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July 2, 2019

Ms. Karen Tritz
Acting Director
Quality, Safety, and Oversight Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
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SUBJECT: ***DRAFT-QSO-19-13-Hospital; Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities***

Dear Acting Director Tritz:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) Center for Clinical Standards and Quality, Quality, Safety, and Oversight Group, on the above referenced draft revisions to the State Operations Manual (SOM), issued to State Survey Agency directors in a May 3, 2019, Memorandum. The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute and ambulatory services.

As noted in the May 3, 2019, Memorandum, CMS is focused on ensuring the health and safety of patients as it relates to the use of shared space and contracted services by hospitals co-located with another hospital or health care entity. CMS is committed to providing the information hospitals need to make decisions about how they partner with other providers in the health care system to deliver high-quality care. CMS intends to provide clarity on how hospitals

may partner with other hospitals or health care entities and share space and contracted services while ensuring the health and safety of patients. The FAH commends CMS's efforts and leadership in this regard and appreciates the opportunity to comment on the draft guidance providing detail as to how shared space arrangements will be evaluated for compliance with the Medicare Conditions of Participation (CoPs). The FAH strongly supports CMS's proposed approach to allow flexibility in hospital partnerships while prioritizing patient care and safety.

The FAH welcomes the additional guidance CMS proposes that would clarify the compliance expectations for hospitals that are co-located with other health care entities. CMS's proposal to provide increased flexibility for co-located entities is beneficial to hospitals and the patients they treat. It has been a longstanding practice of hospitals to share space with other hospitals or health care entities through co-location arrangements. In particular, hospitals commonly share the use of waiting rooms, admitting/reception areas, and main corridors with other providers. The FAH appreciates CMS's recognition of the role co-location arrangements play in the delivery of quality health care.

SPECIFIC RECOMMENDATIONS

"Grandfathering" Exemption

As a general rule, CMS proposes to allow the sharing of public spaces, rather than clinical spaces. The FAH believes it is important to note that some co-location arrangements have been in place for years, if not decades. Some of these relationships exist in older buildings that pre-date any official CMS guidance on co-located space arrangements. Older hospital facilities that have implemented shared space arrangements may face challenges separating public spaces from clinical spaces as contemplated by the draft guidance. Some challenges may arise given the design of older floor plans that may contain corridors that pass by clinical areas and that CMS may not consider non-public under the guidance, as proposed. For example, the design of the building may preclude access to key elevator banks without walking past certain patient care areas. Reconfiguring a hospital building in these cases could be cost prohibitive.

As such, the FAH requests that CMS create a narrow "grandfathering" exemption as part of the final guidance for co-located facilities in existence prior to the release of the final guidance. This exemption would ensure that future co-location arrangements comply with the final guidance, but would not apply overly-restrictive new requirements on co-location arrangements that exist currently and have successfully been surveyed without raising patient safety concerns.

If CMS does not agree that an exemption is needed, the FAH urges CMS to create an exception process for co-located facilities that have been in existence for a minimum number of years (*e.g.*, five or more) prior to the release of the final guidance. This process would offer needed flexibility in order to maintain those co-location arrangements that were established years ago to provide needed services to patients, without requiring possible major construction to address potential issues that would be created by this guidance if finalized as proposed without an exceptions process. Failing to provide an exception process could cause hospitals with older buildings to be deemed in technical non-compliance, notwithstanding the fact that the providers

have been successfully surveyed by multiple agencies for many years, no concerns over patient care have been raised, and the providers meet the spirit of the CoPs from a health and safety perspective.

The proposed guidance indicates that each party to a co-location arrangement must demonstrate separate and independent compliance with the hospital CoPs. However, the proposed guidance does not indicate a timeframe for hospitals to come into compliance, once the guidance is finalized. **The FAH suggests that CMS specify in any final guidance an appropriate timeframe for entities to comply with the guidance, once finalized.** This recognizes that some entities may need time to comply, particularly if the grandfather provision or exceptions process discussed above is not included in the final guidance.

