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Provider-Based Clinics: Regulations, Risks, and Recommendations

Mike Meeks, Corporate Counsel – Legal Compliance
Kyle Robinson, Corporate Counsel

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Agenda

- Provider-Based Status and Key Requirements
- Update on CMS' proposed Rulemaking ("Site-Neutral Law")
- Impact on Current and Future Provider-Based Entities
- Key Considerations/Unanswered Questions
- Recommendations Moving Forward

Disclaimer: The materials presented today are for informational purposes only and not for the purpose of providing legal advice. You should contact your attorney to obtain advice with respect to any particular issue or problem.

Provider-Based Status – Brief Overview

- Prior to the Proposed Rule, Hospitals could choose to treat hospital-owned facilities as freestanding or as "provider-based".
- Types of provider-based facilities
  - Department of a provider (hospital outpatient dept.)
  - Provider-based entities (e.g., RHCs)
  - Remote locations of a hospital
  - Satellite facilities of a hospital
- Requires compliance with 42 C.F.R. § 413.65

Key Requirements of § 413.65

- Licensure
  - Entity operates under main provider's license (state law permitting)
- Clinical Integration
  - Integrated medical records
  - Main provider has oversight of clinical activities
  - Professional staff have clinical privileges at the main provider
- Financial Integration
  - Costs of the entity are reported as a cost center of the provider; shared income and expenses
- Public Awareness
  - Entity must be held out as part of the main provider
  - Patients must be aware that hospital is the service provider

Key Requirements of § 413.65

- Off-campus provider-based locations must also:
  - Operate under the ownership and control of the main provider (*e.g.*, governing body, approval authority)
  - Demonstrate that the same reporting structure and level of accountability exists as for on-campus departments
  - Integrate administrative functions with the main provider (*e.g.*, billing, records, HR)
  - Be located within 35 miles of the main provider (or meet one of several other narrow exceptions)

Impact of Provider-Based Status

- Financial Benefit
  - Possible payment for hospital "facility fee"
  - Increased payment rate for certain services
  - Eligibility for 340B drug pricing (for some hospitals)
  - Ability to count resident training time for GME/IME
- Medicare Coverage
  - Certain services only covered in hospital setting (e.g., partial hospitalization)
- Requires compliance with the hospital conditions of participation (42 C.F.R. § 482, et seq.)

CY 2017 Outpatient Prospective Payment System (OPPS) rule

- July 6, 2016, CMS released the CY 2017 OPPS policy changes (CMS-1656-P).
- Site-Neutral Payment Provision ("Section 603"):
  - Certain items and services furnished by certain off-campus PBDs shall not be considered covered outpatient department services for purposes of OPPS payment and shall be instead paid "under the applicable payment system" beginning January 1, 2017.
  - ***Excepted Items and Services:***
    - ***Excepted Entities:*** *All items and services furnished in a dedicated emergency department.*
    - ***On-Campus PBDs:*** *Items and services furnished in a hospital department within 250 yards of a remote location of the hospital or hospital campus.*
    - ***Grandfathered Locations:*** *Items and services that were furnished and billed by an off-campus PBD prior to November 2, 2015.*

Application of Site-Neutral Law: Excepted Entities

- Site-Neutral Law does not apply to:
  - Items and services furnished in Dedicated Emergency Departments (EDs) (as defined by 42 CFR 489.24(b)).
    - Proposed that all services furnished in an ED, whether or not they are emergency services, would be exempt from the act and thus continue to be paid under the OPPS.
  - Critical Access Hospitals
  - Rural Health Clinics
  - On-Campus provider-based locations
  - Grandfathered Locations

Application of Site-Neutral Law – On-Campus PBDs

- The Site-Neutral Law does not affect provider-based departments:
  - On the "**campus**" of the hospital, as defined in §413.65
    - 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".
  - Within 250 yards from a **remote location of a hospital** (this is new!)
    - Meant to address "multicampus" hospitals.
    - Remote Location of a Hospital: a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing **inpatient hospital services** under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section.
      - (42 CFR §413.65(a)(2))

Application of Site-Neutral Law – On-Campus PBDs

Issue: How will CMS apply its discretion in measuring 250 yards, if at all?

