MEDICARE HOSPITAL CO-LOCATION FIX? NOT THERE YET…

On May 3, 2019, CMS released its long-awaited guidance on hospital co-location and shared service arrangements in the form of a draft survey memo ("Memo"), which is available here. The Memo clarifies how a hospital can co-locate with other health care entities without violating the Medicare Conditions of Participation ("CoPs"). CMS has been promising this guidance since at least 2016, and hospitals have been eagerly awaiting clarity on how they can structure their operations while being compliant with CMS policy.

Below we outline CMS's prior position on co-location issues as well CMS's new guidance on shared space and services in the Memo. It is important to note that the Memo was released as draft guidance that will be added to the State Operations Manual Appendix A – the Interpretive Guidelines for Surveyors to the hospital CoPs – not as coverage, billing or payment guidance. CMS is soliciting comments, which are due by July 2, 2019.

PRIOR GUIDANCE ON HOSPITAL CO-LOCATION ARRANGEMENTS

CMS's application of its position that the hospital (and critical access hospital ("CAH")) CoPs inherently include an exclusive use (24/7/365) requirement has evolved over the years with respect to buildings that house two or more providers or suppliers. These arrangements are often referred to as co-location, mixed-use, space sharing or commingling arrangements. Co-location arrangements can include situations where a hospital is located in the same building or on the same campus as another hospital or another type of Medicare certified provider/supplier (e.g., ambulatory surgical center ("ASC"), rural health clinic, federally qualified health care center, imaging center, etc.). Although most of CMS's enforcement activity has been in the context of hospital provider-based sites and freestanding physician offices (which are not certified suppliers), the Memo does not directly address these scenarios.

Co-location scenarios, especially involving two or more providers (hospitals, skilled nursing facilities, etc.), often also present operational commingling or shared staff issues that invite survey scrutiny under CMS's position that each provider must be able to independently demonstrate satisfaction of the CoPs. As described below, existing CMS sub-regulatory guidance does address these situations, which is not significantly changed by the Memo.

Until the Memo, there was no formal guidance from CMS on co-location arrangements in the Conditions of Participation regulations (42 C.F.R. Part 482 for hospitals and Part 485 for CAHs), the provider-based regulations at 42 C.F.R. § 413.65, the Medicare Manuals or otherwise. Nonetheless, CMS increased enforcement on co-location for hospitals over the past few years and became increasingly restrictive in its review and approval of co-located sites, especially those where the provider-based and non-provider-based locations share the same floor or suite in a building.

The clearest co-location guidance before the Memo was in the form of CMS letters revoking provider-based status for facilities because the provider-based regulations incorporate the CoPs. One of the first such letters that the authors are aware of was a 2011 letter from CMS Region 5, which revoked provider-based status for services at a mixed-use site of an Indiana hospital. The 2011 letter involved a facility with mixed-use space used by the hospital and free-standing physician practices.

In the Indiana letter, and others that followed, CMS relied on the State Operations Manual ("SOM") and the Survey & Certification rules and regulations contained therein. CMS relied primarily on the exclusivity concepts contained at SOM §2026A, requiring that an entire hospital must be certified as meeting the hospital CoPs.

However, the Manual provision that CMS cited did not explicitly address co-location issues. Nonetheless, CMS applied a broader institutional "singular component" concept to a particular hospital department or location. It is important to note that although the above Manual provision only applied to *hospitals*, CMS was applying the same standards to CAHs as well.

Generally, CMS was requiring provider-based space to be completely separate from freestanding space located in the same building segregated by appropriate barriers under the Life Safety Code. When reviewing these co-location arrangements, CMS expected to see separate and distinct space for the provider-based services – including at least separate and distinct patient care areas, signage, waiting areas and registration desks. This usually meant that provider-based space be in a separate suite from freestanding services and the

practices could not share registration, interior hallways or waiting areas.

CMS has also stated that part-time or timeshare arrangements that separate space based on time between hospital-based and freestanding providers do not satisfy the hospital-based requirements. CMS has stated that if physician specialists want to see patients at a hospital-based location, the physicians should bill their professional services with a hospital place-of-service code, and the hospital should submit a facility bill. Alternatively, the freestanding physician would need to be in a completely separate suite from the hospital-based space in order to bill for services with an office place-of-service code.