Timeshare Arrangements

The FAH seeks clarification regarding the use of timeshare, block lease, or similar arrangements, under which hospitals lease clinical space, equipment, and staff to specialists and other practitioners. Timeshare arrangements can include visiting clinician arrangements, where clinicians lease space from a hospital, as well as lease arrangements, where different clinicians lease the same space on different days. These arrangements improve access to care for patients, particularly in rural areas, by ensuring that patients in underserved communities are able to seek care from specialists in their communities without traveling long distances. Timeshare arrangements also improve coordination of patient care, consistent with CMS goals, by allowing patients to access care for different specialties in the same setting and not segmenting care across multiple provider locations. Finally, these arrangements allow for a more efficient use of what might otherwise be dormant space.

CMS has recognized the importance of timeshare arrangements in promoting access to care through its enforcement of the physician referral law (Stark law). In addition to permitting part-time block leases for physicians, CMS implemented an exception to the Stark law allowing hospitals and physicians to share space, equipment, personnel, items, supplies, and services through timeshare arrangements, under certain conditions.[1] In promulgating this exception, CMS stated its belief that timeshare arrangements "may improve access to needed care, especially in rural and underserved areas, by facilitating part-time or periodic access to physicians in communities where the need for the physician is not great enough to support the full-time services of the physician or where physicians, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement."[2] Improving access to care is a guiding principle for CMS, and encouraging timeshare leases is an important mechanism to maintain access to care.

Consistent with CMS's historical commitment to supporting timeshare arrangements to promote access to care, the FAH believes that CMS should clarify that timeshare arrangements are not considered co-located arrangements and, therefore, are not subject to co-location compliance obligations. Applying co-location compliance obligations to timeshare arrangements

[1] 42 C.F.R. § 411.357(y).
[2] Final Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70886, 71327 (Nov. 16, 2015).

could hinder the use of timesharing and reduce access to needed services. **Therefore, the FAH requests that CMS clarify in its final guidance that arrangements in which visiting physicians contract with hospitals to timeshare the use of hospital space, equipment, and staff, as well as lease arrangements where different clinicians lease the same space on different days, are not considered co-location and are not subject to surveyor evaluation for compliance with co-location requirements.** Of course, the privacy and security of patients' personal health information under these arrangements would be protected under the Health Insurance Portability and Accountability Act (HIPAA).[3]

TECHNICAL COMMENTS

The draft revisions to the State Operations Manual generally are helpful in guiding our member hospitals in their use of co-location arrangements. As discussed in more detail below, the FAH offers targeted comments for certain components of the revisions.

Surveying Hospitals Co-Located with Other Hospitals or Healthcare Facilities

CMS states in the proposed guidance that "prior sub-regulatory interpretations prohibited co-location of hospitals with other healthcare entities." CMS further states that "[t]his guidance changes that to ensure safety and accountability without being overly prescriptive." **The FAH appreciates CMS's acknowledgement that going forward, its co-location policy is intended to allow hospitals flexibility in their use of co-location arrangements. The FAH encourages CMS to retain this language in the final guidance, formalizing the change in CMS policy.**

Distinct Space and Shared Space

The FAH supports CMS's revision to allow shared use of public space and paths of travel by co-located entities, which is critical in providing hospitals with flexibility to allow implementation of co-location arrangements that support patient care. This need for flexibility is demonstrated by an experience of one of our member hospitals. An acute care hospital was working with a non-related provider to open a new inpatient rehabilitation facility (IRF) on an unused upper floor of the hospital. State licensure personnel denied the proposed arrangement based on the state's interpretation of Medicare guidance and with confirmation from the CMS Regional Office. The stated rationale for the denial was that the IRF would only be accessible through the hospital's main elevator banks, which were centrally located in the middle of the first floor of the hospital and would have required patients to pass the hospital's admission office. The state offered as a solution that the hospital could construct an exterior elevator to access the IRF, which would have been cost-prohibitive. Therefore, the entities abandoned the project and the community was unable to benefit from the IRF services. This example illustrates the importance of CMS's co-location guidance balancing the promotion of hospital compliance with the CoPs, and with a degree of flexibility for hospitals to improve their patient care operations.