- Referring to Remote Locations:
  - "Hospitals should use surveyor reports or other appropriate documentation to ensure that their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose."
- Takeaway: For existing on-campus departments, the provider must be prepared to identify its measurement methodology and defend the result
  - Inventory identified methodology (Google maps) or general location (adjacent MOB), but CMS discussion may require a finer point on these
  - Attempt to obtain pre-approval of measurement from MAC/RO.

Application of Site-Neutral Law – Case Study

- On-Campus Attestation Submitted
- MAC challenged 250-yard measurement via attestation process
  - Hospital performed straight line measurement from outside edge of hospital (closest to MOB) to outside edge of MOB (closest to hospital) – 226.58 yards
  - MAC entered two addresses into Google "freemaptools" – 383 yards
    - Program dropped the pin on the hospital building at the edge farthest from the MOB – even farther than the main entrance
  - Hospital responded with another Google maps measurement (230 yards) and an explanation that measurements are generally taken using commercially available satellite mapping applications – not "freemaptools"
  - No response yet from MAC.
  - Other MACs are taking new/varied views on measurement points.

Application of Site-Neutral Law – Grandfathered PBDs

- Services provided in new off-campus provider-based "departments" will not receive hospital outpatient payment as of January 1, 2017 (i.e., no facility fee or increased payment for services)
  - Departments are "new" if they first "furnished and billed" for services as a provider-based department on or after November 2, 2015
    - CMS is seeking comments on a potential timeline.
  - If services were not billed prior to November 2, payment may be made under another available payment system

Application of Site-Neutral Law - Grandfathered PBDs

Issues: How will CMS identify "new" off-campus departments?
- Require an attestation?
- Require a separate modifier/POS, as suggested by statute?
- Look to the Section 4 of the 855A for the date the practice location was added?

Whatever the solution, CMS will need a mechanism to tie individual claims to a particular off-campus location – which it currently does not have.

- New modifier –PO for off-campus provider-based hospital services (eff. 1/1/16)
- New POS – 19 for physician services billed in an off-campus provider-based department (eff. 1/1/16); POS 22 still applies for professional services furnished in an on-campus provider-based department

Consideration: Expansion of Services

"If an excepted off-campus PBD furnished and billed for any specific service within a clinical family of services prior to November 2, 2015, such clinical family of services would be excepted and eligible to receive payment under the OPPS."

19 Proposed Clinical Families of Services:

- Advanced Imaging
- Airway Endoscopy
- Blood Product Exchange
- Cardiac/Pulmonary Rehabilitation
- Clinical Oncology
- Diagnostic tests
- Ear, Nose, Throat (ENT)
- General Surgery
- Gastrointestinal (GI)
- Gynecology
- Minor Imaging
- Musculoskeletal Surgery
- Nervous System Procedures
- Ophthalmology
- Pathology
- Radiation Oncology
- Urology
- Vascular/Endovascular/Cardiovascular
- Visits and Related Services

Consideration: Relocation

"Excepted off-campus PBDs and the items and services that are furnished by such departments would not longer be excepted if the excepted off-campus PBD moves or relocated from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015."

- Unit number is considered part of the address.
- CMS is seeking comments on exceptions to this rule:
  - Proposed: disaster/extraordinary circumstance.

