AMRPA
AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

July 2, 2019

Ms. Karen Tritz
Director
Quality, Safety & Oversight Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Re: Draft Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities (QSO-19-13-Hospital)

Dear Director Tritz,

The American Medical Rehabilitation Providers Association (AMRPA) is pleased to submit its response to the draft guidance regarding hospital co-location issued by the Quality, Safety & Oversight Group of the Centers for Medicare and Medicaid Services' (CMS') Center for Clinical Standards and Quality on May 3, 2019. AMRPA is the national trade association representing more than 650 inpatient rehabilitation hospitals and rehabilitation units of general hospitals (referred to by CMS as inpatient rehabilitation facilities (IRFs)), outpatient rehabilitation service providers, long-term care hospitals (LTCHs), and several skilled nursing facilities (SNFs). The vast majority of our members are Medicare participating hospitals. In addition, many of our member hospitals are co-located, sharing a building or campus with an acute care hospital, long-term care hospital, or other type of provider.

AMRPA member hospitals have long been concerned about the application of the Medicare Conditions of Participation regulations (CoPs) to co-located specialty hospitals such as rehabilitation hospitals. Our hospitals have found that many interpretations of the CoPs have imposed burdensome requirements that bear little connection to patient safety or other goals of the CoPs. Therefore, we welcome CMS' clarification of its interpretations and wish to establish an ongoing dialogue with CMS regarding the CoPs and their application to co-located rehabilitation hospitals to ensure that regulatory requirements continue to reflect the current state of care delivery.

While we greatly appreciate CMS' efforts to update the CoP requirements in this area – something AMRPA has long supported – we would like to highlight certain draft guidance interpretations that are problematic to AMRPA hospitals. In particular, some of the interpretations presented would require rehabilitation hospitals to unnecessarily duplicate staff,

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equipment and other hospital resources, with little or no clinical or safety benefit. In addition, the burden that would be imposed by these interpretations would put a serious strain on hospital resources that could otherwise be spent on patient care.

In addition, AMRPA thinks several provisions of the draft guidance would be counter to CMS' and other policymakers' efforts to transition to more efficient and unified delivery of post-acute care (PAC) services. Not only are certain interpretations of the draft guidance problematic to inpatient rehabilitation hospitals, they would complicate recent CMS policies for other PAC settings such as long-term care hospitals (LTCHs), as discussed in Section IV below, which were implemented to promote a more patient-centered approach to the provision of PAC services. AMRPA appreciates that CMS developed this draft guidance perhaps in response to concerns arising primarily within acute-care hospitals. However, the agency must (1) be cognizant of the impact that co-location policies have on specialty PAC hospitals, and (2) ensure that these policies facilitate and promote efficient and patient-centric care. The latter point is particularly relevant/critical for PAC as the sector seeks to move beyond a fragmented and siloed provider landscape to more unified and integrated care delivery models.[1]

We appreciate CMS' close attention to these concerns, which are detailed by topic in the remainder of this letter.

I. Distinct and Shared Space

CMS' interpretation of the CoPs states that co-located hospitals may only share public spaces and public paths of travel, which it defines as non-clinical spaces such as lobbies, waiting rooms and receptions areas, among others. The proposed guidance seems to state that it is not permissible for a patient to travel into a clinical area located in the non-treating hospital for services, as this would be a non-public space. This interpretation presents a serious impediment to the sharing of diagnostic services (i.e., laboratory and imaging) and specialty care (i.e., therapy, dialysis, vision services, etc.). AMRPA questions the reasoning underlying this interpretation. Hospitals often contract for third-party offsite services for patients, and those services are not required to keep separate areas for each hospital. It is unclear why CMS would require such a practice for co-located hospitals. In fact, CMS' interpretation creates a clear incentive for hospitals to outsource these services to such offsite vendors, which is not in the interest of patient safety or efficiency.

