



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

July 2, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Subject: Ref: QSO-19-13 Hospital – DRAFT ONLY – Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities (May 3, 2019)

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) draft policy memorandum *Ref: QSO-19-13 Hospital – DRAFT ONLY – Guidance for Hospital Co-Location with Other Hospitals or Healthcare Facilities* released on May 3, 2019.

CHA appreciates the time and effort the agency has put forth in seeking to clarify the appropriate use of shared space and contracted services by hospitals co-located with another hospital or health care entity. Moreover, we applaud the agency for revising Survey & Certification Memo: QSO-19-13 Hospital, and providing stakeholders an opportunity to share our perspectives on this important issue. Gathering stakeholder input on draft guidance will only further align our shared goals and promote clear understanding and expectations by both regulators and providers. We hope the agency will continue this approach with additional guidance in the future.

The co-location of hospitals with another hospital or health care entity is permitted, and we believe it benefits patients and providers by providing efficient and coordinated care. We anticipate that several long-standing relationships will need to be revisited in light of this guidance and varied implementation of prior guidance across the U.S. We believe several of the proposed changes are a step in the right direction, but additional clarity and flexibility needed to protect patient care and promote innovation and affordability. **CMS has made great strides in proposing draft guidance that promotes shared understanding. However, continued refinements to the language, as well as provider and state survey agency engagement and education, will be imperative for successful implementation.**

The current administration is firm in its goal is to reduce unnecessary regulations to facilitate increased access, lower costs, and improved patient experiences and outcomes. On numerous occasions, CMS has solicited ideas for how the agency can help to facilitate better health care at a lower cost. CHA has welcomed, and been an active contributor to, those discussions. This guidance is yet another opportunity for the agency to reduce unnecessary costs to our health care system while maintaining high quality of care, patient safety, and privacy.

These goals of affordability and efficiency are particularly important in California, where state law requires all hospitals to redesign and retrofit their buildings — or construct new hospital space — by 2022 in order to withstand a seismic event and, by 2030, to be able to provide care to patients in these structures. This statewide seismic compliance mandate requires hospitals to navigate current state regulatory requirements, while anticipating future technology advances, and to make significant capital investments. In response, California hospitals have invested billions of dollars and decades of work to upgrade or replace our facilities to ensure that our patients, employees, and visitors will be safe when the next earthquake strikes. However, the majority of buildings remain in the design stages for meeting the requirement to provide patient care in their buildings following an earthquake by 2030.

It can take on seven to 10 years to build a hospital, at an estimated cost of \$3.1 million per bed (RAND 2019). Hospitals are seeking innovative and cost-saving solutions that will allow them to continue to provide the breadth of services needed. Given the significant investments California hospitals have made, and are making, in their footprints, it is our hope that the changes to the draft guidance proposed are strongly considered as we make decisions today that will impact what our hospitals will look like a decade from now. Preserving flexibility to open the door for innovation and avoid unnecessary additional construction costs will promote affordability for payers and consumers.

In summary, CHA urges CMS to:

- **Think strategically about how to increase flexibility in distinct and shared spaces in the context of both patient safety and affordability.**
- **Consider policies and procedures that address a limited number of shared staff exceptions as outlined in the draft policy — exceptions that we believe are appropriate and continue to prioritize patient safety.**
- **Clarify the shift and training requirement for the contracted services.**
- **Allow hospitals to contract with a co-located hospital for specialized teams, such as emergency response teams, to best address the needs of its patients.**
- **Absent a formal rulemaking process, consider a period of education and non-enforcement — at a minimum, one year from release of the guidance. In addition, we urge CMS consider the Ligature Risk Extension Request (LRER) type of process, as well as a limited exceptions process or “grandfathering” of shared space arrangements.**

Distinct Space and Shared Space

The draft guidance limits space-sharing in clinical spaces but permits space-sharing in non-clinical areas and pathways. Hospitals must have defined and distinct clinical spaces of operation of which they maintain control at all times. The guidance states that co-mingling of patients in a clinical area from two co-located entities would pose risks to patient safety and privacy. Further, a non-hospital patient may not travel through a hospital clinical space on their way to a non-hospital space.

This is a step in the right direction from previous guidance that has led to varied interpretation and, in some instances, surveyors prohibiting the use of shared spaces between co-located hospitals and other entities. However, we believe the current draft guidance can, and should, go further to promote efficient care coordination while maintaining patient safety and privacy.

First, we ask that CMS use clearer language and define each term to promote shared understanding and expectations by hospitals and regulators. For example, there seems to be confusion about the definitions of registration, reception, check-in, and waiting areas. We believe this confusion could be

mitigated with a definition section of the guidance. The examples in the guidance are helpful, but we believe greater clarity can be achieved in the language.

