changes
    - RO interpretation and how do they measure?
    - Will OPPS rule offer further guidance? (straight line from any point)
Definition of Campus

• Takeaways
  – “Main buildings” not defined – CMS generally interprets as primarily inpatient care location/building(s)
  – Only main buildings enlarge footprint via 250 yard rule
  – Region 5 rarely has approved discretionary expansion
  – Maybe if nothing but open space between main buildings and new structure

Bipartisan Budget Act of 2015

• Section 603 of the Budget Bill of 2015
• Amendment to Social Security Act § 1833(t)
  – Impacts hospital services provided in off-campus outpatient departments of a provider as defined in 42 CFR § 413.65(a)(2)
    • Medicare provider-based rule
  – Services provided in off-campus departments excluded from coverage as OPD services effective January 1, 2017
  – Only those departments billing on the DOE are grandfathered
    • Date of enactment is November 2, 2015
    • No grandfather for "under development" sites
Bipartisan Budget Act of 2015

- Amendment to Social Security Act § 1833(t)
  - On-campus department services not impacted
  - Remote location "campus" services not impacted
    - Different definition than provider-based rule; remote location is considered an off-campus location
  - Off-campus ED services (furnished by a "dedicated ED") not impacted
  - Outpatient services paid under a fee schedule not impacted
  - CAHs not impacted
  - "Provider-based entities" not impacted (ex. RHCs)

Open Questions
- How do hospitals enroll and bill for non-grandfathered sites?
- How will CMS pay for services not covered by another applicable payment system?
- Multi-campus hospital structure - JVs & Management Contracts?
- What happens to a site that receives a provider-based revocation back to pre-DOE (November 2, 2015)?
- What happens if voluntary refund required from lack of compliance with provider-based regulation?
Bipartisan Budget Act of 2015

• Open Questions
  – Can grandfathered site relocate, expand, or add new footprint and/or new services?
  – 340B Child Sites after 12/31/2016?
  – Grandfathered site undergoes CHOW to new Main Provider number?
  – I/P Campus moves and leaves behind O/P only at old campus?
• OPPS Rule will Implement Section 603
  – CMS accepted “pre-comments” to consider for proposed CY 2017 OPPS rule

Bipartisan Budget Act of 2015

• 2/5/16 Letter from Committee on Energy & Commerce
  – Requested industry commentary by 2/19/16
  – AHA submitted 13 page response on 2/12/2016
• 4/27/16 Bipartisan Senate Letter asking CMS for flexibility in implementing site-neutral HOPD changes
  – AHA Action Alert; signatures accepted through 5/10/16
• Potential for payment policy flexibility?
BBA Section 603: Proposed Rule

• CMS Published Proposed CY 2017 OPPS Rule on July 14, 2016

• Payment for Non-Excepted Locations
  – "... facilities not operating on a hospital's main campus will be reimbursed under the most applicable of existing fee schedules, including the ... PFS, ... ASC PPS, or the ... CLFS."
  – For CY 2017, CMS proposed the MPFS to be the "applicable payment system" for majority of non-excepted items and services

BBA Section 603: Proposed Rule

• Payment for Non-Excepted Locations (cont.)
  – Physicians furnishing such services to be paid based on non-facility rate under the MPFS
  – Physicians bill and are paid for the services – not the hospital
    • Some type of arrangement between the physicians and the hospital will be necessary
  – Must comply with Medicare laws and regulations – Stark, AKS
    • Consider under-arrangements restrictions and provider-based requirements (management contracts)
    • Little time to make arrangements if physicians currently not reassigned
BBA Section 603: Proposed Rule

• Location Changes
  – Provider-based departments would lose excepted status if location is changed (physical address listed on provider’s hospital enrollment form as of November 1, 2015)
  – If an address with multiple units, the unit number is considered a part of the address
  – Practical considerations:
    • Expansions into new units? In the CAH context, this has been permitted but proposed rule expressly said “no” in an example of expanding into a new suite

BBA Section 603: Proposed Rule

• Service Expansion
  – Exception only applies to services that were being furnished and billed at the off-campus location on November 2, 2015
  – To identify excepted services, CMS created “clinical families of services”
    • 19 clinical families defined by APC and HCPCS codes
    • Services beyond clinical families not excepted
    • No limit based on time or volume
BBA Section 603: Proposed Rules

• Changes of Ownership
  – If hospital has change of ownership, maintain excepted status only if the new owners accept the existing provider agreement
  – Individual off-campus PBD cannot be transferred from one hospital to another and maintain excepted status

BBA Section 603: Open Issues

• Facilities Under Development
• Enrollment of Non-Excepted Facilities
• Billing and Payment for Non-Excepted Facilities
• Limited Relocation Exception
• Services Not Covered Under Other Payment Systems
• Data Collection
• Medical Education
• Provider-Based Denials and Overpayments
• 340B Eligibility
BBA Section 603: What to do Now?

