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July 2, 2019

The Honorable Seema Verma
Administrator
Center for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD

Re: QSO-19-13-Hospital – Draft Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities

Dear Administrator Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 hospital, health system, PACE and post-acute members, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed guidance for hospital co-location with other hospitals or healthcare facilities.

NJHA appreciates CMS's work to produce guidance by which hospitals can co-locate with other hospitals or healthcare facilities. This draft guidance represents an important update to existing CMS policy, and we commend the agency for its overall recognition that the opportunity for co-location provides much needed flexibility for the development of and continued partnership between certain hospitals, health systems and other healthcare entities. While the agency's general allowance of co-location demonstrates an important update, we urge it to consider a series of revisions that will enable successful implementation of this policy in healthcare settings and promote safer, higher-quality care.

For hospitals, the option and decision to co-locate is only as meaningful as the benefits both patients and the providers who treat them receive as part of a more streamlined and coordinated process. Failure to provide critical flexibility for these co-located entities significantly hampers the benefits of such arrangements, diminishing the value of co-location, and likely leading to far less utilization of the option to co-locate. For these reasons, we recommend the agency consider a series of revisions and clarification to key components of the guidance.

Specifically, we ask CMS to revise provisions related to distinct and shared space, staffing contracts and emergency services. In addition, we request that the agency address a number of co-location possibilities not directly discussed in its draft guidance. Specific comments and suggested revised language follow.

Clarity in application of the Conditions of Participation (CoPs) in co-located hospital arrangements is vital to hospitals, healthcare systems and healthcare entities interested in entering such arrangements. Hospitals use co-location to work together to create structures and mechanisms that leverage the services of a partner, co-located hospital to provide safe, high-quality and efficient services to its patients. We are aware that any complex hospital environment may carry some risk and that the natural inclination is to simplify structures as much as possible to provide clarity. However, we believe that some of the draft changes contained in the draft guidance will negatively impact patient care, create significant administrative burden and require increased expenditure of resources without patient safety benefit and, in some cases, impinge on the ability of co-located hospitals to provide the safest possible care. **We are concerned that a one-size-fits-all approach could harm innovative and efficient solutions that are currently successful in delivering top-quality patient care.**

Definitions

CMS introduces a number of terms in the draft guidance but does not fully define the new terminology. In order to provide necessary clarity around the use of certain terms in the proposed guidance, we recommend CMS include a section specifically defining certain terms. Some terms we recommend defining are: distinct space, staffing contracts, emergency services and emergency department.

Distinct and Shared Space

In its draft guidance, CMS proposes to establish a bright line standard for shared and distinct spaces. The agency reasons that this distinction is necessary to ensure patient safety and privacy protection while those patients are treated in a co-located hospital or healthcare facility. Patient safety and privacy protection are top priorities for our members, and we appreciate the agency's attention to those critical issues; however, we fail to understand the justification for such a black-and-white approach. We do not understand the agency's given rationale, and urge CMS to reconsider its approach on this issue by removing the prohibition of patient travel through clinical areas.

Currently, patients may travel through clinical areas within one hospital. We see no reason why those patients should be prohibited from transiting through a clinical space in a co-located hospital if it is the most direct path to a treatment or testing area where they will receive a service. Of course, we are not advocating for unsupervised movement through clinical areas, nor should family members or other non-patients be permitted to do so; however, patients traveling from one co-located hospital to another to receive certain services should be permitted to travel through clinical areas when escorted by authorized staff. Not only will this decrease the need for costly and unnecessary engineering investments, but, more importantly, it will allow patients to receive the most effective and efficient high-quality care.

Under CMS's proposed guidance, patients may have to exit the hospital and come back into the co-located entity through its separate entryway. Or, the patient may have to travel through patient areas to access a public corridor or other public area, and then enter the co-located hospital, and then travel through that hospital's public corridors to get to the service they need. The patient would then have to reverse this process to return after receiving services. The route, as required by CMS's guidance, actually poses a greater threat to patient safety and privacy protection, exposing the patient to the public in the public areas. Further, as drafted, this guidance will significantly increase the chances of inconveniencing the patient and the caregiver(s) accompanying the patient by forcing the patient to traverse a longer, more convoluted route. We firmly believe that our patients deserve the simplest, least cumbersome care we can provide. Being sick or needing medical treatment is stressful enough. Anything we – or CMS – can do to ensure unnecessary hassles are not part of the experience will be to the benefit of the patients our hospitals seek to serve.

We understand and share the agency's concern regarding the need to protect patients from potential infections. All hospitals, including co-located entities, take this responsibility seriously. That said, we do not understand the concern raised in the draft guidance suggesting that the transit of a patient from one hospital through a clinical space owned by another creates an infection control concern that should lead the agency to prohibit that as a path to needed services. The spread of infection does not cease when one entity ends and another begins, and neither should a healthcare facility's infection control plan. A coordinated approach to infection control is better equipped to keep patients safe. Clearly, the contractual language between facilities should indicate which entity has responsibility for ensuring shared spaces (and the equipment and supplies in them) are appropriately cleaned, sterilized and maintained. We urge the agency simply to require that the co-located organizations specify the responsibility for infection control procedures in the contract. Further, CMS should encourage the co-located entities to coordinate their infection control efforts so that both entities are aware of and attentive to any special needs or concerns for infection control based on the patients served.