We provide the below recommendations for clarifications that CMS could make in the final guidance to allow further flexibility needed to improve patient care under specific

[3] 45 C.F.R. § 160; 45 C.F.R. § 164.

circumstances. For example, the guidance states that it would not be acceptable for patients to travel between two co-located entities in the same building using a path through clinical space, whereas travel could be allowed through a public path of travel. The guidance provides that a public path of travel would include, for example, a main hospital corridor with distinct entrances to departments. Other examples provided in the guidance that would not be public paths of travel would include a hallway through an inpatient nursing unit or a hallway through a clinical hospital department. In some circumstances it may be difficult to discern whether a hallway is a public path of travel. Specifically, some hospitals may operate clinical areas, including pharmacies, outpatient clinics, and certain patient care wings, that have been in existence for decades. These spaces maintain existing CoPs through the use of secured doorways off of a main hallway that is a general, public space. The main hallway use is general space; however, the only way to get to a patient room wing or a therapy gym, for example, is to navigate this hallway. In this example, we believe patients and providers should be able to travel from a co-located entity through the main hallway to another co-located space, notwithstanding the fact that there are clinical areas accessible from the main hallway through secured access. **Therefore, the FAH requests CMS clarify that a path of travel between co-located entities through a hallway that provides secure access to clinical areas would be considered a public path of travel.**

Further, CMS's characterization of public space and paths of travel also include examples such as public lobbies, waiting rooms, and reception areas with separate “check-in” areas and clear signage; public restrooms; staff lounges; elevators and main corridors through non-clinical areas; and main entrances to a building. The term "check-in areas," however, may not clearly describe the type of lobby, waiting room, or reception area with separate "check-in" functions that should be deemed a public space. For example, the FAH believes that a lobby, waiting room, or reception area with separate check-in windows should be considered a public space, but the term "check-in areas," as used in the proposed guidance, could be interpreted more broadly to require that a space have a completely walled off, separate check-in area to be considered a public space. The FAH is concerned that such an interpretation could exclude a space with check-in windows from qualifying as a public space, although these are commonly in place in co-location arrangements. **As such, the FAH recommends that CMS revise the example of the public space as a lobby, waiting room, or reception area with separate "check-in windows," rather than "check-in areas."** Alternatively, FAH requests that CMS define “check-in areas” to include “check-in windows.”

We recognize CMS’s concern that sharing space under certain circumstances could pose risks to patient privacy. However, we do not believe that sharing reception areas with check-in windows would pose this risk. Our member hospitals are committed to ensuring patient privacy and must comply with national standards to protect the privacy and security of individuals' personal health information under the Health Insurance Portability and Accountability Act (HIPAA).[4] We believe that permitting the sharing of reception areas with separate check-in windows would still ensure patient privacy given existing protections that hospitals already have in place.

[4] *Id.*

Additionally, in the proposed guidance, CMS notes that it would not be acceptable for patients to travel between co-located entities using a path through clinical space, citing concern for patient privacy, security, and infection control. This raises a question regarding certain situations where co-located entities may be physically connected via a door that would allow a patient to access the co-located entity without having to exit one entity and travel to the other entity through a public hallway. For example, if a hospital is physically located next to an imaging center that is a separate entity, and a clinician orders imaging during a patient's visit, a patient may be able to travel through a door in the hospital that leads directly to the imaging center (such a path also may include traveling through clinical space in the co-located entity), rather than exiting the hospital and traveling through a hallway to enter the imaging center. The FAH does not believe that traveling between the entities through a connected door (or through clinical space when the patient is traveling with supervised hospital staff) would cause privacy, security, or infection control issues, and thus should be permitted. Traveling directly between the entities would increase patient convenience, safety, and comfort while improving efficiency because the patient would not have to change to travel between the entities. **Therefore, the FAH asks that CMS clarify that the proposed restriction would not limit patients from traveling from one clinical space to an adjacent co-located entity, as long as all other applicable requirements are met by the entities.**

