United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

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VIA ELECTRONIC TRANSMITION

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: [QSO-19-13-Hospital] Draft Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities.

Dear Administrator Verma:

Co-location and shared space arrangements under the Medicare program allow hospitals to share space, services and staff with other providers. Hospitals located in rural and frontier communities often choose to enter into these special arrangements with other hospitals, hospital systems, or providers of care in order to offer a broader range of medical services that best meets the unique needs of their patient populations. For example, a rural hospital may lease space once a month to medical specialists from out of town, such as an orthopaedic surgeon, a cardiologist, an endocrinologist, or a behavioral health care provider. These types of co-location and shared space arrangements benefit Medicare patients living in rural and frontier areas by increasing access to specialized medical care, improving care coordination services, and offering more convenient care options as close to home as possible.

Hospitals that want to enter into a co-location or shared space arrangement with another hospital or provider typically work with either a state health department or a contracted Centers for Medicare and Medicaid Services (CMS) agency, accreditor or regional office to make sure that the new arrangement meets Medicare requirements. In May of 2015, however, inconsistent statements made by CMS led to a lack of clarity for hospitals as to how they can enter into co-location and shared space arrangements while maintaining compliance with the conditions of participation (CoPs) for hospitals under the Medicare program under part 482 of title 42, Code of Federal Regulations (CFR) or any successor regulations.

Currently hospitals do not have a complete understanding of what standards constitute separateness, when separate entrances may be required, which types of services may be shared, and how adequate levels of public awareness are reached when one provider leases space to another provider. One thing is clear: rural and frontier hospitals face unique health care delivery challenges that co-location and shared space arrangements can help them overcome. However, out of an abundance of concern, and in the absence of clear direction, some hospitals have begun to unwind or completely dismantle their co-location or shared space arrangements.

On May 3, 2019, CMS released draft guidance seeking to clarify how the agency and state surveyors will evaluate the use of shared space, shared staff, and contracted services by hospitals co-located with another hospital or health care entity.[1] The draft guidance is welcome and necessary. Having long pressed CMS to modernize and improve its existing co-location policy, I applaud the Administration for taking meaningful action to stem hospital and provider confusion surrounding this matter.

The CMS draft guidance represents a significant update to previous sub-regulatory interpretations which may have unintentionally resulted in Medicare beneficiaries, especially those patients living in rural and frontier areas, having difficulty accessing needed medical care. It seeks to clarify compliance, streamline the survey process, prioritize patient care, ensure patient safety and mandate facility accountability – all without increasing provider regulatory burden. By better defining and clarifying allowable co-location and shared space arrangements, CMS is giving hospitals and health systems much needed flexibility and operational certainty when they choose to partner with other health care entities.

During my substantive review of the draft guidance, however, I do believe increased specificity and flexibility in four key areas is necessary to ensure hospitals understand exactly what co-location activities are allowed and those that are not. Clarification is critical to enable successful implementation of any proposed regulatory updates. I respectfully commend the following policy concerns to your attention, which I believe must be addressed prior to CMS finalizing its guidance.

Definitions

CMS incorporates several technical terms into its draft guidance, but does not explain them. CMS should insert a definitions section into a final guidance document. Doing so would improve provider understanding of its policy proposals. Examples include the following:

- Health Care Entity. It is unclear what constitutes a health care entity. CMS should outline what types of hospital and physician providers meet this criteria.

- Distinct Space. Distinct spaces are typically non-public, clinical settings designated specifically to furnish medical care. CMS should define this term to prevent provider confusion.

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[1] United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, *Draft Policy Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities*, Reference Number QSO-19-13-Hospital, May 3, 2019.

- Staffing Contracts. Health care providers enter into various contractual agreements in order to furnish medical care or administrative services in co-located facilities. CMS should also define this term to prevent provider confusion.

- Duty Hours. Hospitals and providers independently decide their staff work schedules and shift lengths. In fact, certain health care professionals work on specialized units (such as surgery, intensive care, or dialysis) which require them to be on call after a regularly scheduled shift ends. Due to varying work hours, CMS should define the term "shift" to clarify what shared staff floating between co-located entities is permitted and what is not.

