Provider-Based Status:
A Compliance Department Case Study and Lessons Learned

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Agenda
• Provider-Based: Background
  – Requirements
  – Obligations
  – Financial Impact
• Provider-Based: Case Study
• Provider-Based: Under Attack
  – Legal and Policy Changes
  – Enforcement
Provider-Based: The Basics

• Regulation 42 C.F.R. § 413.65 defines what operations are part of a Medicare certified provider (vs. supplier)
• It determines what services can be billed under the Medicare provider number
• Provider = hospital, CAH, SNF, HHA, Hospice, CORFs, RHC, FQHC, CMHC
• Historically, § 413.65 applied to ALL providers, but this was amended in 2002 to effectively limit to hospitals/CAHs
  – Exclusions based on “no harm, no foul” theory (i.e., no payment impact)

Provider-Based: The Basics

• Medicare concept
  – Allows services to be treated/billed/paid as hospital services
  – Can apply to other payers if adopted
• Provider-based status is NOT a special payment status – except for certain RHCs
• Services provided in provider-based location are treated as hospital services
  – Patient registered as hospital outpatient
  – Facility services billed on CMS 1450/UB-04
  – Services paid based on hospital outpatient prospective payment system (OPPS) or cost-based (CAHs)
  – This is just like other hospital-based services – ER, radiology, anesthesia, etc.
Provider-Based: Requirements

- **Universal** requirements – all facilities or organizations:
  - **Common Licensure** – if allowed by state law
  - **Financial Integration** – must be included in hospital trial balance and allowable cost centers on cost report, same as any other hospital department
  - **Clinical Integration** –
    - Same clinical oversight as any hospital department: Medical Director, QA, UR, etc.
    - Medical records – unified retrieval system or cross-reference
    - Medical staff of hospital have clinical privileges at site/facility

Provider-Based: Requirements

- **Universal** requirements – all facilities or organizations:
  - **Public Awareness** – patients must be aware when they enter facility that they are being treated as hospital patients
    - Signage, registration forms, phone listings, internet, marketing materials, etc. must all use hospital name
    - Held out to the public and other payers as part of the main provider
  - **Under Arrangement** – not all patient care services at the facility/location may be provided under arrangement
Provider-Based: Requirements

- **OFF-CAMPUS** sites must also meet:
  - **Common ownership** – same legal entity & governing body
  - **Administration and supervision** –
    - Same supervision as any other provider department
    - HR, billing, payroll, benefits, records, purchasing, salary structure done by same employees
  - **Location** – within 35 miles of main provider or meet market share test or be provider-based to 340B DSH hospital

- Management contract rules apply
- Joint venture prohibited off campus (limitations apply if on campus)

Provider-Based: Hospital Department Obligations

- Site of service indicator – professional component must be billed at facility rate
- All terms of provider agreement – deficiencies at any site jeopardize entire hospital provider status
- Non-discrimination provisions applicable to physicians
- EMTALA obligations
  - On-campus – apply as part of hospital
  - Off-campus – apply only if location qualifies as a “dedicated emergency department”
Provider-Based: Hospital Department Obligations

• Treat all Medicare patients as hospital outpatients (facility/technical fee billed on CMS 1450/UB-04)
• Off-campus sites must provide beneficiary notice of dual coinsurance (facility/technical and professional components) before services provided (unless emergent)
• Meet all applicable Medicare hospital conditions of participation
  – Includes hospital building code!

Provider-Based: Financial Impact

• Amount of, or even any, increased revenue is not automatic
  – Varies by: specialty, payor mix, volume, rural vs. urban, APC vs CAH vs RHC
• Compare physician fee schedule payment (CMS 1500, POS 11) to hospital based payment:
  – APCs for technical component (or cost in CAHs)
  – Physician PC only – POS 19/22 - “Facility” rate
• Assess hospital based impact by:
  – Hospital to which location is provider-based
  – By site of clinic practices
Provider-Based: Financial Impact

- Significant portion of Medicare increase is in co-pay
  - 20% of hospital technical charge is greater than
  - 20% of physician fee schedule allowed charge for facility/technical
  - Often covered by Medigap policies

- Consider public relations impact of two co-pays – first in market?

