Provider-based Status and Co-Location

New CMS Guidance and Strategic Steps for Compliance

Briar Andresen
(612) 492-7057
bandresen@fredlaw.com

Katie Ilten
(612) 492-7428
kilten@fredlaw.com

June 12, 2019

Fredrikson & BYRON, P.A.

Overview

- The basics and how we got here
- Shared space

Provider-based Basics

- Part 413, Subpart E “Payments to Providers”
- 42 CFR 413.65
- Hospitals can treat certain facilities/locations as part of the hospital for Medicare payment
  - Integral and subordinate
  - Mostly better reimbursement
    - Facility fee (Medicare)
      - Somewhat lower physician fee schedule payment
    - Patients pay more (two copays)
    - Not all payors recognize provider-based status
  - 340B advantages
  - Different requirements for on-campus vs. off-campus

Writing on the Wall

- Changes to provider-based reimbursement are underway
- Site-neutral payments
  - General unhappiness that E&M services are paid more in an outpatient department than in a physician clinic
  - Same service, higher cost, higher copay
- Since 2014, required submission of data on where services were furnished so that CMS could figure out what services were happening where

Sunset Provisions

- Section 603
  - Part of the Bipartisan Budget Act of 2015
  - "Treatment of off-campus outpatient departments of a provider"
  - Became law on Nov. 2, 2015
- As of Jan. 1 2017, no payment of facility fees for services in new off-campus departments of providers
  - Does not eliminate provider-based status
  - Does not prevent acquisition of departments
  - 42 CFR 413.65 still in effect (603 amends the statute)
  - Applies only to off-campus departments (not on-campus departments, not remote locations of a hospital)

Section 603

- Items and services furnished on or after 1/1/2017 in new off-campus outpatient departments of a provider will not be paid under the OPPS
  - Paid instead under other applicable payment system
  - Removes from definition of “covered OPD services” items and services furnished on or after 1/1/2017 by an off-campus outpatient department of a provider
- Exceptions for:
  - Items and services provided “by dedicated emergency departments”
  - Departments billing under OPPS prior to 11/2/2015
  - Critical access hospitals and rural health clinics

Section 603: Because I said so…

- No administrative or judicial review under section 1869, section 1878, or otherwise of:
  - Applicable items and services (anything other than items and services in a dedicated ED) and other applicable payment systems (whether it is paid under the physician fee schedule or other payment system)
  - Whether a department of a provider meets the term described in subparagraph (B) (whether it is off-campus or on-campus)
  - Information that hospitals are required to report
    - "May include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form"

Current Enforcement Areas

- Shared space
- Provider-based department location disputes

Penalties/Problems

- Overpayments
- Violation of COPs
- Federal False Claims Act?

Shared Space

- Medicare has ramped up attention to space sharing between hospital-based and free-standing services. Although it has instructed contractors in writing that there may be situations in which shared space is appropriate, it has pointed to elements of shared spaces and indicated that provider-based status should be denied.

Shared Space: What is the Law?

- No statute
- One regulation: 42 C.F.R. 413.65
- Preamble language
- State Operations Manual, CMS Pub. 100-07
- Program Memorandum A-30-030 (April 18, 2003)

Shared Space: What is the Law?

- The regulation does not address shared space between provider-based and freestanding entities
- The preamble does:
  - "The question regarding sharing of space, however, can be answered only in the context of a specific case, and we expect that such decisions will be made by our regional offices."
  - April 7, 2000 Federal Register

Shared Space: Can You Do It?

- The CMS Central Office and a few Regional Offices have said “no”
- The reasons given have varied
- Typically a “no” in the form of a denial of an off-campus provider-based department attestation

Region V Letter

- Freestanding rad department within hospital
- Region V position: a facility that shares space with a freestanding facility does not meet the definition of a “department” of a hospital
- Rationale:
  - Provider agreement compliance
  - Public awareness

Public Awareness is Important

- "[T]he public awareness requirement is not met to the extent the singular component is held out as a freestanding supplier of services, even if it is also held out to the public as a furnisher of hospital services…[S]ome confusion of the two is unavoidable."

Potential Harm?

- “By failing to distinguish properly between provider-based and free-standing facilities or organizations, we risk increasing program payments and beneficiary coinsurance with no commensurate benefit to the Medicare program or its beneficiaries…”

Where is the Line?

- "CMS may consider a suite in a medical office building to be a singular component for compliance with the hospital CoPs and Medicare-provider based status requirements…However, CMS cannot consider only portions of a singular component when determining if these criteria are met."

