Provider-Based Status, Under Arrangements, Enrollment, and Related Medicare Requirements

AHLA Institute on Medicare and Medicaid Payment Issues
March 21-23, 2018

Andrew Ruskin
Morgan Lewis & Bockius
(202) 739-5960
aruskin@morganlewis.com

Lawrence Vernaglia
Foley & Lardner LLP
(617) 342-4079
lvernaglia@foley.com

Agenda

- Benefits and drawbacks of provider-based status
- Provider-based status overview of requirements
- Provider-based joint ventures
- CMS' implementation of Section 603 of the Bipartisan Budget Act
- Assessment of "mid-build" exception implementation
- Implications of recent changes for 340B utilization
- Commingled Space

Provider-Based Status Overview

CMS' Overarching Goal

- CMS intends to pay for services under OPPS only when the hospital maintains the proper level of control over the quality of care and finances of the provider-based site.

Benefits and Drawbacks of Provider-Based Status

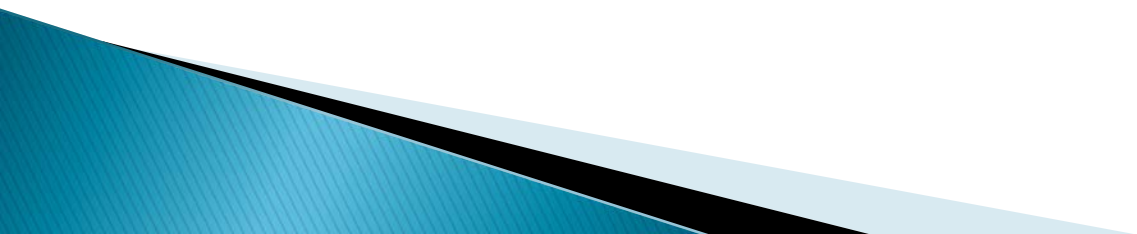
Benefits of Provider-Based Status

- Medicare/Medicaid payment amounts
- 340B drug discount program eligibility
- Bad debt payments
- Main provider/remote location DSH and IME payments
- Inclusion in main provider's third party payer contracts

Disadvantages of Provider-Based Status

- Duplicate coinsurance
- Physician dissatisfaction
- Ever evolving regulatory landscape
- Patient dissatisfaction

Overview of Requirements



Provider-Based Status Requirements: All Outpatient Clinics

- Common Licensure (if allowed by state law)
- Clinical Integration
  - Common medical staff privileges
  - Reporting to chief medical officer
  - Unified medical records
- Financial Integration
  - Proper location on the cost report
  - Consolidated revenues and expenses
- Public Awareness
  - Held out as part of the provider to public and third parties

Provider-Based Status Requirements: All Outpatient Clinics

- Physician Billing.
  - Correct site of service code

- Equal Billing Treatment.
  - All Medicare patients treated as hospital outpatients
  - Facility fee billed on UB-04; professional fee is billed on a 1500 with POS 19, 22, or 23

- Provider Agreement. Provider-based sites must comply with the terms of the provider agreement

Provider-Based Status Requirements: All Outpatient Clinics

- DRG Payment Window
- Beneficiary Notices
- Meet Hospital COPs

Additional Requirements: Off-Campus Entities

- Ownership and control
  - Hospital owns 100% of the business enterprise
  - Common governing body and policies
- Administrative Integration
  - Reporting to hospital chief administrative officer
  - Provider-based site obtains the following services from the hospital (or a third party servicing the hospital and clinic): billing; records; human resources; payroll; employee benefit package; salary structure; and purchasing

Additional Requirements: Off-Campus Entities

Location

- 35 Mile Rule. Off-campus sites may qualify as provider-based if they are within 35 miles of the hospital.

- 75 Percent Tests. Determine whether servicing the same patient population.