SHARED SPACE GUIDANCE IN THE MEMO

First, the Memo clarifies what spaces may be shared or used by both the hospital and the co-located health care entity. For example, public lobbies, waiting rooms and reception areas (with separate "check-in" areas and clear signage), public restrooms, staff lounges, elevators, main corridors through non-clinical areas and main entrances to a building are acceptable to be treated as shared spaces based on the guidance in the Memo. Clinical spaces designated for patient care, however, must remain distinct for purposes of patient privacy, security and infection control. Including waiting rooms and reception areas as public pathways that may be shared is a significant favorable change from some of the enforcement positions CMS has taken, which required these areas to be separate. However, requiring separate check-in areas for registration does not further CMS's stated goal of allowing flexibility and could have the effect of increasing costs through duplicate staffing.

Further, travel through clinical spaces of a hospital by another entity in the building would not be considered acceptable. So, a main hallway with distinct entrances to departments may be acceptable; however, a hallway through an inpatient or outpatient unit could not be shared with other entities. To assess compliance, surveyors are instructed to request a floor plan that clearly identifies the spaces used by the hospital being surveyed and the spaces used by the other co-located entity.

Finally, it is important to note that the Memo only addresses space sharing from the hospital standpoint and the other co-located provider or supplier may have separate, unique space sharing requirements. For example, ASCs and IDTFs supplier standards include their own versions of an exclusive use requirement.

WHAT ABOUT TIMESHARE ARRANGEMENTS?

The most interesting part of the Memo is what is missing. In 2016, CMS indicated that the promised/anticipated co-location guidance would allow timeshare arrangements in provider-based space that met the Stark law exception at 42 C.F.R. § 411.357(y). In other words, if a hospital or CAH entered into an arrangement with a provider that meets the Stark Law exception, the provider may use the hospital/CAH waiting room, registration desk or other space without implicating the co-location restrictions. Under this interpretation, hospitals and CAHs would be afforded much needed flexibility, especially in visiting specialist scenarios. However, the Memo fails to address timeshare arrangements in the hospital setting. Accordingly, it is not entirely clear how CMS would view these arrangements in the context of the Manual and provider-based regulations.

SHARED STAFF GUIDANCE IN THE MEMO

Next, the Memo addresses shared services and/or personnel between a hospital and another co-located entity. The Medicare CoPs require that each hospital independently meet certain staffing requirements for any of the services for which the hospital provides, whether or not those staff are directly employed by the hospital or obtained via contract from another entity. When a hospital obtains staff under contract from another entity, such staff must be assigned to work solely for one hospital during a specific shift. In other words, personnel cannot "float" between the hospital and another health care entity during the same time or work at the hospital while being "on call" at another entity.

For example, the CoPs at 42 C.F.R. §482.23(b) require that the hospital have adequate numbers of personnel to provide nursing care to all patients as needed. The Memo clarifies that a hospital would not be compliant with the CoPs if a nurse was working on more than one unit, building, floor in a building or with more than one provider at the same time or was floating between multiple entities.

The one exception to the limitations on shared staff is for medical staff. Medical staff members may be shared or "float" between co-located hospitals as long as they are privileged and credentialed at each.

Notably, the Memo does not change CMS's position that each provider must be able to independently demonstrate satisfaction of the CoPs. This is true even if the multiple providers are all wholly owned/controlled subsidiaries of a parent company or even if they are all operated

within a single legal entity. There is no such thing as "System" or corporate responsibility for satisfaction of the CoPs. Operational authority must flow up to the administrator and governing body of each provider, and policies and procedures must document this structure. This position has been described in Appendix A under the governing body CoP arising from 42 C.F.R. §482.12, and CMS has not proposed any significant clarifications or changes to this guidance.

PRACTICAL TAKEAWAYS

Under the draft guidance in the Memo, the following principles would apply to co-location arrangements:

- Clinical or patient care space must remain distinct for purposes of patient privacy, security and infection control.
- In contrast, public lobbies, waiting rooms and reception areas (with separate "check-in" areas and clear signage), public restrooms, staff lounges, elevators, main corridors through non-clinical areas and main entrances to a building may be shared between co-located entities.
- The Memo does not address whether timeshare arrangements are allowed in the hospital setting.
- When a hospital obtains staff under contract from another entity, such staff must be assigned to work solely for one hospital during a specific shift and cannot "float" between the hospital and another health care entity during the same time.
- However, medical staff members may be shared or "float" between the co-located hospitals as long as they are privileged and credentialed at each hospital.
- The draft guidance in the Memo would add language to the Interpretive Guidelines for Surveyors for the hospital CoPs. Since the provider-based requirements in the regulations incorporate compliance with the CoPs, these co-location arrangements may create issues from a billing and payment standpoint as well.

Stakeholders are strongly encouraged to submit comments, especially hospitals/CAHs who have or are considering entering into timeshare arrangements in provider-based space. Comments are due on July 2, 2019.

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