- Private pay hospital Place of Service may be significantly higher than freestanding
  - Generally recommend billing as free standing
  - Bad press/lawsuits mostly driven by private pay

- There can be increased costs: facility & operational

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Provider-Based: Financial Impact

- As of January 1, 2014, Medicare no longer separately pays for clinical diagnostic laboratory services for outpatients (except molecular pathology) billed by a hospital/provider-based clinic except:
  - Non-patient (referred) specimen (billed as non-patient lab services);
  - The hospital/provider-based clinic furnishes only the labs tests on a given date of service; or
  - The hospital/provider-based clinic conducts lab tests that are clinically unrelated to other hospital outpatient services furnished the same day.
    - “Unrelated” means the test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services, for a different diagnosis.
Provider-Based: So What Are We Doing?

- **Arbitrage** = Taking advantage of price differences for the same item in different markets (i.e., different Medicare payment systems)
  - Physician Fee Schedule vs. Hospital APC (or cost in CAHs)
- Price difference between markets reflects:
  - Historical basis: APCs based on hospital costs which reflect 24/7 operations, etc.
  - Recognition that hospitals meet higher standards
- Must meet all hospital standards to obtain higher price

Provider-Based: Secondary Considerations

- Miscellaneous benefits/detriments
  - 340B Program - drugs used at provider-based clinics are eligible for 340B discounts
  - Residents in provider-based clinics count for IME/DME FTE count
  - Docs in outpatient departments count for EHR incentives
  - Services in provider-based clinics included in DRG payment window
  - Cannot use Stark group practice compensation methodology for ancillary bonus pools
    - If docs employed by hospital, by definition not a group practice
    - Medical Group Inc. is a group practice, BUT ancillaries will not be part of its business – will be in hospital
Provider-Based: Attestations

• Application to and/or pre-approval by CMS NOT REQUIRED
  • § 413.65 now says may submit “attestation”
    – Notify CMS of provider-based locations
    – State that applicable requirements met
    – Attest to meeting obligations
• May notify CMS of material changes
• Voluntary – self-monitoring process
• Benefit of attestation is reduced look-back period

Provider-Based: Attestations

• No official form published
  – Use CMS “Sample Format” outline from Transmittal A-03-030, April 18, 2003
  – Use MAC sample format if it has one
  – Send to MAC and copy to Regional Office
    • On-campus – supporting documentation not required
      (recommend sending anyway)
    • Off-campus – required
  – MAC may make determination
  – RO should either approve or disapprove
Provider-Based: Attestations

- Benefits of Attestation:
  - CMS only recoups excess payment back to date of attestation
  - Triggers self-review of criteria
  - Supports compliance process
  - Educates staff on requirements
  - § 413.65 says – not provider-based because believed to be!!!!!
  - TO FILE OR NOT TO FILE?
    - Consider possible grandfather protection
  - BUT BE PATIENT – MAC/RO may be slow
    - We have had non-responses and lost attestations
    - Don’t assume no news is good news
- Appeals process available if CMS makes unfavorable determination

Provider Based: Overpayment Methodology

- § 413.65(j) - if a facility is denied or ceases to qualify for provider-based status, Medicare will recover overpayments made from the date of such determination back to the date when the facility began inappropriately billing as provider-based
  - An approved attestation limits lookback period to date of the attestation
- Amount of overpayment = difference between the actual amount paid to the provider for services at the facility minus the amount that CMS estimates should have been paid in the absence of compliance with provider-based requirements
Provider-Based: A Case Study

- Background
- Compliance Program
- Contracting process
- Identification of provider-based issue
- Investigation process
- Self-disclosure
- Process for provider-based initiatives or services

Background - Lourdes

- Not-for-profit, 501(c)(3) corporation that owns and operates a 242-bed hospital in Binghamton, NY
- Serves Broome County (pop. est. <200,000) plus surrounding communities
- Provides inpatient, outpatient, emergency services, as well as a broad array of specialty services (cancer care, women’s health, home health & hospice, mental health)
- Provider-based physician network started in mid-1990s
Compliance Responsibility Program (CRP)

- CRP focuses on proactive compliance activities – Proactive guidance, self-review, monitoring, auditing and reporting
  - Good faith effort to comply with laws and regulations
  - Commitment of high level personnel
  - Heightened awareness and sensitivity to high risk areas through education/communication
  - Commitment to implement corrective action in response to identified compliance issues on timely basis
  - Complementary of existing policies/procedures/guidelines
  - Comply with parent company’s CRP

Elements of Compliance Program

- Standards of Conduct
- Designate Corporate Responsibility Officer (CRO)
- CRP Steering Committee and CRP Work Group
- Develop and implement compliance education and training
- 24-hr. hotline for anonymous reporting
- Corrective action system to respond
- Comprehensive auditing/monitoring
- Investigatory process to identify and timely remediate problems
- Background checks
Role of CRO

- Develop, implement and oversee the CRP
- Coordinate with appropriate leaders to promote CRP effectiveness
- Report directly to CEO with direct access to the Board of Directors, Audit committee, senior management and legal counsel
- Chair CRP Steering Committee
- Staffing of CRP Department: Director, 2 audit specialists
- Engage in annual compliance risk assessment with focus on key regulatory compliance issues
- Determine most effective corrective action approach including education, policy development and, when appropriate, self-reporting (refunds, disclosures, etc.)

