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

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Agenda

- Benefits and drawbacks of provider-based status
- Provider-based status overview of requirements
- CMS' implementation of Section 603 of the Bipartisan Budget Act
- Implications of recent changes for 340B utilization
- Site Neutrality adjustment
- Litigation impacting provider-based clinics
- Commingled space
- Questions for CMS

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

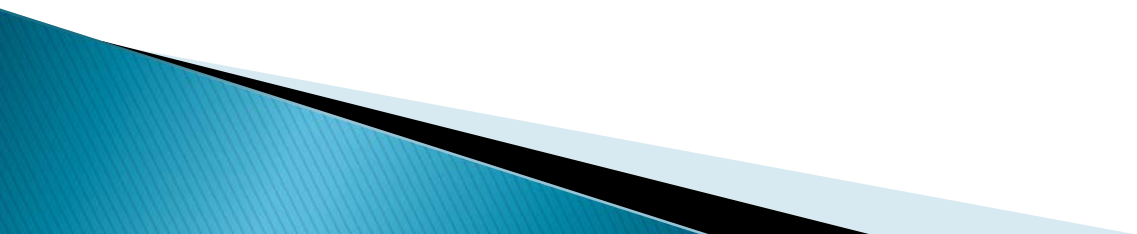
Benefits of Provider-Based Status

- 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.

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

- 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)
- 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"

Relocations *(cont.)*

- Presumably acceptable are:
  - Expansions if they do not entail changing the site's address
  - "Recycling" of provider-based sites
  - Relocations to the campus of a main provider or a remote location
- Provider-based status is still available for relocated sites

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
  - Very complicated rules for determining the address to be used on the claim form

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

Reimbursement for 340B Drugs in Provider-Based Space

Reimbursement for 340B Drugs in Provider-Based Space

- 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

Reimbursement for 340B Drugs in Provider-Based Space *(cont.)*

- Further changes in 2019
  - CMS has stated that it believes that the differential for 340B drugs between excepted and nonexcepted off-campus, provider-based clinics has created undue incentives to shift utilization of 340B drugs to nonexcepted sites
  - CMS has therefore reduced payment to these sites to ASP-22.5%, just as with excepted sites
  - CMS bases this policy on its ability to decide what the "applicable payment system" is under the Bipartisan Budget Act

Site-Neutrality Adjustment

Site-Neutrality Adjustment

- CMS has expressed a concern with the growing volume of E/M services furnished in the HOPD, relative to physician office E/M services
- CMS cites a number of sources as evidence of E/M volume issues, including:
  - Increases in OPPS spending overall
  - A GAO report indicating that physician practice acquisitions from 2007 to 2013 resulted in a shift of E/M services from physician offices to HOPDs

Site-Neutrality Adjustment *(cont.)*

- As a result, CMS is phasing in over two years a policy that reduces E/M to the nonexcepted off-campus provider-based rate for excepted off-campus provider-based clinics
  - This will *not* be budget neutral and will presumably save $610 million for Medicare
- CMS 's supposed legal support for the policy is a statutory provision that allows CMS to come up with a "method" for control unnecessary volume increases

Site-Neutrality Adjustment *(cont.)*

- If comparing off-campus outpatient clinics now with physician offices, physician offices compare quite favorably
- E/M services are paid about the same
- But . . .
  - For 340B covered entities, *physician offices potentially receive higher payment for infused drugs*
- And physician offices do not have issues with dual coinsurance or loss of physician autonomy

Site-Neutrality Adjustment *(cont.)*

- One reason to continue to remain provider-based or continue to open new provider-based clinics would be 340B contract pharmacy prescriptions
- HRSA's current policy is that contract pharmacy prescriptions must be written at child sites
- Child sites must be identified as reimbursable cost centers on the cost report
- Though generally thought of as provider-based clinics billing on a 1450, there's nothing that dictates such a limitation

Litigation Impacting Provider-Based Clinics

Litigation Impacting Provider-Based Clinics

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18)
  - Considered CMS's CY 2018 rule regarding reduction of payment for 340B drugs in excepted off-campus outpatient departments

Litigation Impacting Provider-Based Clinics *(cont.)*

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18) *(cont.)*
  - Determined that hospitals did not need to appeal on a claim-by-claim basis
    - Relied on case law for the proposition that the claims appeal process could be waived after consideration of "whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record."

Litigation Impacting Provider-Based Clinics *(cont.)*

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18) *(cont.)*
  - Given the unequivocal nature of the agency's rulemaking and the rules regarding what is binding on ALJs, the court decided that waiver was appropriate

Litigation Impacting Provider-Based Clinics *(cont.)*

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18) *(cont.)*
  - CMS also claimed that the court was precluded from judicial review of the agency's action because there was no express right to judicial review under the statute
  - Court held that it could review if the agency acted *ultra vires*, which it concluded that it had
  - CMS claimed that the 340B payment reduction was a mere "adjustment" as permitted by statute

Litigation Impacting Provider-Based Clinics *(cont.)*

- *AHA v. Azar* (18-2084, DDC, decided 12/26/18) *(cont.)*
  - Court determined that the reduction was a "fundamental change" and not an "adjustment." Therefore, the court struck down the policy.
  - Relief is an injunction, but due to budget neutrality considerations, the court requested more briefing, and got diametrically opposed answers from the parties
  - CMS has appealed the decision

Litigation Impacting Provider-Based Clinics *(cont.)*

- Challenges to site-neutrality
  - In December, 2018, AHA filed a suit against CMS challenging its site neutrality policy, claiming that CMS's reliance on the statutory provision allowing for volume control safeguards is misplaced
    - There is a significant probability that the Court will again find that the claims appeal process can be waived for all the same reasons
    - There is also a likelihood that the argument regarding "ultra vires" action will again trump any concerns about judicial review preclusion
- Private parties have also sued

Litigation Impacting Provider-Based Clinics *(cont.)*

- The uncertainty surrounding the litigation means that making a rational decision about whether to retain provider-based status has become significantly harder . . .

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 *(cont.)*

- "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

Questions for CMS

Questions for CMS

- Explain the consortium model of the ROs, around provider-based topics

Questions for CMS *(cont)*

- Where are consensus decisions housed, and how can the regulated public find out about these decisions?

Questions for CMS *(cont)*

- Are you aware of CMS ROs using their discretion to expand the definition of campus beyond 250 yards?

Questions for CMS *(cont)*

- How does one get a read from CMS as to what qualifies as a main building?

Questions for CMS *(cont)*

- Do you think that the CMS RO letter on commingled space reflects the way all Regional Offices look at instances commingled space?

Questions for CMS *(cont)*

- Which entities has CMS tasked with reviewing for commingled space? CMS ROs? JC? State agencies?

Any Questions?

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