To illustrate why the ban on sharing of any clinical space is problematic, we offer the following example. Under CMS' draft guidance, a co-located hospital is not permitted to share space where patients are receiving care. This means that if one of the co-located hospitals offers services in a specialized setting, such as a dialysis center or an aquatic therapy pool, the patients at the other hospital would not able to contract to use those services, since patient care is delivered in these areas. This leaves the co-located hospitals with several untenable options: (1) One of the co-located hospitals could not offer that service to patients, while the other does; (2) One hospital could send its patients offsite for these services, despite the service being offered at the

[1] *See* Medicare Payment Advisory Commission, *Mandated report: Developing a unified payment system for post-acute care* (June 2016) and *Implementing a unified payment system for post-acute care* (June 2017).

significantly more convenient co-located hospital site; (3) The hospital could close the onsite service and send all patients offsite for the service; or (4) The hospital could build a duplicate clinical area. In all of these scenarios, the burden imposed on hospitals is high, with little (if any) apparent benefit to patients, and to the extent the policy encourages stressful patient transfers' offsite for care, could be detrimental to patients.

AMRPA understands the need for comprehensive infection control plans and protection of patient privacy. However, the Medicare statute allows hospitals to provide services "under arrangements" with other hospitals, under which one hospital provides services to another hospital and the hospital providing the services bills the other hospital for the services.[2] Rather than impeding hospitals from delivering needed services in the most comprehensive and efficient manner possible, and to continue to allow hospitals to provide services "under arrangement," CMS should instead require hospitals to account for the sharing of specialty space in its infection and privacy protocols. This would ensure that patient safety and privacy, among other concerns, remain addressed while also allowing patient access to the safest and most robust services available onsite at the hospital. In fact, it should be noted that it is common practice for co-located hospitals to adopt or mirror the infection control polices of the host hospital. As both co-located hospitals have matching infection control policies, practices, and training standards, there is little risk to patients accessing contracted services in the other hospital.

As previously stated, hospital already account for co-mingling of patient or clinical space when patients are sent offsite for services. Creating strict rules barring on-site sharing of space, but not offsite sharing, will only incentivize the use of off-site services, which is not in the interest of patient safety or efficiency. Therefore, CMS should provide for sharing of specialty services in situations in which one hospital is providing services "under arrangement" or otherwise utilizing a service in the co-located hospital. In sum, AMRPA believes there is a way to protect patient privacy and safety and also address other concerns that come with shared space that will be far less burdensome than requiring duplication, denial or elimination of services and would not impede the Medicare statutory "under arrangements" provisions.

AMRPA also has concerns about CMS' statement in the draft guidance that patients cannot even simply *travel through* a clinical area to reach a specialty service. Similar to the previously stated concerns regarding shared clinical space, it would be detrimental to patient access to specialty care to impose this unnecessary restriction. For example, by way of necessity, an area like a specialized therapy lab or diagnostic imaging service may need to be located on a ground floor of a building. The CMS draft guidance would exclude the entire co-located hospital's population from utilizing this contracted service simply because they would briefly pass through a clinical area of the other hospital. Rather than create this needless restriction on patient services, CMS should simply require that passage to be incorporated into both hospital's protocols for infection, privacy and any other implicated concerns.

CMS should be mindful that co-location has been expressly permitted through regulations like the Hospital-Within-Hospital (HwH) rules for decades.[3] Accordingly, there are many co-located hospitals that have invested tremendous capital in their current infrastructure based on these

[2] 42 U.S.C. § 1395r(w); Medicare General Information, Eligibility and Entitlement Manual, 100-01, Ch. 5 § 10.3.
[3] 42 C.F.R. § 412.22(e).

permitted arrangements. It would be cost prohibitive for many hospitals to essentially rebuild their facilities to comply with these policies. Member hospitals report that some infrastructure that currently exists that would run afoul of the draft guidance – like centrally located elevator banks – simply could not be rearranged to ensure patients never traverse or enter the co-located, non-treating hospital. Therefore, if CMS were to nonetheless proceed with finalizing this guidance, it should also create a clear grandfather policy for these pre-existing facilities. These grandfathered facilities would need to incorporate the co-location into their protocols to ensure patient safety, while still being permitted to operate their current facility as they had done previously. This approach would avoid hospital closings and restricting beneficiary access to care, while still ensuring patient safety.