CMS also states in the proposed guidance that co-located entities would be individually responsible for compliance with the CoPs in shared spaces. Often, one co-located provider leases space from the other co-located entity. We are concerned that, under the proposed guidance, a lessee would be partially responsible for the compliance of the lessor's public spaces. Placing this responsibility on the lessee would be burdensome and unnecessary, given that the lessor generally is responsible for the upkeep of its public spaces and compliance related to any space owned by the lessor. The lessee would have little control over compliance in the hospital's public areas and would have limited ability to address compliance issues that could arise. In addition, if a lessee is co-located, for example, on the top floor of another entity, it may not always be aware of a situation in a shared hallway on the main floor of the building that could risk non-compliance with the CoPs, yet under the guidance the co-located entity would be responsible for such a non-compliance situation. **As such, the FAH asks that CMS clarify in the final guidance that only the lessor is responsible for compliance in public spaces.**

Finally, we urge CMS to clarify that shared clinical space is permissible when two co-located entities share a clinical room for certain types of specialty care when neither entity can afford, or does not need, the room for its sole use at all times. This would occur under a previously established and set schedule for use of the room to ensure that only one entity is using the space during a specific day or time.

<u>Contracted Services; Staffing Contracts</u>

The FAH supports CMS's proposed revisions that would confirm that hospitals may provide services and staff under contract or arrangement with a co-located hospital or entity. Such arrangements for services and staffing are common among hospitals, and the FAH appreciates CMS's recognition of these practices. We request, however, that CMS provide added flexibility in the final guidance relating to staffing contracts, as discussed below.

Directors

The draft guidance states that directors of laboratories, nursing, and pharmacy may serve in these roles in two co-located hospitals or entities, but it cannot be simultaneously. The draft guidance further states that when staff are obtained under arrangement from another entity, they must be assigned to work solely for one hospital during a specific shift and cannot "float" between the two hospitals during the same shift. The FAH recognizes the concern if certain hospital staff were to float between two entities. However, we believe this concern would not apply if laboratory, nursing, and pharmacy directors were to float between co-located entities, but rather patient care could be enhanced if these positions were permitted to serve both entities simultaneously. For example, when treating cancer patients in co-located units, a director of pharmacy could better coordinate and streamline the care furnished to patients, which would significantly reduce potential errors in prescribing and dispensing medications in the co-located units. This principle also applies to directors of nursing and laboratories. Therefore, the FAH urges CMS to revise the draft guidance to permit co-located entities to have one director of a department. In addition, this flexibility should be extended to "director-level" employees, such as managers, since they also could provide a more coordinated and efficient approach if serving both entities. Finally, we urge that other hospital staff be permitted to float between co-located entities with regard to staff that provide services on an as-needed basis, rather than for continuous care in a designated unit of a hospital (*e.g.*, phlebotomist). In these cases, floating ensures patients are treated in a more efficient, timely, and coordinated manner.

Governing Body

The draft guidance discusses that when utilizing staffing contracts, the governing body must ensure certain criteria are met such as adequacy of staff levels, adequate oversight and periodic evaluation of contracted staff, and proper training and education, among others. The FAH recognizes that these are critical factors for ensuring that hospital staff provide patients with high-quality, efficient, and effective care. To better implement this provision, however, we urge that CMS permit delegation of these staffing contracts assurances to each entity's respective clinical leadership groups that handle these issues. These groups are more experienced in these issues and better positioned to respond to any inquiries that may arise.

Clinical Services Contract

The proposed revisions clarify that when hospitals provide clinical services under contract or arrangement from a co-located entity, "the hospital is not necessarily required to notify its patients and their representatives of all services provided under contract or arrangement…" The FAH agrees that requiring notifications of all services is unnecessary, as such a requirement would be complicated, burdensome, and confusing to patients. As CMS notes, services provided under contract or arrangement with a co-located entity are provided under the oversight of the hospital's governing body. Therefore, the hospital ultimately is responsible for contracted services, just as the hospital is responsible for services provided directly by the hospital.