Special Cases – Special Rules

- Joint Ventures
  - On-campus JV allowed if:
    - On campus of provider/owner
    - Provider-based to one of the owners
    - No minimum ownership required

Special Cases – Special Rules *(cont.)*

- Management Contracts
  - Provider must be in administrative, financial, and clinical control
  - Provider employs all patient care personnel (other than physicians and mid-level practitioners)
  - Policies of provider control

Special Cases – Special Rules *(cont.)*

- Stark Issues associated with JV's
  - CMS added in 2008 to the definition of a "DHS entity" the entity that *performs* the service, as well as the one that bills for it
    - This change renders it almost impossible for physicians to have an ownership interest in a JV that furnishes services under arrangements to a provider-based clinic
  - Question is what does it mean to "perform" or be a true "under arrangements" billing arrangement

Special Cases – Special Rules *(cont.)*

- AKS issues associated with JV's are identified in OIG's Contractual Joint Venture Special Fraud Alert. Risk factors include:
  - Contractor that is otherwise a would-be competitor becomes the manager
  - The provider has little financial risk
  - Contractor is furnishing marketing services
- Question is one of actual involvement of the provider

Approval Process

- Prior approval of provider-based status is not required

- "Attestation" process
  - Voluntary*
  - Eliminates risk of retrospective recoveries
  - Available only when there is a differential in payment

* Note 21st Cures Act

BBA Section 603 Implementation
What has Changed
What Stayed the Same

Bipartisan Budget Act of 2015, Section 603

- As of 1/1/17, no "off-campus outpatient department of a provider" may bill under OPPS unless:
  1. It is a "dedicated emergency department"(DED) *or*
  2. It is grandfathered
- Non-grandfathered sites need to bill under another payment system, which has been created by CMS

DED not subject to Site Neutrality

- DED: Must meet at least one of the following:
  - State licensure as an emergency room or emergency department; ***or***
  - Holding out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring an appointment; ***or***
  - Provision of at least one-third of all of outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.
- Final Rule: All services in the DED are exempt from site-neutrality, not just emergency services.

"On-Campus" Definition has New Importance

- On-Campus not subject to site neutrality
  - Buildings or structures within 250 yards from main building – Final Rule clarifies that 250 yards can be measured from anywhere at the building
  - 250 yards from "remote location" also protected
  - Final Rule provides no guidance for "on campus" – remains an RO determination

On-Campus Definition

"This definition would encompass not only institutions that are located in self-contained, well-defined settings, but other locations, such as in central city areas, where there may be a group of buildings that function as a campus but are not strictly contiguous and may even be crossed by public streets."

Fed Reg Vol. 65, No.68/April 2, 2000


Hospital Road
Main Hospital
615 S New Ballas Rd
Patient Parking
Hospital Road
Hospital Road
County Maintained Rd
Behavioral Health
No Access Road
County Maintained Rd
New Building Locating

Remote Locations

- These are secondary campuses
- CMS RO determination as to whether campus must have inpatient acute care or can be entirely rehab, psych, etc.
- Unclear whether CMS's recent concerns with "micro-hospitals" applies
  - S&C Memo 17-44
  - Question of relative volumes of inpatient vs. outpatient services, based in part on ALOS and ADC data

Grandfathering of Off-Campus Sites

- How do off-campus sites get grandfathered?
  - If the "department of a provider . . . was billing under [OPPS] with respect to covered OPD services furnished prior to the date of the enactment of this paragraph" [*i.e.*, 11/2/15]

Relocations

- Proposed and final rule generally preclude relocations
- CMS purports to base its policy on the definition of "department," which incorporates the physical facility (as well as the personnel and equipment)
  - Claims that therefore the location must remain "fixed"
- Overarching concern is with acquiring new physician practices
  - Fear is that, if relocate to a larger space, a site could bring in new physicians
- Must remain at site listed on 855
  - Specific down to the suite number (but no limitation as to how many interior walls can be torn down)
  - Exception proposed for natural disasters and changes in law

Relocations *(cont.)*

- In the final rule, CMS identified that CMS ROs are to make the final determination, based on concerns relating to "significant public health or public safety issues."
  - Process has been described in informal guidance
  - CMS has issued an application
  - Must be submitted within 30 days of the date of the "extraordinary circumstance"
- CMS ROs are likely to implement inconsistently, and will likely be very hesitant to use authority, especially at first