Discovery of Actual or Potential Violation

- Background: Hyperbaric oxygen therapy (HBOT) is a medical treatment that involves delivering high dose oxygen to the body in an enclosed environment for the purpose of enhancing the patient’s healing process
- Patient is treated in a special pressurized chamber where the patient breathes 100% oxygen through specialized head gear, causing the high dose oxygen to be dissolved into the patient’s blood and helping to reduce swelling, control infection and stimulate growth of new blood vessels
- Generally 2 hours and performed daily for 6 days/week
- Typical treatment is 4-7 weeks depending on patient need
- Used for chronic non-healing diabetic foot wounds, compromised skin grafts, chronic bone infections and bone/tissue injuries from radiation therapy treatments
HBOT History at Lourdes

• In 2007, Lourdes entered into a written agreement with an HBOT contractor for services provided to hospital outpatients
• Treatments were provided in a mobile HBOT facility owned by the HBOT contractor
• Facility was located ~ 2 miles from hospital campus and affixed to an off-campus hospital building
• Only HBOT services were provided at this site

Responsibilities of HBOT Contractor & Hospital

• HBOT Contractor:
  – Provided trained technicians to perform HBOT services
  – Provided qualified physicians to supervise services and perform medical director and other administrative duties on behalf of hospital
  – Billed and collected all professional fees
• Hospital:
  – Billed and collected all facility fees associated with HBOT
  – Paid contractor for services performed
Hospital Contracting Process

• After entering the HBOT contract, the hospital developed a more formalized contracting process including use of a contract management system
  – Contract owner submits requests for new contracts or amendments/addendums to existing contracts
  – All such agreements require compliance, risk and legal reviews, including but not limited to, review of federal, state and local laws governing the agreement

HBOT Contract

• Initial agreement was for 5 years
• Initial agreement was extended while both parties worked to negotiate a new agreement
• During this negotiation period, the agreement was reviewed against the provider-based regulations
• Operational concerns were identified and brought to the attention of the CRO who immediately started an investigation
• Confirmed certain aspects of the arrangement did not meet the provider-based requirements, resulting in services being inappropriately billed and paid by Medicare
Analysis

• Noted that no patient care was compromised
• Lookback period included the entire term of the agreement
• If hospital had acted in careless disregard or deliberate ignorance of the provider-based regulations or other program requirements in submitting claims to and receiving payment from the Medicare program, could have implicated violations of the FCA or CMP laws
• Complex analysis of claims, but hospital expressed desire to fully cooperation with the OIG to resolve the matter

Immediate Corrective Action

• Began with immediate bill hold for all services provided on or after the date of discovery
• Identified alternate treatment arrangements for patients, thus ceasing current treatment service arrangement
• Financial analysis of overpayment – explain rationale to OIG (>2Mil) – mention Medicaid which was minimal
Self-Disclosure

• Followed “Provider Self-Disclosure Protocol” to the OIG in September 2013
• OIG → NYS AUSA with response to Hospital
• Final Settlement Agreement entered in October 2014
• Continued to work with NYS OMIG for Medicaid refund

Lessons Learned

• Provider-based regulations are complex
• Hospital had many physician clinics that met provider-based status but this was slightly different
• Recognize the importance of risk, compliance and legal reviews of all agreements even if previously reviewed
Lessons Learned con’t.