In addition to being unnecessary, requiring notification to patients of all contracted services would be burdensome. During a patient's visit or stay in a hospital, the patient generally interacts with many individuals who provide contracted services. It would be impractical for hospitals to notify patients of each contracted service received. Requiring notification could lead to citations for technical violations, given the difficulty of tracking each contracted service provided, even though these violations would not impact patient safety. **Therefore, the FAH supports the proposal not to require notification to patients of all services provided under contract.**

Emergency Services

Under the proposed guidance, hospitals without emergency departments (EDs) that contract for emergency services with another hospital's ED would be subject to the requirements under the *Emergency Medical Treatment and Labor Act* (EMTALA). Such a policy would appear to subject hospitals without EDs to new compliance obligations. However, the proposed guidance also states that hospitals without EDs must have appropriate policies and procedures in place for addressing individuals' emergency care needs 24 hours a day and 7 days per week, including recognizing when the patient must be transferred to another facility to receive appropriate treatment. These two provisions seem to conflict. Further, it is unclear why a hospital without an ED would be subject to EMTALA requirements when the guidance would allow such a hospital to address emergency medical needs through policies that may involve transferring patients to other facilities, rather than treating patients for their emergency medical needs. It would seem inappropriate to extend EMTALA requirements to hospitals without EDs, given that EMTALA applies to hospitals with EDs.[5] In addition, a co-located hospital without an ED does not hold itself out as having an ED and may not have the necessary staff to treat all types of patients that present at an acute care hospital with an ED. **Therefore, the FAH asks that, as part of the final guidance, CMS not require hospitals without EDs that contract with hospital EDs to meet EMTALA requirements.**

We also seek clarification regarding a provision in the draft guidance stating that hospitals without EDs that are co-located with another hospital may not arrange to have the other hospital respond to its emergencies in order to assess the patient and provide initial treatment. In these instances, our member hospitals often have multiple response teams that are available to respond to a co-located entity in case of an emergency. As long the responding hospital has multiple, independent response teams available, we believe Medicare beneficiaries would be better served having various emergency options available to potentially deal with a medical emergency, while ensuring the most appropriate expertise needed for a particular medical emergency. **We recommend that CMS revise the guidance to afford more flexibility for these co-located entities and their patients when multiple response teams are available.**

[5] 42 C.F.R. § 489.24(a)(1) (applying special responsibilities of Medicare hospitals in emergency cases to "a hospital that has an emergency department").

Survey Procedures

Distinct and Shared Space

CMS indicates that sharing spaces "used for medical records and patient registration/admission" could pose risks to patient privacy, suggesting the possibility that sharing space used for medical records could lead to non-compliance. Our member hospitals are committed to ensuring patient privacy. However, the FAH does not believe that prohibiting the sharing of medical record space is necessary in situations where hospitals take measures to protect the privacy of patient records. For example, if providers maintain patient records or paper files in a locked filing cabinet in a shared room where other providers also maintain patient records that are locked in a separate filing cabinet, it seems that co-location of this space should be permissible as it would not jeopardize patient privacy when efforts are made to protect those records. Moreover, health care providers must comply with national standards to protect the privacy and security of individuals' medical records and personal health information under the Health Insurance Portability and Accountability Act (HIPAA).[6] The FAH believes that permitting the sharing of medical record space in this manner could still ensure the privacy of patient records given existing patient privacy protections that hospitals already have in place. **Therefore, the FAH asks that CMS clarify in the final guidance that the sharing of space used for medical records would not lead to non-compliance if patient records are appropriately locked or otherwise secured.**

Further, we are concerned that prohibiting the sharing of medical record space is outdated in the world of electronic health records (EHRs) where records are stored online, in servers, or in a cloud, and where the sharing of patient data can improve patient safety. We urge CMS to revise the draft guidance to reflect the use of EHRs in storing medical records.

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The FAH appreciates the opportunity to comment on the draft revisions to hospital co-location guidance, and praise CMS's efforts to provide additional clarity and flexibility for hospitals partnering with other health care entities to provide patient care services. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

[6] 45 C.F.R. § 160; 45 C.F.R. § 164.