Consideration: Change of Ownership

- What are the implications of a merger, relocation or addition of a new service line?
  - Merger, CHOW should not impact existing characterization of the location as on-campus, off-campus, new or grandfathered
    - Billing provider changes, but provider agreement with all existing treatment (e.g., DSH, GME, SCH status, etc.) remains intact
  - Strong arguments exist that adding a service to an existing (grandfathered) location does not change the fact that the location is a grandfathered outpatient department
    - Provider-based rules and cost report identification is space / location-focused, not service focused

Unanswered Questions

- Will there be any exceptions for departments under development as of November 2, 2015?
  - Some legislation proposed, currently stalled
  - Unlikely for CMS to permit via regulations without a legislative fix

Unanswered Questions

- What rules apply for physician supervision?
  - If a provider-based location (new/existing on-campus or grandfathered off-campus):
    - All therapeutic services subject to "direct" physician supervision
    - Diagnostic services subject to same supervision standard by service
  - No current changes to these rules
    - Some services may be supervised by a physician or NPP
    - All supervisors must be able to perform the underlying service within the state's license scope
    - All supervisors must be credentialed by the hospital to furnish the underlying service
    - Supervisor must be immediately available (undefined) and interruptable to take over the service
    - Follow current CHI supervision policy

Recommendation: Inventory of Provider-Based Locations

- Goals:
  1. Determine if any off-campus locations (currently operating) were **not** billing Medicare for outpatient services on or before 11/02/2015
  2. Determine if any off-campus locations not billing Medicare by 11/02/2015 are RHCs, dedicated EDs or connected to a CAH
  3. Craft enrollment/billing plans for any locations identified in Goal #1
  4. Consider options for off-campus departments currently under construction
  5. Review measurement of 250 yards for on-campus designation

Recommendation: Inventory of Provider-Based Locations

- For now…
  - Delay plans to relocate or expand services of existing off-campus departments
  - If future clinics are in planning stages, consider whether an on-campus location is possible or re-evaluate costs/reimbursement as freestanding clinic
  - Consider possible advocacy and policy approach

Recommendation: Inventory of Provider-Based Locations

- Outline go-forward options for <u>new</u> off-campus provider-based locations:
  - The location must enroll in Medicare as another type of supplier using Form 855B (Clinic/Group Practice, IDTF, Intensive Cardiac Rehab, Pharmacy, Radiation Therapy Center, Other, etc.)
    - This is true even where the location is still owned, operated and controlled by the hospital (and DRG payment window likely still applies)
  - The off-campus location is NOT included in the hospital's 855A
    - The only locations to be identified on the hospital's 855A (section 4) are those that will be billed as hospital outpatient services from addresses that are different from the hospital's main address identified in Section 2 of the hospital's 855A
    - Review the inventory list of hospital department locations to ensure that each location is properly identified on the 855A

Recommendation: Inventory of Provider-Based Locations

- Outline go-forward options for <u>new</u> off-campus provider-based locations:
  - Once enrolled as another supplier type, technical services (diagnostic tests, labs, infusions, injections, etc.) are billed on a 1500, place of service 11 for clinics (or other for specific supplier types)
  - Physician services still billed on a 1500 with correct POS, may be billed by the hospital in connection with the technical service (via reassignment) or separately by independent physicians or TPN (or similar)
  - Costs of the hospital-owned clinic identified generally in a non-reimbursable cost center on the cost report (not an outpatient department)

To Attest or Not to Attest

- Attestation is not mandatory
- Benefits
  - Certainty of status
  - If found to be non-compliant, recoupment is retrospective to the date of the completed attestation
    - Without an attestation, recoupment is retrospective for all periods subject to reopening (4+ years)
    - Either way, recoupment is limited to the difference between OPPS and Physician Fee Schedule payment amounts
  - Improved tracking of compliance with the provider-based regulations
- Concerns
  - Apparent rise in denials
  - Higher stakes in light of Site-Neutral Law
  - Certification of accuracy extremely difficult with changing interpretations
- Required under some proposed Site-Neutral "fixes" or amendments?

The Best Is Yet To Come…

- 2017 Hospital Outpatient PPS and Ambulatory Surgical Center Final rule sent to the Office of Management and Budget (OMB) for review.
  - Typically the last step in the review process before a rule is released.
- OPPS/ASC final rule must be posted by November 1st by statute – CMS typically meets that deadline.

Questions?

Mike Meeks
michaelmeeks@catholichealth.net
303-383-2691

Kyle Robinson
kylerobinson2@catholichealth.net
720-568-3714