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Hospital Outpatient Strategy Update

Monica Hon,
JD, Vice President/Director of Client Solutions

Susan Maupin,
JD, RN, Vice President/Director of Healthcare Operations

Advis

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Agenda

- Regulatory Overview and Background-PB Status Still Viable
- Navigating “Exact Match” Enforcement
- Optimizing the 340B Savings Program
- Diversifying Outpatient Strategy
- Pending Legislation: “Site Neutral” Reimbursement
- Risks and Recent CMS Enforcement Trends
- CMS Enforcement Examples and Communication

Outpatient Strategies & Regulatory Updates

- Presented by two consultants with extensive experience with CMS regional offices, MACs and hospitals throughout the ever-changing regulatory landscape that surrounds Medicare Provider-Based Status and Hospital Development and Management.
- Please feel free to raise your hand or type a question into the chat box to allow for a dynamic webinar experience!

What's new in 2024?

- Unfortunately, exact match frustration continues and looming federal scrutiny for provider-based locations keeps threatening the end of provider-based status as we know it
- Provider-based status is still a viable option for many hospital providers and if it's being contemplated, now is the time to decide.
- Diversification of the outpatient strategy is increasingly of interest to offer a non-hospital option to your savvy patient population, to ensure your hospital is an option (with commercial payers steering patients away from the hospital outpatient service line) and to simply ensure a place in the market.

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Brief Regulatory Overview & Background

Provider-Based Designation

- "Provider-based" is a Medicare designation, available to all hospitals, and recognized by some commercial payers, that allows hospitals to operate and bill off-site clinics as hospital departments if certain conditions are met
  - Such off-site locations are treated as though they are departments located within the four walls of the hospital.
- CMS codified the concept of provider-based status as 42 CFR 413.65 in 2000. (See 65 Fed. Reg. 18504 (Apr. 7, 2000)).
- Since then, employing provider-based status has steadily increased in utilization, typically through hospital acquisitions of physician group practices.

Provider-Based Definitions

- "Main Provider"
  - Hospital that either creates or acquires ownership of another entity/department to deliver services under its name, ownership, and financial and administrative control.
- "Remote Location"
  - Offers inpatient services at separate, yet integrated, hospital campus.
- "Provider-Based Department"
  - Offers services "of the same type" as hospital and does not separately meet the Conditions of Participation ("CoPs").
  - Often referred to as hospital outpatient departments or "HOPDs."
- "Provider-Based Entity"
  - Offers services "of a different type" from main provider and may separately meet the CoPs (e.g., RHC, HHA).
  - Separate provider/supplier agreement from the main provider.

Provider-based Status is Still A Viable Option

- "On-Campus"
  - Generally located within a 250-yard radius or connected to main provider by covered walkway, shared parking lot, etc.
  - Case-by-case test with CMS discretion.
- "Off Campus"
  - Generally located within a 35-mile radius of main provider.
  - Specific exceptions exist that depend on DSH rates and patient zip codes.
  - As-the-crow flies test from door to door.
- Contrary to the word on some streets, Off Campus Provider-Based Locations are still available for entry into a new market. More on this in the next slides.

“Site-Neutral” Reimbursement

- CMS issued the 2017 OPPS Final Rule to implement the Bipartisan Budget Act of 2015, which financially impacted off-campus HOPDs.
- New regulations became effective January 1, 2017.
- Changes also did not impact:
  - On-campus HOPDs (generally within a 250-yard radius of main hospital).
  - HOPDs located within a 250-yard radius of a remote location of the main hospital.
  - Hospital-based freestanding emergency departments.
  - Excepted (grandfathered) off-campus HOPDs (those generally located within a 35-mile radius of the main hospital that existed prior to November 2, 2015).
- Can still establish new HOPDs (both on or off campus).

"Site-Neutral" Reimbursement (cont.)

