CMS Issues Final Guidance Allowing Flexibility for Co-Locating in Hospital Space

Insights 12.13.21

PROFESSIONAL

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On November 12, 2021, nearly two-and-a-half years after releasing draft co-location guidance (Prior Draft Guidance), the Centers for Medicare & Medicaid Services (CMS) released its long awaited final Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities (Final Guidance).[1] The Final Guidance seeks to clarify how CMS and state surveyors will evaluate sharing of hospital space, services, personnel, and emergency services in compliance with the hospital Medicare Conditions of Participation (Hospital CoPs)[2] and was welcome news to many hospitals and other providers—reversing prior sub-regulatory guidance that prohibited co-location within hospital space.

The Final Guidance expressly allows hospitals to co-locate with other "health care providers" so long as the co-location arrangement does not risk compliance with Hospital CoPs—providing flexibility for hospitals to enter into mutually advantageous co-location arrangements. Unfortunately, in a deviation from the Prior Draft Guidance, and without explanation, CMS excluded private physician offices (including those participating in timesharing or leasing arrangements) from the definition of "health care providers" permitted to co-locate in hospital space "for the purpose of this [Final Guidance]." The final guidance also excludes Critical Access Hospitals (CAHs) from participating as a co-locating "health care provider" based on the specific distance and location requirements applicable to CAHs. It is unclear whether CMS intended this as a prohibition on hospitals co-locating with physician offices and CAHs, or whether CMS expects to apply different rules and standards to those co-location arrangements.

Sharing of Physical Space

One of the most substantive components of co-location analysis is the physical space shared by the two providers. Since previous CMS policy prohibited hospitals from sharing space with other providers, each provider's space had to be completely bifurcated between them (separate hallways, waiting rooms, restrooms, etc.). When first proposing greater flexibility in the Prior Draft Guidance, CMS differentiated between defined and distinct spaces such as nursing units and other clinical care space (over which the hospital must maintain control at all times), on the one hand, and permissible types of non-clinical shared spaces, such as main hallways, public lobbies, waiting rooms, and public restrooms, on the other hand. Emphasizing the clinical nature of the distinct spaces as designated for patient care, and requirements to protect patients (including their right to personal privacy and to receive care in a safe

environment), the Prior Draft Guidance provided several examples of what would and would not be permissible shared space locations. For example, the Prior Draft Guidance noted that travel between separate entities utilizing a path through *clinical* spaces of a hospital by another entity co-located in the same building would not be considered acceptable, but that a shared public path of travel through a main hospital corridor with distinct entrances to departments would be permissible.

Unfortunately, CMS scaled back significantly on the guidance regarding shared space in their Final Guidance, including eliminating mention of the differentiation between shared and distinct space, as well as other clarifying references to "public spaces" and "public paths of travel" and examples of types of sharing that would or would not be acceptable. CMS did, however, implicitly acknowledge that sharing of supply storage space, where each hospital identifies their supplies separately, would be permissible, noting that a water leak dripping on sterile packeted supplies in that storage room could lead to a physical environment and infection control deficiency for the hospital (and potentially for the other co-located provider).

The Final Guidance does not focus on the actual nature of the sharing of physical space. In fact, it eliminates the requirement from the Prior Draft Guidance that surveyors review a floor plan showing the space utilized by each of the co-located providers. Instead, the Final Guidance instructs surveyors to evaluate more generally as to whether the hospital being surveyed can demonstrate compliance with the Hospital CoPs. In determining whether the nature of a hospital's co-location might risk compliance with those requirements, CMS notes considerations such as patient rights, infection prevention and control, governing body, and physical environment. If any shared spaces are found to be in violation of any of the Hospital CoPs, both providers may be found to be non-compliant and cited.

Notwithstanding CMS' limited illustrations of permissible space sharing in the Final Guidance, their examples from the Prior Draft Guidance are still helpful guideposts to those looking to enter into co-location arrangements. For example, it would be best practice for a shared reception area to have separate patient check-in desks that are clearly labeled, and for shared hallways to have clear signage on doors leading to the respective provider's clinical space, so it is clear to the public which functions are performed beyond the door and the provider that is performing them (e.g., laboratory, outpatient clinic, pharmacy, radiology, etc.).

Other Shared Arrangements

The Final Guidance also addresses co-location in the context of contracted services, staffing, and emergency services.

With respect to services required for compliance with Hospital CoPs, such as laboratory, dietary, pharmacy maintenance, housekeeping, and security services, CMS affirmed that hospitals may provide these services either directly or under contract with another entity (co-located or otherwise). Likewise, hospitals may satisfy the Hospital CoPs staffing requirements by either directly providing the staffing for the services, or indirectly through staffing arrangements with other providers (co-located or otherwise).

A seemingly helpful change was the elimination of those portions of the Prior Draft Guidance that prohibited staff from simultaneously providing services to both co-located providers (though staff members could work for both providers, just not during the same shift). The Final Guidance instead simply requires hospitals to evidence that the hospital's staff are meeting the needs of patients for whom they are providing care, while continuing to meet statutory and regulatory staffing requirements for the activity. By eliminating the express prohibition on "floating" between the two co-located providers, it appears that CMS may be acknowledging that, under certain circumstances, co-located hospitals may be able to independently meet their requirements even if certain staff are floating between co-located providers during a shift. On the other hand, it is possible that CMS removed the examples because of a reluctance to provide specific guidance that goes beyond the literal language of the applicable regulations, rather than signaling approval of certain staff "floating" between the co-located providers.

CMS does expressly require that the training and education provided to contracted staff must be the same as that provided to directly employed staff, to ensure the same quality of care and services are provided. The governing body of the hospital

remains responsible for adequacy of staffing levels, oversight and evaluation, proper training and education, adherence to quality and performance improvement standards, and accountability to clinical practice requirements, even as to contracted staff.

In the portion of the guidance dealing with emergency services, CMS eliminated references from the Prior Draft Guidance that restricted a hospital's use of staff from a co-located hospital to respond to emergencies, and instead refers more generally in the Final Guidance to ensuring that the hospital has policies and procedures in place to address emergencies for the patient population the hospital typically cares for.

CMS also scaled back the Prior Draft Guidance by eliminating various other specific requirements of surveyors that were included, such as requiring that the surveyors obtain a list of all services that the hospital contracts out to co-located or other entities; review staffing contracts, staff schedules, and samples of personnel files; and interview the governing board, to ensure that the governing board is meeting its responsibilities. Of course, surveyors may nevertheless do so when conducting surveys.

The Final Guidance, which is effective immediately, is intended for surveyors of hospitals and will be incorporated into the CMS State Operations Manual Appendix A for Hospitals. It does not address the specific location and separateness requirements of other Medicare-participating entities, such as psychiatric hospitals, ambulatory surgical centers, rural health clinics, and Independent Diagnostic Testing Facilities.

Overall, this new guidance does offer flexibility for hospitals wishing to co-locate with other providers, but it still leaves uncertainty about how CMS will view co-location with private physician offices and CAHs, as well as same-shift staff floating arrangements between co-located providers. The key takeaway if considering co-location is that these arrangements need to be entered into carefully. Each co-located facility will need to ensure it can independently demonstrate satisfaction with its respective requirements when being surveyed and watch out for pitfalls that could cause both of the co-located entities to wind up with condition-level deficiencies that put their provider status at risk. Also, state licensing regulations may prohibit co-locations that are otherwise permissible under CMS guidance.

[1] Available at https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf .

[2] 42 C.F.R. pt. 482.

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