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CMS Leaves Hospitals Guessing on Expectations for Compliant Co-Location Arrangements

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On November 12, 2021, the Centers for Medicare and Medicaid Services (CMS) released an updated version of its Quality, Safety and Oversight Group memorandum, QSO-19-13-Hospital, containing much-anticipated final guidance on how state surveyors are to evaluate hospital compliance with Medicare hospital conditions of participation (CoPs) in connection with hospital co-location arrangements with other hospitals and "healthcare providers." Co-location arrangements refer to any arrangement under which a hospital shares space, services, staff or emergency response services with another healthcare entity. The final guidance removes most examples of compliant and noncompliant co-location arrangements from the draft guidance and instead provides only general statements that hospitals are expected to ensure that any co-location arrangements in which they are engaged, comply with the requirements of 42 CFR Part 482. Adding further uncertainty to the post-guidance requirements, CMS explicitly excluded critical access hospitals and private physician offices from the definition of "healthcare providers" for purposes of the guidance, but did not explain whether this exclusion means that co-location arrangements with these entities are prohibited or that the final guidance should not be used to evaluate co-location arrangements with these entities.

With the release of the final guidance, hospitals should take the opportunity to evaluate their co-location arrangements and develop documentation supporting their interpretation of the CoPs governing co-location arrangements generally, and specific support and analysis for each co-location arrangement in which they participate.

Background

Hospitals that participate in the Medicare program are required to comply with the Medicare hospital CoPs. The hospital CoPs are certification standards that a hospital must meet in order to participate in the Medicare program. The CoPs are typically interpreted by CMS, but accrediting organizations (AOs) such as The Joint Commission have accreditation standards that align with the CMS requirements. Compliance with hospital CoPs is typically assessed during surveys by state agencies or, for accredited hospitals, through The Joint Commission or other AO surveys. Surveys may also be

performed following certain types of patient safety complaints or alleged EMTALA violations. Continued noncompliance with the CoPs and failure to take corrective action to the satisfaction of CMS can result in termination from the Medicare program.

Beginning in 2015, CMS staff publicly presented CMS's views on how certain hospital co-location arrangements may result in noncompliance with the CoPs. The presentations, memorialized in PowerPoint slide decks rather than more formal guidance documents, established principles of co-location such as "hospital space must be hospital space 24/7" and "hospitals must demonstrate 'independent compliance' with the CoPs." These served as the basis for hospitals' understanding of the general guardrails for establishing compliant co-location arrangements. Hospitals and other stakeholders expressed concerns that CMS should not "regulate by PowerPoint" and argued that if CMS intended to take enforcement action under the CoPs against hospitals engaging in co-location arrangements, it needed to more formally issue its interpretation of how the CoPs should be applied to co-location arrangements.

In May 2019, CMS released more formal draft co-location guidance in the form of a Quality, Safety and Oversight Group memorandum, addressed to state survey agency directors. These memos provide guidance and instructions to state survey agencies that are tasked with overseeing hospital compliance with the CoPs, but also are relied on by hospitals to understand CMS compliance expectations. The draft co-location guidance was generally consistent with the preceding PowerPoint guidance. Click here for our summary and analysis of the draft co-location guidance, including specific examples of permitted and prohibited co-location arrangements. CMS sought public comment on the draft co-location guidance.

Final Co-Location Guidance

The final co-location guidance incorporates many material changes from the draft co-location guidance. At a high level, the final guidance eliminates many of the specific examples of prohibited or permitted arrangements provided in the draft guidance and replaces the examples with a hospital's general requirement to comply with the hospital CoP regulations, as well as any other statutory or regulatory requirements that may apply (without identifying what those may be). The final guidance also excludes critical access hospitals and private physician offices from the definition of "healthcare providers" as used in the final guidance, rendering the guidance unclear as to whether co-location arrangements with these entities are regulated, and if so, how they should be assessed under the CoPs.