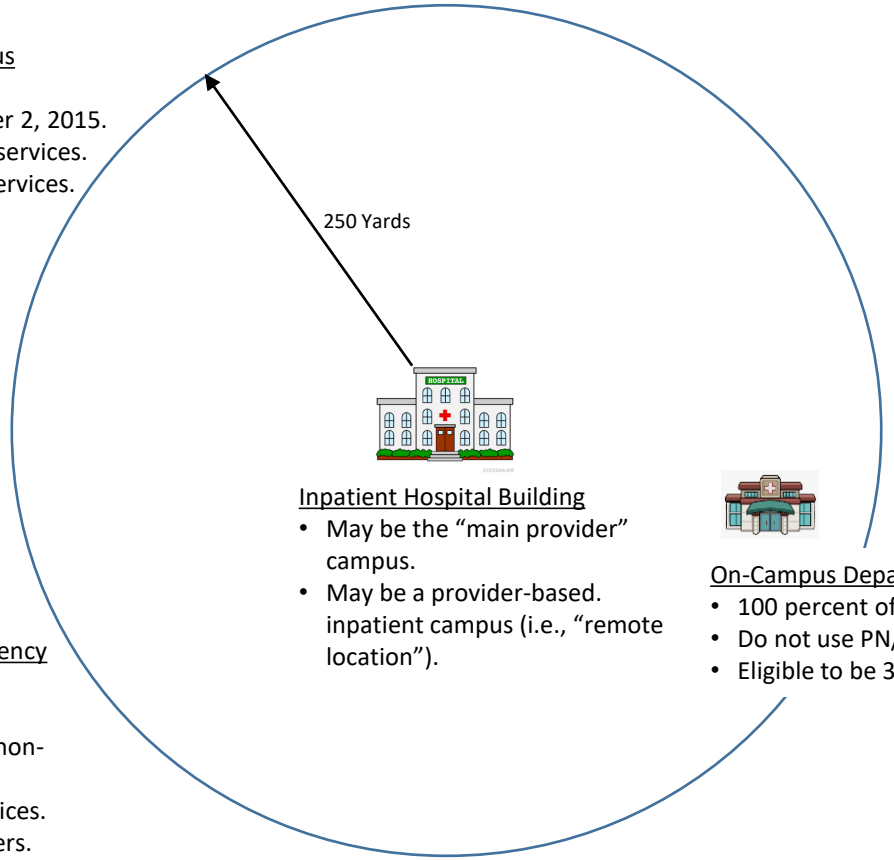
- Non-excepted off-campus locations (e.g., any location established after 11/2/2015) receive "site-neutral" reimbursement from CMS:
  - Professional reimbursement is unchanged.
  - 40% of Outpatient Prospective Payment System ("OPPS") institutional reimbursement.
  - "PN" modifier reported on each claim line with each nonexcepted item and service including those for which payment will not be adjusted, such as separately payable drugs, clinical laboratory tests, and therapy services.
  - Other payers are increasingly following this practice or are not reimbursing the hospital clinic visit charge.
  - **However, non-excepted HOPDs** are still eligible for 340B **as reimbursable cost centers.**

“Site-Neutral” Reimbursement (cont.)

- Excepted (grandfathered) off-campus locations receive “site-neutral” reimbursement from Medicare for G0463 (clinic visits).
- This is the facility component billed by the hospital, generally in conjunction with an outpatient evaluation and management or consultation service
- Reimbursed at 40% of the OPPS rate for CY 2020 and beyond; Similar to other non-excepted services.
- Rural sole community hospitals are now exempt from the site-neutral reimbursement of clinic visits at excepted off-campus HOPDs.
- *Additional site neutral legislation is currently under consideration by Congress.*

"New" or Non-Excepted Off-Campus Department
- Established on or after November 2, 2015.
- 40 percent of OPPS for all OPPS services.
  - PT, OT, ST are not OPPS services.
- Must use PN modifier.
- Eligible to be 340B child site.

Excepted Off-Campus Department
- Established and billing for OPPS services before November 2, 2015.
- 100 percent of OPPS.
  - Hospital clinic visits (CPT G0463) at 40% of OPPS.
- Must use PO modifier.
- Eligible to be 340B child site.
- Relocation to another off-campus location resulting in change of street address results in loss of "excepted" or "grandfathered" status.



Provider-Based Off-Campus Emergency Department
- 100 percent of OPPS.
  - For both emergency and non-emergency services.
- Must use ER modifier for all services.
  - Do not use PN/PO modifiers.
- Eligible to be 340B child site.
- Establishment date does not impact. Medicare reimbursement (e.g., before or after November 2, 2015).

Inpatient Hospital Building
- May be the "main provider" campus.
- May be a provider-based. inpatient campus (i.e., "remote location").

On-Campus Department
- 100 percent of OPPS.
- Do not use PN/PO modifiers.
- Eligible to be 340B child site.

Provider-Based Departments, Locations, Modifiers and Medicare Reimbursement Summary

Provider-based Requirements

- Licensure and Certification
  - Operated under hospital license where permitted by state.
- Clinical Integration
  - Clinical services are fully integrated with hospital (e.g., staff privileges, clinical oversight, policies/procedures, etc.).
  - Medical records integration – same EHR or “cross-reference” to the main provider.
- Financial Integration
  - Shared expenses/income between hospital and provider-based sites.
  - Reported on hospital’s Medicare Cost Report (reported on lines 50-118).
- Public Awareness
  - Held out to public and payers as part of hospital and not merely health system.

Provider-based Requirements (cont.)