Region VIII Letter

- Hospital leased office space in hospital building to visiting specialty physicians 2-3 days per month
- Region VIII conclusion: “A facility that shares space or time with a freestanding facility cannot have provider-based status as a department of a hospital.”
- Rationale:
  - Public awareness
  - Provider agreement compliance

Where is the Line?

- "There are many elements that are common to shared space arrangements that are likely to cause confusion…These include a shared entrance into the facility, shared registration and waiting areas, passing through a freestanding area to get to the purported hospital area, co-mingling of staff, and signage indicating that a single facility is both hospital space and freestanding space."

Where is the Line?

- "Building plans that do not clearly demarcate a purported hospital space as a distinct space is [*sic*.] another possible indicator that the space is not a self-contained component. Rent that is paid to a tenant of a building rather than directly to the building owner or landlord may also be an indication that a space does not itself constitute a singular component."

Where is the Line?

- “A department of a provider requires sufficient separation from any other facility. Sufficiently separated space is indicated by such features as exclusive entrance, waiting, and registration areas, permanent walls, and a distinct suite designation recognized by the United States Postal Service if the hospital department does not occupy an entire building.”

Medical Office Space

- A main provider hospital may not lease or otherwise obtain use of a portion of a singular component and create a smaller component within that space or sharing time. Certain features, such as shared entryways, interior hallways, bathroom facilities, treatment rooms, waiting rooms, and registration areas are all indications that purported hospital space or time may instead be a part of a larger component…"

Consequences for Failure to Comply?

- Each letter was an initial determination that found the hospital was overpaid back to the date on which the attestation was submitted

November 2018: CMS Previews New Guidance

- AHLA webinar featured David Wright, Director of CMS's Center for Clinical Standards and Quality
- New guidance forthcoming that would ease restrictions on co-located hospital and freestanding space
- Hallways, waiting areas and elevators could be shared, so long as patient safety and quality are not compromised
- Also expected guidance to liberalize the options for a hospital to share space with visiting physicians, particularly in rural areas where visiting specialists may be co-located with hospital space

March 2019: CMS Previews Again

- AHLA conference featured David Wright again
- Said guidance was forthcoming
- More hints: simultaneous shared staff not okay (must have temporal separation); no walking through clinical spaces to reach shared space

May 3, 2019: Draft Guidance Issued

- Quality, Safety & Oversight Memo to State Survey Agency Directors
- Comments due July 2, 2019
- Covers “space sharing or contracted staff arrangements with another hospital or health care entity”
- Tool for surveyors to assess compliance with CoPs
- Does not apply to CAHs

New Term: “Co-Location”

- “Co-location occurs where two hospitals or a hospital and another healthcare entity are located on the same campus or in the same building and share space, staff, or services.”

The General Rule

- “In general, under this guidance, sharing public areas such as entrances and waiting rooms would be permissible. However, due to infection control, patient management, confidentiality, and other quality and safety concerns, the use of shared clinical spaces would be limited.”

A Hospital Must Have Distinct Space

- A hospital must have “defined and distinct spaces of operation for which it maintains control at all times.”

What Must be "Distinct" Spaces?

- CMS defines "distinct spaces" as including "clinical spaces designated for patient care and [] necessary for the protection of patients, including but not limited to their right to personal privacy and to receive care in a safe environment under 482.12(c)(1) and (2) and right to confidentiality of patient records under 482.13(d)."

Shared Clinical Space NOT Okay

- “[C]o-mingling of patients in a clinical area such as a nursing unit, from two co-located entities, could pose a risk to the safety of a patient as the entities have two different infection control plans” and “jeopardize the patient’s right to personal privacy and confidentiality of their medical records.”

Shared Clinical Space NOT Okay

- “[A] hospital should not share space where patients are receiving care. This would include, but is not limited to, any space within nursing units (including hallways, nursing stations, and exam and procedure rooms located within nursing units), outpatient clinics, emergency departments, operating rooms, [PACUs], etc.)”

Shared Spaces that are Permitted

- “Public spaces and public paths of travel that are utilized by both the hospital and the co-located healthcare entity.”

Shared Spaces that are Permitted

- “Examples of public spaces and paths of travel would include public lobbies, waiting rooms and reception areas (with separate ‘check-in’ areas and clear signage), public restrooms, staff lounges, elevators and main corridors through non-clinical areas, and main entrances to a building.”

Travel Through Clinical Spaces NOT Permitted

- Clinical space = any non public space where patient care occurs
- E.g., a path of travel through an inpatient nursing unit
- E.g., path of travel through clinical hospital department (e.g., outpatient medical clinic, lab, pharmacy, imaging, PACU, ED, operating room)

Permitted Public Path of Travel

- E.g., main hospital corridor with distinct entrances to departments
- “It is necessary to identify, for the public, which healthcare entity is performing the services in which department.”

