CMS ISSUES LONG-AWAITED DRAFT GUIDANCE ON HOSPITAL CO-LOCATION AND SPACE SHARING

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U.S. Health Care Alert

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SUMMARY

On May 3, 2019, the Centers for Medicare & Medicaid Services ("CMS") issued long-awaited draft guidance[1] addressing compliance with the hospital Conditions of Participation ("CoPs") and survey procedures in regard to hospitals co-located with other hospitals or healthcare entities. The guidance aims to clarify how shared spaces, services, personnel, and emergency services may be organized in a hospital co-located with another hospital or healthcare entity. CMS notes its goal of ensuring safety and accountability without being overly prescriptive. Once finalized, the guidance will be incorporated into Appendix A of the State Operations Manual.

As discussed in greater detail below, this guidance modifies CMS' prior position on hospital co-location. Historically, CMS has largely prohibited space sharing between hospitals and other healthcare entities. If finalized, this guidance will provide some additional flexibility in structuring compliant co-location arrangements, although it still contains significant limitations and may not go as far as some providers would have liked. CMS is seeking comments through July 2, 2019.

HISTORY OF CO-LOCATION AND CMS GUIDANCE

CMS defines co-location as an arrangement under which 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. A desire to co-locate has increased in recent years as hospitals and healthcare providers seek to improve coordination of care and efficiently deliver services to patients. Historically, CMS' position has effectively been that hospitals are barred from sharing clinical or nonclinical space with other healthcare entities because such sharing prevented the hospital from complying with the CoPs, although that position was not formalized in guidance.

ANALYSIS OF DRAFT GUIDANCE

The draft guidance clarifies the circumstances under which a hospital can be co-located with another healthcare provider consistent with the CoPs. CMS provides several examples of permitted co-location, as well as prohibited

arrangements. Additionally, the guidance specifically addresses contracted staff and services and emergency services and discusses how state survey teams will evaluate compliance with this guidance.

The guidance focuses primarily on co-located hospitals, but is likewise applicable to hospitals co-located with other healthcare entities. The term "healthcare entity" is not defined in the guidance, but CMS lists ambulatory surgical centers ("ASCs"), rural health clinics ("RHCs"), federally qualified healthcare centers ("FQHCs"), imaging centers, and separately Medicare-certified providers and suppliers as examples of healthcare entities. CMS cautions that the guidance is specific to the requirements under the hospital CoPs and does not address the specific location and separateness requirements that apply to other types of providers/suppliers, such as psychiatric hospitals, independent diagnostic testing facilities, ASCs, and RHCs[2].

Compliance with Medicare CoPs

While permitting co-located providers, the guidance emphasizes that when a hospital is in the same location as another healthcare provider, each provider is responsible for demonstrating separate and independent compliance with the CoPs.

The guidance also contains procedures for CMS and state agency surveyors (collectively, "Surveyors") to evaluate a hospital's space sharing or contracted staff arrangements when assessing the hospital's compliance with the CoPs. A short discussion of these instructions is included in each of the sections below.

Distinct Space vs. Shared Space

Under the guidance, a hospital must have defined and distinct clinical spaces, meaning that these spaces must remain under the control of the hospital at all times. CMS describes clinical space as any nonpublic space in which patient care occurs. Thus, the guidance explains, clinical spaces must be distinct and may not be used in a manner that comingles patients in a clinical space. CMS bases this position by noting that shared clinical spaces could jeopardize a patient's right to personal privacy and confidentiality of his/her medical record information and could pose safety risks. The effect of this guidance is that clinical spaces may not be shared.

By contrast, the guidance states that nonclinical spaces may be shared by co-located providers. Shared spaces are described as public spaces and public paths of travel that are utilized by the hospital and co-located healthcare entity. CMS provides the following examples of public spaces and public paths of travel that may be shared:

- public lobbies
- waiting rooms
- reception areas (with separate "check-in" areas and clear signage)
- public restrooms
- staff lounges
- elevators and main corridors through non-clinical areas
- main entrances to a building

However, where a path of travel goes through a clinical space, that would not be considered a public path of travel and would be prohibited based on patient privacy, security, and infection control concerns.