Given the adoption of electronic health records by hospitals, we do not understand CMS's espoused concern regarding the privacy of medical records in co-located facilities. Electronic health record (EHR) systems have safeguards to prevent the inappropriate access of information and to ensure the security of the data in the record. One of the benefits of EHRs is that individuals with legitimate reason to access the patient's information can do so from many different locations, and those who inappropriately access the records can be identified and the hospital can address the issue accordingly. Physical proximity to where a patient's record is kept is no longer necessary or helpful in accessing the record. Thus, we fail to understand why the agency is concerned that co-location of two providers might offer greater opportunity for violations of patient's health record privacy.

In light of the issues raised in this section, we strongly suggest CMS revise this section to allow for supervised patient movement through clinical spaces.

Staffing contracts

CMS proposes a series of requirements around staffing contracts for co-located hospitals and healthcare facilities. We thank the agency for placing an emphasis on the importance of adequate staffing in each facility, but we have concerns about the justifications for and implications of some of the proposed provisions in this section. Specifically, we ask the agency to revise provisions surrounding the prohibition on nursing, pharmacy, and laboratory directors and certain other staff from "floating" and the role of the governing body regarding contracted services.

CMS proposes to prohibit directors of nursing, pharmacy and laboratory from working simultaneously in co-located hospitals and healthcare facilities. The agency explains that the proposed guidance does not preclude these individuals from serving their roles in both hospitals; however, they may not do so at the same time. In its provided justification, CMS states that each hospital must be able to provide necessary services, like nursing, at all times and, if directors of these departments "float," the requirement cannot be met. We disagree and find this provision a potentially significant barrier for those hospitals interested in co-locating. In fact, the ability for one director to serve both entities at the same time, when appropriate, likely is in the best interest of the patient. We also recommend that the agency consider allowing other director-level employees, such as facility managers to "float." Similar to clinical directors, these other types of director-level staff would provide a more coordinated approach to their work. **Therefore, we recommend CMS revise the first paragraph on page three to remove the proposed language prohibiting director "floating" and replace it with the express allowance for co-located entities to have one director of a department should they choose to do so.**

In addition to allowing directors of certain departments to "float," we urge the agency to consider also permitting certain staff to float. We understand and value the importance of ensuring that nurses assigned to units only serve patients in their designated units to ensure high-quality patient care. They should not be allowed to work in co-located hospitals simultaneously. However, other employees who provide necessary services to and for whichever patients need those services should be permitted to "float" between co-located hospitals to provide services as needed – or what might be called "on demand services." Further, those who provide services that require the use of a special room or equipment should be allowed to care for patients from the co-located organizations when those patients are brought to them. Additionally, staff providing registration or administration services should be allowed to "float" to improve patient experience.

We urge CMS to permit contracts between co-located facilities to allow patients to be served by any employee who does not have designated responsibility for the continuous care for a group of patients; specifically, to allow this employee to provide services to any patient within either healthcare organization who requires a service that employee is trained and able to provide.

We hope the agency agrees that a decrease in shuttling patients between hospitals, whenever possible, is the best option for the patient. Further, as an added benefit of this revision there undoubtedly will be an increase in efficiency for the contracted services in both hospitals. **Therefore, we recommend CMS simply remove the non-float provisions for staff other than**

those with continuous responsibility for the welfare of patients, giving co-located hospitals the option to increase efficiency and coordination when necessary and appropriate.

We appreciate the agency's commitment to ensuring that staffing levels are adequate and staff are appropriately trained. In order to better account for the importance of meeting these requirements, we urge CMS to add language permitting the delegation of assurances concerning staffing contracts to each entity's respective clinical leadership groups that handle these issues if applicable. These clinical leadership groups are more experienced in these issues and better positioned to respond to any inquiries that may arise.

Second, the agency states that "governing body approved medical staff may be shared, or 'float,' between the co-located hospitals." This language is assumed to include doctors, nurse practitioners, dentists, physician assistants and other similarly trained staff, but we ask the agency to confirm and, if possible, provide an approved list of medical personnel permitted to "float."

Emergency Services

CMS proposes a series of requirements related to the provision of emergency services for co-located hospitals and healthcare facilities. Specifically, the agency addresses policies and procedures that each facility must have in place; requirements for who must respond to a medical emergency; contracting for emergency services; transfer agreements between co-located facilities; and EMTALA requirements for those hospitals without emergency departments (EDs) that contract for emergency services. While we appreciate the agency's commitment to ensuring that patients experiencing medical emergencies are treated and stabilized immediately, we find a number of the proposed requirements concerning.

The agency's language conflates the provision of ED services, which are meant to provide care to individuals in the community who are experiencing urgent medical situations, and hospitalized patients who are being cared for at the facility and who experience an emergency situation. We ask the agency to provide clarity to the term "emergency services." Clarity regarding the meaning of these terms is critical for our hospitals to make the right compliance decisions. In its draft guidance, CMS seems to assume that the provision of emergency services is synonymous with the term "emergency department," or, at the very least, that only ED staff provide emergency services. However, this is not the case, and there are significant differences between emergency services and an ED.