- Emergency Services. Hospitals provide swift medical attention to any individual experiencing an emergency no matter where it may take place within the facility. This often requires initial assessment, preliminary treatment, resuscitation, stabilization, and transfer to a co-located health care facility for additional care services. The draft guidance does not define either the term "emergency services" or the term "emergency department". CMS should clarify its terminology so that hospitals and providers understand the specific situations that would trigger Emergency Medical Treatment and Labor Act (EMTALA) obligations.

Distinct Space and Shared Space Patient Travel

Medicare evaluates each participating hospital to determine its compliance with the program's CoPs. Co-located hospitals are expected to maintain control over both distinct spaces and shared spaces of operation at all times. Distinct spaces are non-public clinical settings designated to furnish medical care. They are necessary in order to protect patient safety, confidentiality, and security. Shared spaces, such as main building entrances, lobbies, elevators, public restrooms, and staff lounges, are common areas and paths of travel utilized by both co-located facilities.

On pages 1-2 of the draft guidance, CMS states that patient travel through shared clinical spaces may pose an infection control risk. I fully support the agency's primary mission to protect patient safety, care quality, and confidentiality. That said, I have heard from multiple stakeholders concerned that there are certain patients who might be better served if allowed to travel through appropriate clinical shared spaces in order to receive needed services. Let me be clear: I do not support unsupervised, general population travel through clinical areas of a co-located hospital. I would ask the agency, however, to carefully consider if there are any appropriate circumstances in which co-located facilities should be allowed to coordinate with each other in implementing a streamlined patient travel plan that reduces administrative burden while ensuring complete facility compliance with Medicare's CoPs in the clinical common areas outlined in the draft guidance.

Staffing Contracts

Each hospital that participates in the Medicare program is required to meet specific staffing requirements. This applies to all services that the hospital furnishes – whether the staff member providing the service is employed by the hospital, through an arrangement with a co-located hospital, or under contract with another entity. The draft guidance states that certain providers who offer services in both co-located facilities, such as nurses, are prohibited from doing so

concurrently. Those staff members can only work for one health care entity during a shift and are not allowed to "float" between the co-located facilities.

It is vital that each facility's staffing levels are adequate and that contracted workers are properly trained in their duties. The draft guidance goes on to state, however, that governing body approved medical staff can be shared or "float" between co-located hospitals if they are privileged and credentialed at each facility. Hospitals and health care entities could assume that this ambiguous language refers to physicians, physician assistants, nurse practitioners, and other similarly trained medical staff. I believe it is imperative that the final guidance identify the specific medical personnel allowed to "float". Many rural and frontier hospitals and providers may, out of an abundance of caution, decline to offer co-located services if they are not absolutely certain which medical staff are permitted to "float" and which ones are not.

Emergency Services

The draft guidance contains several policies that outline how co-located hospitals and health care entities may furnish emergency services. I would ask CMS to refine and clarify this proposed language in order to reduce provider confusion. Hospital emergency departments furnish services to individuals coming to the facility from the community who are experiencing an urgent medical event. They also provide care to patients admitted to the hospital who may experience an emergent event. Because an emergency can occur anywhere in a hospital setting, it is important that the Agency clarify its terminology in order to reflect policy intent. Doing so will go a long way toward helping hospitals and other health care entities that want to enter into co-location and shared space arrangements be better equipped to make informed compliance decisions.

CMS faces a difficult task to finalize clear co-location standards that can apply to a wide range of administrative and clinical situations. I appreciate the agency offering Congress and health care stakeholders the opportunity to provide constructive policy feedback as we work toward a mutual goal: appropriate, practical, and innovative co-location requirements. Upon the issuance of final guidance, I ask that CMS conduct robust education and outreach not only to hospitals, hospital systems, and other health care entities, but also to surveyors. The surveyors must receive in-depth training to ensure accurate and uniform implementation of the new requirements.

Thank you for your consideration of these comments. Should you have questions, please contact Erin Dempsey of my Finance Committee staff at 202-224-4515.

Sincerely,

Chuck Grassley

Senator Charles Grassley (R-IA)
Chairman
Senate Committee on Finance