CMS provides the following examples of public and nonpublic paths of travel:

- A public path of travel is, for example, a main hospital corridor with distinct entrances to departments (such as outpatient medical clinics, laboratory, pharmacy, radiology). It is necessary to identify, for the public, which healthcare entity is performing the services in which department.
- By contrast, the following examples would not be public paths of travel:
  - A hallway, corridor, or path of travel through an inpatient nursing unit; or
  - A hallway, corridor, or path of travel through a clinical hospital department (e.g., outpatient medical clinic, laboratory, pharmacy, imaging services, operating room, post anesthesia care unit, emergency department).

The guidance instructs Surveyors to ask for a floor plan that distinguishes the spaces used by the hospital being surveyed and the spaces used by the other co-located healthcare entity. The floor plan must clearly identify which healthcare entities use the spaces. If two healthcare entities utilize the same space, noncompliance identified in that space can be cited against both entities. For example, where a Surveyor identifies noncompliance with a shared space, the Surveyor could initiate a complaint against the healthcare entity not currently being surveyed.

When reviewing the floor plan, Surveyors will specifically look for the following space sharing situations and assess compliance with the CoPs:

- Whether spaces within the co-located hospital are defined and identified as belonging to the hospital being surveyed;
- Whether spaces that belong to another entity can only be accessed by traveling through public paths of travel from within the hospital;
- Whether spaces that appear to be shared by the surveyed hospital and the other entity as public spaces are identified as belonging to both; and
- Whether there are any shared spaces and/or services between the hospital and the other co-located entity.

When surveying physical spaces and locations of a hospital, Surveyors will evaluate whether any clinical care space is being shared between the hospital and the other healthcare entity with which it is co-located. The guidance states that, in general, 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, and post-anesthesia care units. Additionally, the sharing of spaces used for medical records and patient registration could potentially pose risks to patient privacy and likewise may indicate non-compliance with the CoPs.

Given this guidance, hospitals with co-location arrangements should evaluate whether any space meeting the definition of clinical space is shared with another healthcare entity, particularly whether a patient must travel

through clinical space to get to non-clinical space. Where such space is shared, the hospital would need to take steps to limit the shared space only to space that is public space or a public path of travel.

Contracted Staff and Services

A hospital may obtain certain services from other healthcare entities under arrangements, including from co-located healthcare entities. Such services could include food preparation services, laboratory services, pharmacy services, housekeeping, and security services.

In regard to sharing of staff between co-located providers, the guidance makes clear CMS' position that clinical staff cannot "float" between providers. Instead, any such contracted staff must be assigned to work for only one hospital during a specific shift. For example, a hospital must be able to provide nursing services at all times. Where nursing services are shared between two co-located hospitals, CMS opines that neither hospital can meet this standard. The exception to this rule is that medical staff privileged and credentialed at two or more hospitals may be shared between those hospitals.

The guidance for Surveyors states that where a hospital has contracted for services, such as laboratory or dietary services,[3] the Surveyor will ask hospital leadership to provide a list of all services that the hospital has contracted to use from the other co-located entity or healthcare entities. CMS explains this information is critically important as Surveyors must know what specific space/locations to survey and what services are being directly provided by the hospital being surveyed or are being provided by another entity.

With respect to contracted staff, the Surveyor is responsible for surveying the actual physical location where the contracted services (such as the laboratory or kitchen) are being provided if it is physically located and provided on-site. When a contracted service is not located or is not being provided on-site, such as a laundry service for hospital linens, the Surveyor is not required to survey the off-site location.