Survey Procedures

- Surveyors must ask for a floor plan distinguishing hospital and co-located space
- Surveyors must request a list of all contracted services shared with/used from other co-located entity
- Non-compliance for one = non-compliance for both

Status of Leased Space?

- From CMS at AHLA presentation on June 5, 2019:
- “There may be instances where a provider may lease space from a hospital.”
- “A leased space is not co-location as the tenant is responsible for that space under the terms of the lease agreement with the landlord hospital.”
- “The only time that leased spaces would be subject to survey for life safety code and any deficiencies would be the responsibility of the landlord hospital.”

Status of Timeshare?

- From CMS at AHLA presentation on June 5, 2019:
- “There may be instances where visiting providers may use space, equipment, supplies, etc. within a hospital at particular times, but not lease the space.”
- “In a timeshare, the hospital is responsible for maintaining the space, equipment, and supplies to maintain compliance with the Conditions of Participation.”

Contracted Services

- "A hospital is responsible for providing all of its services in compliance with the hospital CoPs. Services may be provided under contract or arrangement with another co-located hospital or healthcare entity, such as laboratory, dietary, pharmacy, maintenance, housekeeping, and security systems. It is also common for a hospital to obtain food preparation and delivery services under arrangements from the entity in which it is co-located, in addition to utilities such as fire detection and suppression, medical gases, suction, compressed air, and alarm systems such as oxygen alarms."

Contracted Services/Staffing

- "Each hospital is responsible for independently meeting staffing requirements of the CoPs and any of the services for which the hospital provides…When staff are obtained under arrangement from another entity, they must be assigned to work solely for one hospital during a specific shift and cannot 'float' between the two hospitals during the same shift, work at one hospital while concurrently being 'on-call' at another, and may not be providing services simultaneously…"

Contracted Services/Staffing

- “For instance, under section 1861(e)(5) of the Act, a hospital must be able to provide nursing services at all times and if such staff are being shared between two entities at the same time, meeting this definition is not possible. This would also apply to the lab, pharmacy, and nursing director. This does not necessarily preclude those individuals from serving those roles in both hospitals, but it cannot be simultaneously.”

Contracted Services/Staffing

- CMS's examples:
  - Nursing
  - Nursing Director
  - Pharmacy Director
  - Dietician
  - "Other staff related to contracted services (respiratory care, code teams, etc.)"

Contracted Services/Staffing

- This does NOT apply to hospital medical staff. They may “float.”
- Contracted staff must be trained the same way as employed staff.
- Staff must always be “immediately available to provide services.”
- What does this mean for a shared lab? Pharmacy?

Survey Procedures

- Surveyors will only survey physical locations where contracted services are provided if the location is on-site
- Surveyors will look for inclusion of contracted service outcomes in QAPI program
- Surveyors will also look for
  - Adequacy of staffing levels
  - Oversight and evaluation of contracted staff
  - Training and education of contracted staff
  - Contracted staff's knowledge of QAPI standards
  - Accountability of contracted staff.

Survey Procedures

- Surveyors will review “staffing and schedules of staff to ensure that staff are immediately available at all times to perform services required by the hospital.”
- Surveyors will “[a]sk to see staffing schedules to verify that individuals providing contracted services are only scheduled to work at one facility per shift.”

Emergency Services

- “Contracting with another hospital or entity for the appraisal and initial treatment of patients experiencing an emergency is permitted when the contracted staff are not working/on duty simultaneously at another hospital or healthcare entity.”

Emergency Services

- “Hospitals without emergency departments that are co-located with another hospital may not arrange to have that other hospital respond to its emergencies in order to appraise the patient and provide initial emergency treatment.”
- A hospital without an emergency department may still make an appropriate transfer to a co-located hospital

Survey Procedures

- Does the hospital have its own trained staff to respond to emergencies?
- Does the hospital have proper emergency equipment?
- Is the staff properly trained for appraisal of emergencies, initial treatment and referral?

Open Questions, Areas for Comment

- Public path of travel next to a clinical unit – do you need a door?
- Separate registration
- Shared contracted services – pharmacy staff, lab staff, custodial and hospitality staff
- Contracted services – agreement requirements
- Distinct part units
- Leased space versus time share arrangements
- Scope of guidance

Contact Information

Briar A. Andresen
612.492.7057
bandresen@fredlaw.com

Katherine B. Ilten
612.492.7428
kilten@fredlaw.com