- Multidisciplinary approach/new process for review of “new business” to be sure of complete understanding - needs to be a transparent process for all those who have information related to the new service to ensure provider-based requirements are met
- Continue to refine our contracting process
- The CRP will be part of the self-disclosure – credibility is important

Provider-Based: Under Attack

- Legal and Policy Changes
  - MedPac Recommendations
  - Place of Service/Modifier Changes
  - Budget Bill 2015 & New Off-Campus Exclusion
  - State Efforts
- Enforcement
  - OIG Focus
  - Mixed Use
  - Public Awareness
Provider-Based: MedPac Recommendations

- Differences in payment for provider-based versus freestanding locations has been a focus for years
- March 2015 Report to Congress – reiterated recommendations to adjust hospital outpatient rates to align more closely with freestanding clinics
- Recommends reducing or eliminating differences in payment rates for selected APCs
- GAO Report December 2015 – Congress should direct HHS to equalize payment for E&M and other services deemed appropriate

Provider-Based: Place of Service/Modifier Changes

- Final OPPS Rule: Requires hospitals to identify on claims those services provided in off-campus provider-based departments
- Hospital Claim: HCPCS Modifier “PO” on CMS 1450/UB-04
  - Voluntary reporting beginning January 1, 2015
  - Required reporting on January 1, 2016
- Physician Claim: New place of service (POS) codes on professional claims (CMS 1500)
  - POS 19 (New): Off-Campus Outpatient Hospital
  - POS 22 (Revised): On-Campus Outpatient Hospital
  - Changes effective January 1, 2016
Provider-Based: Budget Bill 2015

- Signed into law on November 2, 2015
- Excludes from payment under OPPS any services furnished at an off-campus outpatient hospital department beginning January 1, 2017
- Creates a grandfathered status for any off-campus outpatient departments that billed Medicare under the OPPS prior to November 2, 2015
- Different definition of “off-campus” from § 413.65 - includes facilities within 250 yards of a remote location of hospital
- No exception for facilities under development or construction
- Exception for services provided in an off-campus emergency department
- Exclusion does NOT apply to CAHs or provider-based entities (i.e., RHCs)
  - This is an OPPS/APC exclusion similar to the rule covering PT/OT/ST

Provider-Based: State Efforts

- Effective 1/1/2016 in Connecticut:
  - If physician practice converts to hospital outpatient department, must give notice to all patients treated in prior 3 years within 30 days of acquisition that the patient will now be billed a facility fee
- Each hospital outpatient department patient bill must:
  - Clearly identify the facility fee & list Medicare payment as comparison
  - Inform the patient that it could be cheaper at a freestanding location
- Effective 1/1/2017:
  - Scheduled non-emergent service triggers notice requirements within 3 business days of scheduling: price, Medicare comparison, etc.
- Applies to all patients – not just Medicare
Provider-Based: OIG Focus

• 2013 Survey regarding provider-based services
  – OIG sent information requests to hospitals regarding ownership and operations of provider-based facilities
  – Hospitals selected at random based on Certification and Survey Provider Enhanced Reports data
  – Stated purpose was “to determine the number of hospitals that own provider-based facilities”
  – *But*, collected information could potentially result in additional OIG or CMS enforcement contacts with specific hospitals

Provider-Based: OIG Focus

• 2013 Work Plan
  – “We will determine the impact of hospital-owned physician practices billing Medicare as provider-based physician practices. We will also determine the extent to which practices using the provider-based status met CMS billing requirements.”
  – “In 2011, the [MedPAC] expressed concerns about the financial incentives presented by provider-based status and stated Medicare should seek to pay similar amounts for similar services.”

• 2014, 2015 and 2016 Work Plans – more of the same
Provider-Based: Mixed-Use

• “Mixed Use” sites refers to sites that are part provider-based, part freestanding
  – No formal guidance - only CMS enforcement practice learned through attestations and discussion with CMS representatives
• CMS becoming more restrictive in its review and approval of mixed-use sites (especially when mixed use is within same suite)
• CMS position will allow one building to have both, but generally requires clear separation between uses
  – I.e., separate suites, entrances, registration and waiting areas
• Consider impact of this position on visiting specialists

Provider-Based: Public Awareness

• Public Awareness – Naming/Branding/Signage
  – The Hospital name is required
  – Multiple tag lines are fine
    • St. Elsewhere Hospital
    • Oncology Clinic
    • St. Elsewhere Medical Group
    • St. Elsewhere Health System
  – Hospital does not need to be first or biggest - but, avoid fine print
  – Not just signage – applies to marketing materials, registration, phone listings, websites, etc.
Provider-Based: Practical Takeaways

- Increased CMS/OIG scrutiny of provider-based locations, especially off-campus
- Consider compliance audit to ensure rule requirements are met
  - Signage/public awareness, mixed use, Life Safety Code standards, etc.
- Consider billing audit to ensure:
  - All Medicare patients (primary and secondary) are billed as hospital outpatients
  - Billing professional component with correct Place of Service (require in contracts if physicians bill)
- Reassess financial impact (benefits, costs and patient experience)
- “Pick one and be it” for each site
- Consider attestation process for potential “grandfather” protection