Second, we believe there are many instances where it should be permissible for a patient of Hospital A to be escorted by authorized staff through clinical areas occupied by co-located Hospital B if needed. For instance, patients in Hospital A may need lab work, imaging, or other services during their appointments. Rather than having the patient gather their belongings, potentially redress, and exit one suite to walk in a public hallway to another suite seems unnecessary and not in the best interest of the patient if there is a connecting door or a hallway through Hospital B's clinical space. Patient safety can be maintained through an escort by authorized staff, and patient privacy can be protected by the use of hallways that travel through the clinical space of Hospital B.

CMS states in its guidance that infection control remains a concern. Additional guidance requiring that hospitals co-located with other entities have a common set of policies and procedures to ensure coordinated infection control procedures would address this concern. Further, each entity would remain accountable for abiding by these policies and procedures, but the policies and procedures would remain the same.

Another example of the challenges posed by this prohibition on using clinical space for travel is the case of an adult hospital with a pediatric unit that has a specialized Neonatal Intensive Care Unit (NICU) operated by a children's hospital. Again, the mom, who may be a patient at the adult hospital, would want to be close to her child and should be allowed to be escorted through the clinical space from the adult hospital to the pediatric unit and into the NICU without having to exit and reenter from another separate entrance. The alternative — to somehow disentangle the important colocation of labor and delivery and pediatric services by an adult hospital with the NICU space operated by a children's hospital — is administratively burdensome and not in the best interest of patient care.

In addition, CMS raises concerns that travel through clinical space could jeopardize the patient's right to personal privacy and confidentiality of their medical records. The statement on page 2 could be interpreted to mean that CMS believes patients' medical records are readily accessible while walking through any distinct clinical space, which we know is not the case.

Further, page 6 of the survey procedures notes that, "the sharing of spaces used for medical records and patient registration/admission could also potentially pose a risk to patient privacy as an unauthorized person could have access to patient records without consent." The vast majority of hospitals are currently working with electronic medical records that are protected through various mechanisms, including authorized user log in and password protection. We do not believe this is a fully considered rationale and should not prohibit the flexibility of shared space in this instance. It is important to note that both entities are required by HIPAA to have appropriate administrative, physical, and technical safeguards to minimize incidental disclosures (glare screens, passwords, and timed automatic logouts so unauthorized individuals cannot gain access, etc.). HIPAA requires all "covered entities" to provide training to all members of their workforce and to comply with HIPAA, as well as state privacy laws.

In addition, the draft guidance is inconsistent with other federal and state initiatives to integrate patient medical records across providers to further power patient-centric care. Providers have been actively working with federal and state agencies to eliminate siloed models for health information systems in order to have electronic medical records that reflect care across the continuum of

providers. Even in such integrated systems, including hospitals co-located with other entities, hospitals do, and will continue to, maintain appropriate controls of their medical record services to meet Medicare Conditions of Participation (CoPs) for medical record contents, orders, and access to such records. However, integrated electronic medical record systems inevitably require some consolidated administrative services to derive efficiencies, and each hospital should have appropriate policies and procedures in place to ensure compliance consistent with the CoPs.

CHA strongly supports patient privacy; in fact, California has some of the most stringent patient privacy legislation in the country. Further, hospitals in California are at significant risk of financial penalties for any breach or violation of such protected health information. We do not believe that CMS has fully supported its rationale for the risk to a patient’s medical record, and we strongly urge CMS to think strategically about how to increase flexibility in distinct and shared spaces.

We believe that consideration of these changes is firmly aligned with this administration’s goals of reducing health care costs. Added flexibility as outlined above and articulated by the American Hospital Association will create real efficiencies in hospital redesign, retrofit and rebuild as we look toward our seismic deadlines in California and significantly decrease the costs of hospitals faced with having to reconfigure existing space.

However, if CMS does not believe it has the ability to provide additional flexibility on the guidance itself, we believe a number of strategies must be considered to mitigate the significant financial and service impacts such guidance will have on existing relationships. We are certain it is no surprise to CMS that there are many hospitals co-located with other hospitals and health care entities where the lines of distinct clinical space and public space are blurred. For years, these arrangements have been surveyed and found to be acceptable by both CMS and the deeming accrediting organizations. Many of these arrangements would no longer meet the requirements if implemented — or it would be so costly to fix that providers would have no choice but to discontinue the service and lose the cost efficiencies and care coordination gained through these types of arrangements.

We believe CMS must consider a number of approaches to address these circumstances on a case-by-case basis. This is particularly important in states like California, where many of these arrangements will be temporary as new construction is underway. As discussed in more detail below, CMS should consider a period of non-enforcement prior to implementation; give further consideration to the Ligature Risk Extension Request process in CMS’ draft guidance, *DRAFT-QSO-19-12-Hospitals - Clarification of Ligature Risk Interpretive Guidelines* (released April 19, 2019); and, in the rare instances where there are extenuating circumstances, CMS should strongly consider a “temporary grandfathering” provision to address the needs of providers on a go-forward basis.