In sum, CMS should take a practical approach to ensuring safety, and allow hospitals to take a robust - but specially tailored - approach to ensuring patient safety. Every hospital is built differently, and hospitals are in the best position to continually monitor and ensure the highest quality care for the patients in their unique buildings. Therefore, CMS should not create arbitrary and categorical rules, such as blanketly prohibiting any shared clinical space in a hospital. Instead, each hospital should have its protocols evaluated by surveyors on a case-by-case to ensure the arrangement adequately protects patient safety.

Recommendations:

1. CMS should permit the sharing of space for contracted specialty services such as therapy, dialysis, vision, imaging and others to ensure patients are able to receive the most robust array of services possible onsite during their inpatient stay. Allowing hospitals to provide for patient safety through their infection and privacy protocols would be a far more effective way of balancing patient protection and access to care.
2. CMS should permit travel through clinical areas of the co-located hospitals for the provision of contracted specialty services.
3. If CMS does ban the sharing of clinical space, CMS should provide an exception to the prohibition in situations in which one hospital is providing services "under arrangement" to another hospital or is obtaining services "under arrangement" for its patients.
4. Should CMS nonetheless decide to prohibit sharing of certain spaces between co-located hospitals, CMS should publish a comprehensive list of which spaces may and may not be shared, and thoroughly explain under which circumstances such spaces may be shared. For example, CMS should explain exactly how a service being provided via contract or "under arrangement" changes the analysis for that shared space. AMRPA strongly supports greater transparency on this complicated and critical issue.
5. If CMS does proceed to ban the sharing of clinical space, it should provide a grandfather exception for those hospitals with pre-existing infrastructure that necessitates the sharing or traversing of clinical areas.

II. Staffing and Staffing Contracts

Similar to concerns about shared space, AMRPA finds CMS' draft guidance pertaining to contracted staffing to be overly burdensome while providing little benefit to patients. AMRPA agrees that all hospitals should be required to provide adequate staffing to ensure patient safety and care needs are met at all times. However, when it comes to delivering specialty and

diagnostic services, it is again unclear what patient interest is served by barring the sharing of this staff during the course of one shift – especially among staff that are particularly well-suited to treat patients from the two hospitals during the course of one shift. Hospitals may be staffing well beyond the minimum levels needed to provide the CoP required services, and when hospitals are providing supplemental specialty services, they should be permitted to share such staff.

To provide an example, a co-located hospital may operate a neurological recovery lab that is staffed by personnel that are specially trained to use the neurorehabilitation equipment in the lab. Patients would be served by the lab on an appointment basis, with a limited number of patients being treated in the lab at a given time to ensure adequate supervision. There is no reason that the clinical therapists delivering the treatment in the lab on an appointment basis should not be able to treat patients from both hospitals during the course of one shift. It is unnecessary and unreasonable to require a therapist to clock out from one hospital and into another to provide services to both hospitals. Again, these restrictions appear contrary to the Medicare statutory provision that allows hospitals to provide or obtain services "under arrangement." Likewise, even in instances where there is not a shared space, specialists such as physical therapists should be able to float from one hospital to the other to deliver their specialized care, as this poses no risk to patient safety or privacy that could not otherwise be accounted for in both hospitals' protocols.

These unnecessary restrictions proposed by this draft guidance would again discourage co-located hospitals from offering a robust array of specialty services onsite. Under this guidance, it would be more efficient for co-located hospitals to outsource the care to a singular provider (where the patients could be intermingled) than to duplicate services onsite. In addition to adding burden to hospitals, this is potentially stressful and detrimental to patients. Rather than creating this barrier to treating patients in both hospitals, CMS should ensure that shared specialty staff are properly trained by both hospitals and adhere to the policies of both hospitals. This would ensure all of CMS' interests – such as patient safety and privacy – are satisfied, while not minimizing patients access to needed specialty staff.

