CMS Releases Long-Awaited Final Hospital Co-Location Guidance

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On Friday, November 12, 2021, the Centers for Medicare & Medicaid Services ("CMS") released a Quality, Safety & Oversight Group memorandum finalizing its hospital co-location guidance, titled "Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities" (the "Final Guidance"). The Final Guidance updates and finalizes CMS's previous draft guidance released May 3, 2019 (the "Draft Guidance") instructing surveyors regarding requirements for complying with the hospital conditions of participation ("CoPs") for hospitals co-located in the same building or on the same campus with other hospitals or providers.

CMS's co-location guidance affords hospitals and their co-located providers certain flexibilities with co-location arrangements, while ensuring the provision of safe and high quality care to patients. The Final Guidance emphasizes that hospitals and their co-located hospitals or other providers are required to be in compliance with Medicare regulations, including the CoPs, conditions of coverage and other regulations, as well as other applicable federal and state laws.

Of note, the Final Guidance is not as prescriptive as the original Draft Guidance. In the Final Guidance, CMS has removed many of the specific examples that were discussed in the Draft Guidance, and appears to defer more broadly to hospitals and their co-located providers in identifying arrangements that create efficiencies when sharing space while also staying in compliance with regulations. The scaled back Final Guidance is consistent with recent agency steps to comply with the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), which strengthened notice-and-comment rulemaking requirements under Medicare and has caused the agency to walk back certain guidance that goes beyond the four corners of applicable regulations. A redline comparing the Final Guidance to the Draft Guidance is available here.

In sum, as detailed below, the Final Guidance makes clear that each co-located provider type is required to be independently compliant with the regulations specific to their participation in Medicare. This final guidance, however, only addresses assessment and enforcement of the hospital CoPs (42 C.F.R., Part 482), and does not address other regulations, such as the separateness requirements for psychiatric hospitals and ambulatory surgical centers. The Final Guidance will be incorporated into the CMS State Operations Manual Appendix A for Hospitals, available here.

Application

The CMS co-location guidance is applicable to hospitals, or parts of hospitals, that are co-located with other hospitals or health care providers. The co-located services provided by either of the co-located providers may be inpatient, outpatient, or a combination of both. Providers subject to the Final Guidance that can be co-located with hospitals may include the following types of Medicare-participating facilities, among others:

- Parts of or all of separately certified hospitals, including acute care, cancer, children's, long term care, psychiatric, and rehabilitation hospitals;

- Ambulatory surgical centers (ASC);
- Rural health clinics (RHC) and federally qualified health centers (FQHC); and
- Independent diagnostic testing facilities (IDTFs).

In the Final Guidance, CMS clarified that its hospital co-location guidance does not apply to:

- Critical access hospitals (CAHs); or
- Private physician practices in leased or shared space agreements in hospitals.

Key Provisions

Healthcare Providers — In the Final Guidance CMS specifies that it applies only to co-location arrangements with Medicare certified providers/suppliers (i.e., hospitals, ASCs, RHCs, etc.), but not to physician practices. Although CMS has said as much in informal settings since issuing the Draft Guidance, this is the first official statement to this effect. Nevertheless, one of the most common co-location arrangements in the industry is an off-campus, provider-based hospital outpatient department being co-located in a medical office building that also houses private physician practices. We submit that if a surveyor were to perform a site visit of such a facility, it would be within the surveyor's jurisdiction to cite the hospital's non-compliance with CoPs even though the surveyor has no such jurisdiction over the co-located private physician practice. Moreover, even if the Final Guidance, by its own terms, does not apply to physician practices, it seems fairly likely that someone (e.g., a whistleblower or the MAC) may utilize the Final Guidance as determining whether co-located off-campus provider-based space is sufficiently distinct to remain hospital space 24/7.