- EMTALA Considerations
  - On-campus hospital departments must abide by EMTALA policy.
  - Off-campus sites should treat emergencies to the greatest extent possible and transfer to the main hospital unless emergency dictates the closest hospital.
- Billing and Coding
  - Specific place of service codes on 1500s and appropriate modifiers on UBs.
  - Off-campus financial notices of liability.
- Ownership and Control
  - 100% owned by hospital – Potential exceptions for certain on-campus.
  - Governed by same board, bylaws, rules/regulations, etc.
- Administration and Supervision
  - Under direct supervision of and integrated with hospital.
  - Reporting relationships have the same “frequency, intensity, and accountability” as those within the four walls.

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Exact Match & Coding

Updates & Latest Guidance

Billing & Coding

- Institutional Claims (UB-04)
  - **“PO”** Modifier
    - Old – Established before November 2, 2015 or “Mid-Build.”
    - Modifies payment for “G0463” (clinic visit) at 40% of traditional OPPS in CY2021 and beyond.
    - Remaining services are paid at 100% of OPPS.
  - **“PN”** Modifier
    - New – Established after November 2, 2015.
    - Triggers payment under the MPFS at 40% of traditional OPPS, Neutral for G0463.
  - **“ER”** Modifier
    - All off-campus EDs regardless of effective date (does not apply if ED is located within a 250-yard radius of remote inpatient location.
    - No payment impact yet – for purposes of collecting data on off-campus ED utilization.

Exact Match

- Include all practice locations on the CMS 855A enrollment form.
- Report the service facility location for off-campus, outpatient, provider-based departments of a hospital in the 2310E loop of the 837I claim transaction.
  - CMS defines specific scenarios for multi-campus hospitals and encounters at multiple locations on the same date of services.
- Addresses used on Institutional claims for services at off-campus HOPDs must ***exactly*** match the address used on the hospital's Medicare enrollment record.
- "Exact" means that claims bearing "Road" or "Suite" may be rejected if the Medicare enrollment record lists "Rd" or "Ste" for the applicable address.
- Exact match edits will also look for appropriate modifiers, "PO" or "PN".
- Enforcement will result in RTP claims and cash flow interruptions if records do not match or if modifiers are not appropriately used.

“Excepted” (Grandfathered) Status (cont.)

- Most physical expansions of excepted (grandfathered) off-campus locations are permitted so long as street address – including suite number – stays the same.
  - Unwritten → Advis confirmed with multiple CMS regions.
  - Importance of the 855A enrollment record is stressed by CMS as means to prove grandfathered status.
  - Proof of OPPS claim billing prior to 11/2/15 date is also requested.
- No relocations of excepted (grandfathered) off-campus locations unless “extraordinary circumstances” on case-by-case basis.
- “Excepted” status only transfers in CHOW/merger if buyer assumes Medicare agreement of seller.
- Clinic location must also be within a 35-mile radius of new owner hospital.

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Optimizing your 340B Savings Program

What is 340B?

- The 340B Drug Pricing Program is a federally mandated drug pricing program that allows certain healthcare organizations, “Covered Entities”, to purchase certain drugs at a **significant discount (on average, 30-60%)**
- The 340B Program enables hospitals to stretch its resources and use its savings to reach more patients and provide more comprehensive healthcare services, especially to patients in need.
- However, the 340B Program is heavily regulated by HRSA and its Office of Pharmacy Affairs (OPA).

The 340B Program

- Two most important criteria for a patient to be eligible in a hospital setting for a 340B drug:
  - Outpatient or observation status at the time of drug administration.
  - Receiving services at a hospital location.
- Along with departments within the main hospital, off-site hospital departments are also considered 340B eligible locations, known as Child Sites.
- Even with new off campus provider-based locations that will not receive the full OPPS payment or perhaps have no differential, it may benefit a hospital by expanding its 340B savings to those departments and their patients.

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Diversification

Whether by force or by choice

Commercial Payer/Marketing Trends

- We are seeing more regions across the nation losing outpatient services, specifically in imaging to freestanding non-hospital options by Commercial Payers like Aetna, BCBS and Humana.
- Hospital strategy should include a review of a decline in outpatient services and review surrounding competitors and determine the ROI of establishing a hospital owned freestanding outpatient service line to capture that market.
- Consider the development of an IDTF.

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Recent Legislative Activity

Site Neutral Pending Legislation

- Some of the legislation included mandatory attestation submissions for all existing off campus provider-based locations.

PATIENT Act (H.R. 3561) and **H.R. 5378** – Site neutral payment for drug administration services in off-campus HODs. H. R. 5378 includes mandatory attestations. Approved by the House and sitting in the Senate.

MPACT Act (H.R. 4473 – Site neutral payment for cancer diagnosis/treatment services in on- and off-campus HODs.

SITE Act (S. 1869) – Site neutral payment for all services in off-campus HODs at 40% of OPPS, and in off-campus ERs located more than 6 miles from a hospital at 30% of OPPS.