Relocations *(cont.)*

- So what now?
  - It's always worth asking the CMS RO if a relocation is acceptable whenever a relocation is necessary
  - Expansions should be acceptable if they do not entail changing the site's address
  - "Recycling" of provider-based sites should also be acceptable
  - Relocations to the campus of a main provider or a remote location are acceptable
  - Provider-based status is still available for relocated sites

Judicial Review Preclusion

- No administrative or judicial review of:
  - Whether the services furnished are services of a dedicated emergency department
  - Whether a provider-based clinic is off-campus or on-campus
  - Whether a provider-based clinic benefits from grandfathered status
- Should still be able to appeal whether a site qualifies, and has always qualified, as provider-based
  - Remote locations have different appeal rights, depending upon the reason they are denied remote location status

Payments for Non-Grandfathered Sites

- Hospitals bill under a new system
  - Non-grandfathered sites are to use the modifier “PN”
  - Grandfathered off-campus sites are to use the modifier “PO”
  - Two copays will continue to be generated

Payments for Non-Grandfathered Sites *(cont.)*

- Generally paid at 40% of the OPPS rate in 2018
  - Based on a "relativity" analysis using claims identified with the "PO" modifier
- Apply the same packaging rules as applied under OPPS
- Applies same supervision rules as applied under OPPS
- Exceptions for
  - OT/PT/ST
  - Separately payable drugs
  - Preventive services
- No outlier payments, but silent as to bad debt

"Under Arrangements"

- CMS has not responded to comments regarding whether under arrangements billing is acceptable, even as to a new site
- CMS has for many years accepted that diagnostic services could qualify for OPPS billing even if furnished under arrangements
  - This is consistent with the governing statute
- No reason to view the site where an under arrangements service is furnished as an off-campus provider-based department

21st Century Cures Act

- Mid-Build Protections
  - February 13, 2017 filing deadlines (certifications and attestations)
  - Mid-Build certifications have not been approved
  - But associated P-B attestations have been
  - Audits completed by 12/31/18
  - Options for current billing at Mid-Build sites
- Cancer Hospitals
  - 60-day deadlines for filing an attestation.

Implications for 340B Program of Provider-Based Status

Implications for 340B Program

- 340B is a drug purchasing program, not a payment program
- Hospitals must qualify as “covered entities” in order to purchase drugs under the 340B program
- HRSA’s historic guidance has stated that 340B drugs can only be administered in space that is on a reimbursable cost center
  - Must be identified as such on the cost report
  - Current view is that prescriptions filled at a contract pharmacy need to be written in provider-based space

Implications for 340B Program *(cont.)*

- Non-grandfathered sites will still qualify as provider-based
  - They will be identified on a reimbursable line on the cost report
  - They will have charges associated with services furnished at their location
- Questions remain as to what is absolutely necessary to qualify as a "reimbursable cost center"

Implications for 340B Program *(cont.)*

- As of 1/1/18, Medicare reduces reimbursement for Part B drugs purchased under 340B to ASP – 22.5%
- Intent is to remove pretty much the entire financial benefit of using these drugs in this setting
- Exceptions include: (a) vaccines; (b) pass-through drugs; (c) children's hospitals; (d) rural SCHs; and (e) drugs used in non-grandfathered space.
- Requires adding a modifier (JG) on the claim line for the drug
- $1.6 billion in reallocated funds

Space Layout & Co-Location Issues

Co-Location Principle

- July 2011 CMS RO Letter
- General principles:
  - All certified hospital space, departments, services, and/or locations must be 100% hospital usage 24/7
  - "Hospitals are not permitted to "carve-out" areas as non-hospital space"
  - Cannot be "part time" part of the hospital and "part time" another hospital, ASC, physician office, or any other activity"
- Flagged co-location with physician offices as issue
- CoP and provider-based violations at risk
- 2017-2018 promised further guidance TBD

Co-Location Principle

- “indications that a purported hospital space may instead be a part of a larger component”:
  - Shared entryway
  - Interior hallways
  - Bathroom facilities
  - Treatment rooms
  - Waiting rooms and
  - Registration areas

Any Questions?

Andrew Ruskin
Morgan Lewis & Bockius
(202) 739-5960
aruskin@morganlewis.com

Lawrence Vernaglia
Foley & Lardner LLP
(617) 342-4079
lvernaglia@foley.com