Space — CMS instructs surveyors not to focus on the actual sharing of physical space but instead to assess whether the hospital or its co-located provider can demonstrate compliance with the regulations independently. Specific considerations for evaluation when providers are co-located include compliance with the patient rights, privacy, infection control and prevention, physical environment, and governing body CoPs. Notably, CMS deleted the entire discussion in the Draft Guidance that had set up a dichotomy between shareable public spaces and travel paths (e.g., lobbies, waiting areas with separate check-in desks, public restrooms, and public corridors) versus clinical spaces that CMS had said should not be shared (e.g., exam rooms and areas where patients are receiving care and treatment, including hallways located within clinical departments). Rather, the Final Guidance leaves it to hospitals to consider and ensure compliance with the relevant hospital CoPs. That said, the examples in the Draft Guidance may still prove useful as guideposts in assessing the appropriateness of co-located provider space. Importantly, CMS notes that any identification of non-compliance for one provider may also result in non-compliance for the co-located provider when sharing space and facilities.

Contracted Services — One or both of the co-located providers may utilize contracts for any number of services provided to patients and staff, including food preparation and delivery services, utilities, fire detection and suppression, medical gasses, suction, compressed air, and alarm systems. The providers may even contract with their co-located provider for such services. The hospital governing body CoP addresses the use of contracted services (42 C.F.R. § 482.12(e)). The Final Guidance states simply that this same CoP and associated guidance on the use of contracted services that applies in single-site settings also applies in co-located arrangements. Providers must comply with all requirements, whether services are provided directly or through contracts.

Staffing — The hospital and its co-located provider must independently meet staffing requirements for services offered by each facility. Adequate staffing may be achieved through employed and contracted staff, which may include

contracts with the co-located provider. Whether employed or contracted, staff providing services in each facility must receive training and education on their facilities policies and procedures, be periodically evaluated and assessed for competency, and support quality improvement activities to ensure the provision of safe and high quality care to their patients. In the Final Guidance, CMS has deleted language in the Draft Guidance that had expressly prohibited shared hospital staff who service both co-located providers (e.g., medical staff and/or nursing, laboratory, and pharmacy personnel) from providing services simultaneously to both or providing concurrent "on call" services for both facilities. As noted above, the removal of these examples may be due more to CMS's reluctance to provide specific guidance that goes beyond the literal language of the applicable regulations than CMS signaling its approval of staff "floating" between co-located providers during the same shift. Rather, the Final Guidance puts the onus squarely on hospitals to assess and ensure compliance with the CoPs governing medical staff, nursing services, and contracted services generally. As with the now-deleted Draft Guidance examples regarding shared space, providers may still want to consider CMS's previously offered examples of compliant (and non-compliant) arrangements go-forward. The staffing requirements for co-located providers, including the use of employed or contracted staff, apply to both clinical and non-clinical settings.

Emergency Services — Hospitals that do not have an emergency department, or a "dedicated emergency department" as defined by the Emergency Medical Treatment and Labor Act (EMTALA), must still have policies and procedures to address responding to emergency situations in their own facilities. That is, in co-location arrangements, each separately certified provider must have such emergency response policies and procedures in place. These policies may include the transfer of patients or other individuals (e.g., staff, visitors, volunteers, students) from one provider to the other in order to meet the emergent needs of those impacted. Hospitals that offer emergency services through an emergency department must comply with the emergency services CoP and EMTALA.

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The Final Guidance provides instructions for surveyors when assessing compliance with hospital requirements in co-location situations. The important takeaway of the CMS memorandum and guidance is for each co-located facility to ensure they are independently meeting their own requirements, whether hospital, ASC, RHC or other, and be able to demonstrate such when surveyed. While the Final Guidance focuses chiefly on the hospital being surveyed, it also notes that non-compliance identified with respect to shared spaces or services in one provider may also result in a complaint being filed for the co-located provider, and ultimately could place both providers at risk, up to and including the potential loss of Medicare and Medicaid funding.

The Dentons Health Care Group provides timely updates and insights on Medicare and Medicaid issues and is available to assist with policy interpretation and implementation.

Your Key Contacts

Susan Banks
Partner, Denver
D +1 303 634 4329
susan.banks@dentons.com

Holley Thames Lutz
Partner, Washington, DC
D +1 202 408 6836
holley.lutz@dentons.com

Mary Ellen Palowitch
Senior Managing Director,
Washington, DC
D +1 202 496 7004
M +1 410 533 4468
maryellen.palowitch@dentons.com