AMRPA is especially skeptical of restrictions on the staffing of contracted services that are not patient facing or have minimal interaction with patients, such as diagnostic imaging or laboratory technicians. Offsite laboratories or imaging centers are not required to have staff dedicated solely to each contracted hospital's patients. This is because there is no clinical or operational reason to divide services in that way. However, under the draft guidance, CMS proposes that these types of staff must be clearly delineated between each hospital simply because of their onsite location. We again encourage CMS to take a practical approach and not require these staff members to be dedicated solely to one hospital or another, so long as adequate staffing for both hospitals is satisfied and patient safety and privacy concerns are addressed in hospital protocols.

During an American Health Lawyers Association (AHLA) webinar and CMS listening session on the draft co-location guidance (June 5 and June 27, respectively), CMS suggested that the restriction on a staff member "floating" between two hospitals applied only if the COPs require that hospital staff a particular position rather than require that the hospital provide a particular service. For example, CMS indicated in the June 5 webinar that a Pharmacy Director could not

float because the Medicare COPs require that a hospital have a Director of Pharmacy (42 C.F.R. § 482.25(a)(1)), but that a pharmacist could float. If CMS' restrictions on whether a staff member may float are tied to requirements in the COPs, CMS should make this clear in its final guidance.

Finally, AMRPA questions the reasoning CMS stated during these listening sessions for imposing these staffing restrictions. CMS stated that the sharing of staff between two co-located hospitals means the staff member would not be immediately available for the hospital because they may be attending to a patient in the other hospital. However, this is no more likely to occur between two co-located hospitals than it is to occur within one hospital. Many co-located hospitals, especially co-located specialty hospitals, may have fewer beds combined than one acute care hospital. It makes little sense that CMS would require one 100-bed acute-care hospital to only have one staff member, but two co-located specialty hospitals with a combined total of 50 beds to have two of that same staff.

Recommendations:

1. CMS should permit the sharing of specialty staff, such as therapists, between co-located hospitals during the same shift.
2. CMS should permit the sharing of onsite diagnostic staff such as imaging and laboratory technicians between co-located hospitals.
3. CMS should publish a comprehensive list of staff that are permitted to float during the same shift and provide clear guidance regarding the circumstances under which such floating is permitted.
4. AMRPA supports the draft guidance's statement that the medical staff of a hospital may float between hospitals if properly credentialed at both hospitals.

III. Emergency Services

AMRPA hospitals recognize and appreciate the importance of each hospital having the capability to respond to its own emergencies for initial assessment and treatment of a patient. We agree that each hospital should be fully prepared, with its own independent staff, to engage in such efforts. However, AMRPA is concerned that the wording of CMS' current guidance could discourage a lifesaving intervention from taking place.

CMS' guidance states "Hospitals without emergency departments that are co-located with another hospital may not arrange to have that other hospital respond to its emergencies." AMRPA is worried that this would serve as a complete bar to a co-located hospital's staff involving themselves in an emergency. This is concerning because some emergencies are unpredictable and require an immediate response. At any given moment, a staff member from a co-located hospital, such as respiratory therapist, may be nearer to the patient experiencing the emergency than the respiratory therapist for the treating hospital.

In situations where immediate lifesaving intervention is needed, there should be no bar on a co-located clinician responding to an emergency. Hospitals should be permitted to allow for the temporary intervention of co-located hospital staff until the treating hospital staff arrives. To be

clear, AMRPA does not believe that co-located hospitals should be allowed to meet lesser standards than non-shared hospitals when it comes to adequate response capabilities. Rather, AMRPA recommends that the nearest and most immediate staff member, regardless of which hospital their shift is assigned to, be permitted to intervene when patient safety is at risk.