Surveyors will review the contracts for staffing services with co-located entities to ensure that they provide for the following:

- Adequacy of staff levels;
- Adequate oversight and periodic evaluation of contracted staff;
- Proper training and education of contracted staff;
- Contracted staff have knowledge of and adheres to the quality and performance improvement standards of the individual hospital;
- Accountability of the contracted staff related to clinical practice requirements; and
- That staffing and schedules ensure that staff are immediately available at all times to perform services required by the hospital.

Finally, the Surveyor will ask the governing body to verify that any clinical services being provided under contract from the other entity are not being simultaneously shared with another hospital or entity and, among other criteria, will request staffing schedules to verify that individuals providing contracted services are only scheduled to work at one facility per shift.

Given this guidance, hospitals with co-location arrangements should evaluate their respective services and staffing contracts and ensure that staff are not shared in a manner that prevents the hospital from complying with clinical staffing requirements under the CoPs. Among other staffing-related criteria, each hospital's governing board is responsible for ensuring adequate staffing levels and oversight of contracted staff and must ensure that contracted staff are accountable for their clinical practice requirements.

Emergency Services

Hospitals without emergency departments are required to have appropriate policies and procedures in place for addressing individuals' emergency care needs 24 hours per day, seven days per week. The draft guidance describes CMS' expectations in regard to policies and procedures and notes the circumstances under which a hospital may and may not contract for emergency services from a co-located hospital. Under the draft guidance, a hospital without an emergency department that is 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. However, after initiating treatment, the hospital may transfer a patient to the co-located hospital for further treatment if appropriate.

When evaluating the emergency care of patients in a hospital without an emergency department that is co-located with another healthcare entity, the Surveyor will review for the following:

- Whether the hospital responds to its own patients in hospital emergencies, with its own trained staff (not another hospital's or entity's staff);
- Whether the hospital has the proper emergency equipment in the event that a patient requires resuscitation;
- Whether hospital staff is properly trained in the use of the emergency equipment;
- Whether the hospital's emergency equipment properly maintained; and
- Whether the hospital's staff is properly trained for appraisal of emergencies, initial treatment, and referral when appropriate.

If the hospital has no emergency department, but has its emergency services provided under a contract with an emergency department of a co-located hospital, the Surveyor will verify that the hospital meets the Emergency Medical Treatment & Labor Act requirements. Where emergency services are provided by staff under contract, the Surveyor will verify that staff are immediately available at all times and only committed to services at that hospital during those time.

CONCLUSION

Hospitals have long awaited formalized co-location guidance from CMS. This draft guidance represents a notable departure from the agency's prior position on shared spaces. As discussed above, if finalized, this guidance would give co-located providers the ability to share public areas and public paths of travel and is likely to allow hospitals to make structural changes that promote greater care coordination and enhance patient-centered care, although it may not provide as much flexibility as some providers would like. If finalized, hospitals should perform a

comprehensive review of their co-located spaces and shared personnel and services to ensure compliance with this guidance and to be prepared to provide the documentation and floor plans anticipated to be requested upon survey.

CMS is accepting comments on this draft guidance until July 2, 2019. Comments should be submitted to HospitalSCG@cms.hhs.gov. Contact the authors of this article or your K&L Gates attorney with questions related to the draft guidance or co-location of hospitals and healthcare entities.

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[1] Memo to State Survey Agency Directors, DRAFT ONLY- Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities (QSO-19-13-Hospital) (May 3, 2019).

[2] Please note this guidance also does not address other rules that might apply to co-located hospitals, such as the hospital-within-a-hospital rules or the satellite facility rules. *See* 42 C.F.R. 412.22(e), (h).

[3] In addition to the co-location guidance, Surveyors evaluate compliance with the CoPs through the use of contracted services can be evaluated by following the interpretive guidance and survey procedures under 42 CFR §§ 482.21, 482.12(e). These regulations require that Surveyors ask to see documentation as to how the contracted services are incorporated into the hospital's quality assessment and performance improvement program.

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