Space

Prior to the issuance of the final guidance, CMS articulated specific examples of hospital locations that could and could not be shared. The final guidance removes the examples and requires hospitals to consider whether the co-located space results in risks to compliance with the CoPs. The final guidance suggests that hospitals evaluate CoPs related to patient rights, infection prevention and control, governing body and/or physical environments, "among others." However, CMS does not articulate how these CoP requirements should be applied to shared space, other than to indicate that hospitals should "demonstrate their compliance to protect and provide a safe environment for their patients, including but not limited to, their right to personal privacy and to receive care in a safe environment . . . and right to confidentiality of patient records." This is a departure from the draft guidance, which included specific information on which spaces would be considered clinical space (and therefore not able to be shared) and nonclinical space (which generally could be shared).

Contracted Services

CMS made the most limited changes between the draft and final guidance in the contracted services section and retained all of the examples of services that a hospital may obtain under contract from the draft guidance. Hospitals are permitted to obtain services under contract and many of the most commonly-contracted services are included in the examples. Consistent with the general principles under the CoPs, but not explicitly stated in the draft guidance, the final guidance requires that a hospital evaluate all contracted services under the "governing body" CoP to ensure that the services are provided under the oversight of the hospital's governing body.

Staffing

CMS made material changes to the staffing requirements in the final guidance, including removal of references to hospitals being required to "independently" meet staffing CoPs and deletion of the restriction on hospital staff "floating" between the hospital and another entity. This change appears to open up opportunities for significantly more flexible staffing arrangements, so long as the arrangements are supported by "evidence that the hospital's staff are meeting the needs of the patients for whom they are providing care."

Emergency Services

The final guidance removes references in the draft guidance to restrictions on hospitals using staff from a co-located hospital to respond to emergencies and replaces these references with more general statements about a hospital's obligation to ensure that policies and procedures are in place to address potential emergency scenarios typical of the patient population. The final guidance reiterates that hospitals that provide emergency services are required to comply with EMTALA.

Analysis

The final guidance will come as a relief to many hospitals, while simultaneously creating frustration and confusion. Although many hospitals and stakeholders viewed the bright lines provided in the draft guidance (and preceding PowerPoint guidance) as overly prescriptive, burdensome and outside of CMS's authority to implement through sub-regulatory guidance, the final guidance generally refers back to the CoP regulations, without additional insight into how these requirements may be applied by CMS or state surveyors. Surveyors and AOs retain discretion with respect to how to apply this final guidance to hospitals, and the guidance does not significantly clarify how hospitals should comply with the CoPs for co-location arrangements. This could lead to inconsistent results where co-location concerns are identified as part of a survey.

In particular, the clarification that the final guidance does not apply to critical access hospitals or private physician offices creates confusion about how co-location arrangements that involve, for example, a hospital outpatient department that is co-located with an affiliated physician practice will be evaluated. The final guidance suggests, but does not confirm, that CMS is more concerned with arrangements where two separately enrolled facilities, such as two separately enrolled hospitals, or a hospital and another facility such as an ambulatory surgery center or rural health clinic, are co-located or share services. The few remaining examples included in the guidance focus on co-location arrangements with separately enrolled hospitals, as opposed to arrangements involving a hospital and a physician practice group.

The final guidance appears to remove many of the most controversial aspects of the draft guidance,

including the restrictions on comingling of hospital space with space used by other healthcare providers, “floating” nursing staffing arrangements between a hospital and another healthcare provider, and use of staff from a co-located hospital to provide rarely needed services (*e.g.*, “code teams”). Notably, however, the final guidance also appears to place the burden on hospitals to demonstrate how their co-location arrangements meet the applicable CoPs, including the CoPs related to nursing services and emergency services. The final guidance also removes necessary insight into how CMS may interpret the CoPs with respect to co-location arrangements and does not provide guidance on how surveyors may apply the CoPs.

Hospitals should be aware that statutes, regulations and guidance outside of the CoPs may be implicated by co-location arrangements. For example, although CMS removed references to specific co-located space arrangements from the final guidance, many of the arrangements that were previously restricted under the draft guidance may remain prohibited by state licensure laws or other Medicare program rules, such as the Medicare provider-based rules.

The issuance of the final guidance provides an opportunity for hospitals to review and evaluate their current co-location policies and arrangements. In light of the issuance of the final guidance, hospitals should implement (or update) policies and procedures for co-location arrangements that are consistent with the final guidance, including developing and maintaining documentation of all co-location arrangements and the legal support for how a hospital’s co-location arrangements comply with the CoPs.

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