The draft guidance also states that if a hospital has no emergency department (ED) but has its emergency services provided under contract with an ED of a co-located hospital, the hospital without the ED must also meet the requirements of the Emergency Medical Treatment & Labor Act (EMTALA). AMRPA cannot understand why this would be the case and emphasizes that this is a wholly inappropriate application of EMTALA. Many rehabilitation hospitals are co-located with acute-care hospitals that have EDs and may contract for services from that acute-care hospital. However, rehabilitation hospitals, by CMS' own regulation, treat patients that are stable.[4] To subject the rehabilitation hospital to EMTALA rules would require this specialized hospital to begin accessing and stabilizing patients that are far outside the hospital's specialty and expertise. This presents not only patient safety concerns but significant administrative and financial burdens for rehabilitation hospitals. It is beyond AMRPA's understanding why CMS would require a hospital *without an ED* to treat emergencies when there is a co-located hospital *with an ED* on site. It would make far more sense for only the co-located hospital with the ED to be required to be subject to EMTALA.

Recommendations:

1. AMRPA agrees each hospital should be staffed and have protocols in place to respond to and initially assess and treat patients experiencing an emergency. However, CMS should not discourage nearby staff from co-located hospitals from temporarily intervening if needed.
2. AMRPA strongly urges CMS to not subject co-located hospitals to EMTALA just because they contract for services from a co-located hospital with an emergency department.

IV. Co-Location and Governing Body Citations

AMRPA recognizes that the CoP regulations ultimately place responsibility for compliance with participation requirements on the governing body of the hospital. However, AMRPA finds it unnecessary and redundant to require duplicate citations for singular violations. It is clearly understood that any violation of the CoPs is a serious issue that must be dealt with promptly. It is also understood that responsibility ultimately lies with the governing body. Therefore, a singular citation for the specific violation is more than enough to ensure compliance. Adding a redundant violation of the governing body CoP only serves to confuse the issue at hand, as well as create additional paperwork – in contrast to the goals of the Department. Therefore, CMS should only require a singular citation per violation.

[4] 42 C.F.R. § 412.622(a)(3)(iii) (In order for an IRF claim to be considered reasonable and necessary the patient must be sufficiently stable at time of admission to be able to actively participate in an intensive rehabilitation therapy program).

In addition, AMRPA believes the draft guidance should make clear that it is appropriate for the governing body to entrust oversight to compliance officers or other appropriate staff that ultimately report to the governing body. The guidance, as currently written, does not provide for that flexibility, and insinuates the governing body must be involved in the minutiae of day-to-day operations that is nearly always delegated to compliance officials. Therefore, CMS should clarify the governing body's ability to assign oversight duties to compliance officials who report to the governing body, who bear final responsibility.

CMS also states in the draft guidance that a citation regarding shared space should be considered a violation of the CoPs for both entities, and the other co-located entity will be referred for a separate survey. AMRPA wishes to make CMS aware that many of these co-located arrangements operate through a lease agreement – where one entity owns the property and leases the space to the other entity. Therefore, many common areas like entryways would only be under the legal control of the lessor, with the lessee unable to make changes to those areas since it does not own or control the property. Therefore, only the owner the co-located space should be held responsible for common areas that the lessee is unable to control due to legal restrictions. This commonsense clarification would ensure the entity that actually has control is held responsible for compliance.

Recommendations:

1. CMS should only require one citation per violation, and not create confusion by requiring redundant citations.
2. CMS should clarify that the governing body may appoint compliance officials to oversee the daily operational compliance with the CoPs.
3. CMS should account for lease arrangements when determining which entity should be cited under the CoPs, and not hold hospitals responsible for space it cannot control.

V. Recommendations on Integrating Sites of Care

Last year, CMS reversed a longstanding policy and began permitting hospitals excluded from the Inpatient Prospective Payment System (IPPS) to host IPPS-excluded hospital units.[5] This meant that a long-term care hospital (LTCH) could begin hosting a rehabilitation unit. Since an LTCH can also incorporate sub-acute facility elements into its hospital, the LTCH is essentially able to incorporate all post-acute care (PAC) facilities in one location as one unified hospital. Given that transfers through the continuum of care are both administratively burdensome and taxing on (or even directly detrimental to) patients, the ability to consolidate all of these levels of care in one location as one unified hospital is a significant reform that provides notable efficiencies for LTCHs.