Additionally, rapid response and transport teams are not emergency services. While emergency services are a response to a patient in crisis, rapid response teams are sent to assess patients who may be experiencing unusual symptoms or who may be deteriorating unexpectedly, but not in crisis. One important function of the rapid response teams is to stave off crises. Because they are not emergency services, we believe they should be services for which a hospital can contract. The agency should directly and expressly remove rapid response teams from the emergency services provisions of the guidance.

Patients undergoing diagnostic procedures and treatment at hospitals may experience emergency situations. We agree with CMS that all hospitals must be able to provide an appraisal and initial treatment to patients under their care who experience a medical emergency. Further, we agree that hospitals must have policies and procedures in place to identify when a patient is in distress, how to initiate an emergency response, how to initiate initial treatment and recognizing when the patient must be transferred to another facility to receive appropriate treatment. However, these services to hospital patients may or may not be provided by the ED staff in hospitals that have an ED, and would necessarily be provided by other clinicians in hospitals that do not have an ED. We believe that CMS's guidance attempts to sort out the rules for provision of emergency services to hospital patients, not the community, so we are confused by the reference to EMTALA. For EMTALA to apply, the hospital would have to be holding itself out to the community as a provider of emergency services, not simply responding to the emergency needs of patients already being served at the hospital. **We urge CMS to remove the draft language regarding EMTALA.**

We also recommend the agency revise its draft language regarding contracting for the provision of emergency services. In its proposal, CMS states that a healthcare facility may contract for the provision of emergency services from a co-located hospital or facility, but the contracted staff may not work or be on duty simultaneously in both facilities. Our concern stems from the agency's proposal not to allow emergency response teams to respond to a medical emergency in a co-located entity while being on-duty in their primary facility. In the interest of ensuring the highest quality of care for those patients experiencing a medical emergency, we strongly urge the agency to modify this proposed requirement.

The focus should be on the ability to respond to an emergency, regardless of where the emergency occurs, rather than proposing that each hospital respond to their own emergencies, even if staff from the co-located hospital is more experienced and better equipped to respond. We understand the agency's concerns and appreciate its focus on ensuring that co-located entities are prepared and able to respond to emergencies. However, the outright prohibition on allowing emergency response teams to respond when necessary is definitely not in the best interest of patients nor the providers who care for them. **Rather, we suggest CMS revise this language to allow a contracted emergency response team from a hospital to respond to an emergency in the co-located facility, as long as the initial hospital maintains at least one response team available to respond to a code at the primary hospital. This same principle would apply to a hospital experiencing two codes simultaneously.**

Survey Procedures

We appreciate CMS's proposed changes to the survey process to reflect the updated requirements related to ligature risk. As the agency considers comments on this guidance, we urge it to adapt the survey requirements accordingly. Further, while these updates are necessary to ensure compliance for the benefit of both patients and the staff who cares for them, it is equally critical that surveyors receive appropriate and thorough training to ensure uniformity across the entirety of the surveyor profession. This means increased training and demonstrated comprehension of the new requirements to ensure commonality among survey determinations. An in-depth

understanding of what is acceptable and what is not is imperative in these instances to make it clear that hospitals in compliance on paper also are compliant in the minds of surveyors. To achieve this uniformity, we recommend CMS provide increased specificity and direction concerning surveyor training. The goal should be to ensure that hospitals are held to an objective standard without the possibility for or incidence of subjective treatment because of surveyor discretion. Lack of uniformity not only creates frustration, but it can also affect patient care and critical hospital resource allocation.

Additional Language

In addition to the areas addressed by CMS in the proposed guidance, we ask the agency to provide additional language around certain arrangements not directly addressed. First, we assume the agency's intent is that this guidance will not apply to visiting physician services, time-sharing arrangements or physician leasing agreements. We ask the agency to confirm this assumption and provide language expressly allowing for such agreements. There are many instances when hospitals provide space to visiting physicians for certain hours or days of the week in order to provide clinical care to patients. The option to enter into these types of agreements is particularly vital for small and rural hospitals, which do not have physicians on staff at all times and rely on visiting physicians to provide care that would otherwise require patients to travel long distances to visit the nearest hospital for that specific care.

Second, we urge CMS to address the issue of shared clinical space by expressly allowing for such arrangements. For example, there are situations where co-located hospitals share a clinical room for certain types of specialty care when neither hospital can afford or needs the room for its sole use at all times. In those instances, the co-located hospitals have a set schedule for use of the room in order to guarantee only one hospital is using the space during a specific day or time. We ask the agency to confirm that these specific arrangements are permitted, and we expect both hospitals to have the appropriate protocols in place to ensure compliance.

We thank you for the opportunity to provide these comments on this proposed guidance. Should you have any questions, please do not hesitate to contact Jonathan Chebra, Senior Director of Federal Affairs, at jchebra@njha.com or 609-275-4100.