- Be aware that given risks to grandfathered or excepted status, provider-based compliance risks are heightened
- Maintain documentation for grandfathered locations
  - CMS noted that it and its contractors will continue to conduct audits of hospital billing to ensure off-campus provider-based departments are billing appropriately
  - CMS expects hospitals to maintain proper documentation showing what lines of service are provided at each grandfathered off-campus provider-based department

BBA Section 603: What to do Now?

- Comments were due September 6, 2016
- Consider the cost versus the benefits of provider-based status versus enrolling as another provider/supplier type
- Plan for mechanism for billing for non-excepted services after January 1, 2017
- Consider financial impact for budget purposes = what if Medicaid and private pay follow?
- Final rule expected late October/early November
60-Day Rule for Medicare Parts A and B

- CMS recently published a much-awaited Final Rule regarding reporting and returning of Medicare Part A and B Overpayments (81 Fed. Reg. 7654-7684)
- Fraud Enforcement and Recovery Act Of 2009 (FERA) imposed False Claims Act liability for failing to meet an "obligation" to return money to the government. 31 U.S.C. § 3729(a)(1)(G)
- ACA § 6402(a)
  -- Person who has received an overpayment must:
    - Report and return the overpayment to the appropriate person; and
    - Notify the person to whom the overpayment was returned of the reason for the overpayment in writing
  -- Deadline for reporting and returning is the later of:
    - The date which is 60 days after the date on which the overpayment was identified; or
    - The date any corresponding cost report is due, if applicable

Results of combining FERA and ACA § 6402(a)

- Failure to report and return an "identified" overpayment within 60 days creates an obligation under the FCA
- Thus, FCA liability created for knowingly retaining (i.e., not reporting and returning) any overpayment within 60 days of the date on which the overpayment was "identified"
60-Day Rule for Medicare Parts A and B

For Medicare Parts A and B, Final regulations (81 Fed. Reg. 7654-7684, effective March 14, 2016) clarified some ambiguities:

- “Identified” means a person has, or should have:
  1. Determined that an overpayment was received; and
  2. Quantified the amount of the overpayment

- "Should have" means you must exercise "reasonable diligence" in identifying issues (may include prospective and retrospective measures)

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60-Day Rule for Medicare Parts A and B

- Confirmed 6-year lookback period (absent fault or similar fault)

- Acknowledged 6 months as a reasonable timeframe for investigation/quantification of the overpayment, barring extraordinary circumstances

- Self-disclosure stops the clock on the 60-day reporting and repayment period and remains stopped throughout the negotiation and settlement process
60-Day Rule – Medicare Parts C and D and Medicaid

- CMS issued a Final Rule related to Medicare Part C and D overpayments in the May 23, 2014 Federal Register, 79 FR 29844
  - Also a 6-year lookback period (absent fraud)
  - Applies to the MCOs and Plan Sponsors
    - But look for contractual compliance obligation
- No Final Rule has been published that addresses Medicaid requirements and will be addressed in future rulemaking

60-Day Rule – Medicare Parts C and D and Medicaid

- In Indiana, Indiana Medicaid does not have a lookback period so it is defaulting to 7 years, which is the medical record retention statute
  - A final rule on this would be important as it would trump state law if a final rule was issued to have the same lookback period for all parts (6 years)
60 Day Rule in Action: Mount Sinai

- The OIG announced a $2.95M settlement with Mount Sinai Health System on August 24, 2016.
- This is the first time the 60 day rule in action in a court.
- Mount Sinai could have faced treble damages as well as $4.9 million in False Claims Act penalties for the 444 payments in question that totaled almost $900,000.

Please visit the Hall Render Blog at [http://blogs.hallrender.com](http://blogs.hallrender.com) for more information on topics related to health care law.

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