However, the same opportunity that is newly available to LTCHs has not been afforded to rehabilitation hospitals, which are also IPPS-excluded hospitals. Since there is no LTCH unit under Medicare, like there are rehabilitation and psychiatric units, there is no ability for an

[5] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates, 83 Fed. Reg. 41144, 41513 (Aug. 17, 2019).

existing rehabilitation hospital to incorporate an LTCH unit and thereby operate all levels of care as a unified hospital. Instead, the only path an existing rehabilitation hospital has to incorporate an LTCH in the same location is to utilize a hospital within hospital (HwH) model, which is one of the co-located entities governed by this draft guidance.

In making the change to IPPS-excluded unit restrictions last year, CMS acknowledged the appropriateness and advantages of an LTCH and IRF operating under the same roof. However, despite rehabilitation hospitals' tremendous contributions to Medicare beneficiaries and to the entire continuum of post-acute care, an artificial business disadvantage has been created for rehabilitation hospitals as a result of this policy.

Existing rehabilitation hospitals that are co-located with an LTCH as an HwH should be afforded the same flexibilities that an LTCH with an IRF unit are afforded. This should include a significant loosening of the separateness requirements in the context of IRF and LTCH co-location, such as the shared staffing and shared clinical space requirements. Not only would this help create parity among existing post-acute sites of care, it would open up this efficient arrangement to areas of the country that have IRFs, but face an LTCH shortage. We therefore urge CMS to revise its current policy and to use this guidance as an opportunity to provide IRFs the same flexibility of LTCHs to integrate sites of care at their locations, which would break down administratively burdensome sites of care and allow hospitals to focus more of their resources on patient care.

Recommendation:

1. CMS should provide additional flexibility to HwH arrangements that involve two IPPS-excluded hospitals, such as a rehabilitation hospital and a long-term care hospital, to provide parity among types of hospitals, break down artificial silos of care, and facilitate innovative care delivery options for patients.

VI. Subregulatory Guidance Authority

As a separate and final matter, AMRPA is concerned about the lack of nexus between the subregulatory guidance and the actual text of the CoP regulations that it serves to interpret. The Medicare statute requires that any program requirements that involve the ability of entities to furnish services under the program must be promulgated through formal regulations.[6] The Supreme Court recently clarified that there are no exceptions to the formal Medicare rulemaking requirements for interpretative rules or guidance.[7] In addition, the Department of Justice has recently determined that it will not utilize any guidance that has not undergone notice and comment rulemaking in any enforcement actions.[8] Therefore, AMRPA believes that this type of guidance should be subjected to formal notice and comment rulemaking and subsequently added

[6] 42 U.S.C. § 1395hh(a)(2) ("No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).").
[7] *Azar v. Allina Health Servs. aff'd*, No. 17-1484 (U.S. Jun. 3, 2019).
[8] Memorandum from Associate Attorney Gen. Rachel Brand to Heads of Civil Litigating Components, U.S. Dep't of Justice (Jan. 25, 2018) (available at: https://www.justice.gov/file/1028756/download).

to the Code of Federal Regulations. If CMS fails to utilize this approach, we underscore the need to ensure that stakeholder input is closely considered and reflected in final guidance. AMRPA stands ready to work with CMS however needed to assist with this endeavor.

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AMRPA welcomes continued opportunities to collaborate with CMS to ensure Medicare participating hospitals continue to deliver the highest quality patient care. If you have any questions about AMRPA's recommendations, please contact us or Kate Beller, J.D., AMRPA Executive Vice President for Policy Development and Government Relations, (kbeller@amrpa.org / 202-207-1132).

Sincerely,

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