The Primary Care and Health Workforce Expansion Act, Sec. 802 – Site neutral payments at “medium amount charged” in a physician’s office for all HOD services, regardless of on- or off-campus.

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Risks and Recent CMS Enforcement Trends

Provider-based Requirements and Enforcement

- CMS has recently focused on the following issues/risk areas:
  - Leadership Considerations
    - Administration and Supervision (e.g., reporting structure)
    - Clinical Integration
  - Physical Plant & Marketing Considerations
    - Public Awareness
    - Physical Location
  - Back-office Considerations
    - Medical Record Integration
    - Billing and Coding
  - Policy Considerations
    - Financial Notice of Liability (Off-Campus)
    - EMTALA Considerations
  - Maintaining “Excepted” (Grandfathered) Provider-based Status

Provider-based Requirements and Enforcement (cont.)

- How does CMS enforce?
  - Patient Complaint Survey – Often tied to a patient's lack of knowledge related to the clinic's status as HOPD
  - Accreditation & Extension Survey

Physical Plant & Marketing: Public Awareness

- Held out to public and payers as part of the main hospital.
- Does not require all payers be billed the same, merely that all payers are aware the location is provider-based.
- When patients enter the site, external and internal signage makes clear that they are entering the hospital and will be billed accordingly.
- Website and any other materials accessible by the public also hold the site out as part of the main hospital.
- CMS utilizes totality of circumstances standard.

Physical Plant & Marketing: Public Awareness (cont.)

- Any area used as an HOPD must follow the standard branding and naming convention, signage, notices, and other patient-facing materials, similar to other parts of the hospital.
- Therefore, all HOPD identification signage should at a minimum include the following language, "*a department/an outpatient department of [Hospital Name]*".
- When the public **enters the HOPD location**, it should be clearly identified and held out as a part of the specific hospital, and this is particularly important when referencing any billing practices.

Physical Plant & Marketing: Space Sharing

- Historically, CMS has not allowed a provider-based location to share space with another non-hospital provider within a specific provider-based suite.
- Due to the inconsistency in enforcement, in 2019 CMS released **draft guidance** to attempt to clarify its position with respect to space sharing.
- In 2021, CMS released final guidance, but it is less descriptive than the 2019 draft guidance.

Physical Plant & Marketing: Space Sharing (cont.)

- 2021 final guidance
  - Private physician offices and critical access hospitals specifically excluded from guidance.
  - Some healthcare providers may co-locate (e.g., hospitals with other hospitals, HOPD located in the same building as another hospital or separately Medicare-certified provider/supplier such as an ASC or RHC).
  - Hospital must consider whether spaces used by another co-located provider risk compliance with these requirements.
    - Areas of consideration – Patient rights, infection prevention and control, governing body and/or physical environment.
  - Only example in guidance – Sharing a supply storage room; if surveyor identifies a water leak that ruined sterile packed supplies, this would be a deficiency for the hospital being survey and could also trigger a complaint for the co-located hospital.
  - Open questions on “Public spaces”/“Public paths of travel.”

Mitigate Risk – Internal Review

- Advis recommends reviewing compliance with all provider-based requirements every three years. The review should include:
  - Licensure and Certification
  - Clinical Integration
  - Financial Integration
  - Public Awareness
  - EMTALA Considerations
  - Billing and Coding
  - Ownership and Control
  - Administration and Supervision

Mitigate Risk – Attestation

- Current voluntary attestation process involves submission of documents to CMS to prove compliance with regulations. This could change depending on pending Congressional efforts.
- Attestation preparation process serves as internal provider-based compliance audit.
- Minimizes exposure to Medicare/Medicaid overpayments.
- Potential retrospective benefits of attestation process should be balanced against timing, cost, and other considerations.
- Important to demonstrate compliance in existing “grandfathered” off-campus departments.

Mitigate Risk – Attestation (cont.)

- MAC conducts initial review and provides recommendation to CMS for approval or denial.
- Recently, the MAC will no longer grant extensions for additional document requests – if information is not returned within 30 days, then the MAC will recommend that CMS deny the attestation.
- The MAC has standard document request form, but it is overreaching.
  - Do not provide documentation that is not required by the provider-based regulations. Rather, argue the merits with the MAC. This prevents against providing documentation that may lead to an ancillary compliance review.
- Attestation process often requires more than six months to one year from date of filling to final determination.
- Given increased scrutiny, it is important to ensure HOPDs are in compliance with all CMS regulations and enforcement action trends prior to submitting any attestation.

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CMS Enforcement Examples and Communication

Questions?

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Thank you

Monica Hon, JD, Vice President
mhon@advis.com

Susan Maupin, JD, RN, Vice President
smaupin@advis.com