Shared Staff

The draft guidance permits staff sharing between the hospital and the co-located entity under limited circumstances. Each Medicare-certified hospital is responsible for independently meeting staffing requirements. 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, work at one hospital while concurrently being “on-call” at another, and may not provide services simultaneously. The exception is medical staff, who may be shared, or “float,” between the co-located hospitals if they are privileged and credentialed at each hospital.

CHA appreciates CMS' intent in separating staff. Common sense dictates that staff cannot be in two places at once. But we believe that appropriate policies and procedures can address a limited number of staff exceptions to this policy — exceptions that we believe are appropriate while putting patient safety at the forefront. And we believe there is confusion about the intersection between contracted services and contracted staff as outlined in the draft guidance.

Such changes are critically needed as California's health care workforce pipeline is not keeping pace with the growing demand for services. Hospitals and health systems, particularly in rural or low-income areas, struggle daily to ensure Californians receive the care they need and deserve. California already has shortages of physicians, pharmacists, behavioral health professionals, lab scientists, technicians in home health, geriatric specialists, physical therapists, and imaging technologists, making it harder to access care. This is further complicated by a geographic scarcity, or a maldistribution, of health professionals throughout the state.

California hospitals operate under extremely burdensome regulatory guidelines that include limited scope of practice for many clinical professionals, and we are the only state with nurse-to-patient staffing ratios in all hospital units. These requirements drive up labor costs that in turn increase health care costs. Therefore, we must be innovative in all our staffing approaches to reduce costs while continuing to provide high-quality health care services.

More specifically, CHA urges CMS to further clarify and consider certain positions as acceptable for exception, similar to medical staff. One such appropriate example could be a specialty nurse who consults for wound care, peripherally placed central lines, or other services that are infrequently needed in a co-located hospital or outpatient setting. Likewise, it would make sense to permit a phlebotomist to be shared and available to both hospitals as needed and on demand. For co-located hospitals, especially where one hospital is significantly smaller or where one hospital's co-located operations are limited to outpatient care, it is costly and sometimes impractical to maintain such teams or individuals. This prohibition on sharing staff could inadvertently limit beneficial access to specialty services without any clear quality or safety rationale.

In addition, under the draft guidance, contracted staff must be assigned to only one entity during a shift and cannot provide services at two co-located entities simultaneously. We anticipate there will be multiple and differing definitions of "shift," and we ask that CMS consider additional framing language to ensure consistent application of a definition that allows flexibility for hospitals. We are concerned that CMS has proposed a strict prohibition on pooled staffing arrangements that are in the best interest of patients, but that can operate and ensure that each co-located hospital satisfies all applicable CoPs and regulatory requirements, including that each has sufficient staff to meet the requirements. With the appropriate policies and procedures in place, we believe patient care can be enhanced and not negatively impacted.

CMS, in this draft guidance, prohibits directors of nursing, pharmacy, and laboratory from working simultaneously in both co-located entities. **We believe CMS has missed a significant opportunity to streamline administrative costs, ensure standardized policies and procedures, and enhance performance improvement initiatives across both entities, and we recommend CMS exempt these leadership roles from the prohibition on shared staff.** While we agree that a director of nursing cannot provide direct patient care at the same time as administrative duties, the administrative duties outside of patient care are appropriate and would benefit patient care. For example, if a hospital and a small co-

located hospital share an accomplished director of nursing, under this draft guidance the small co-located hospital would potentially lose the value of that d's leadership and be forced to hire a less experienced administrator. The economy of scale and promotion of quality in patient care would be lost.

Contracted Services

The draft guidance notes that hospital services may be provided under contract or arrangement with another co-located hospital or health care entity, such as laboratory, dietary, pharmacy, maintenance, housekeeping, and security services. Surveyors are directed to obtain a list of all services that a hospital obtains through contracts with others, including the hospital or entity with which it is co-located.

In reading this section of the guidance, **we believe CMS should make clear that this is not an exhaustive list, but rather examples of contracted services. In addition, perhaps noting what services CMS believes should not be contracted would be a more appropriate list for consideration.** The draft guidance seems to be inconsistent with existing regulatory guidance related to contracted services for hospitals generally.

For example, a food and dietary services CoP contemplates such arrangements, including that a hospital's dietitian may provide services on a consultant basis (42 C.F.R. 482.28). Similarly, a pharmacy services CoP contemplates the role of a consulting pharmacist who is responsible for the developing, supervising, and coordinating the activities of the pharmacy (42 C.F.R. 482.25).

Further, in the draft guidance, CMS expects that all contracted providers receive same level of training as the hospital's co-located entity that purchases services. This language is of concern in light of our surveyor experience. **We do not believe that CMS intends this to ensure that orientation/training on all policies and procedures is required of all contractors, but rather that the agency seeks to align with current policy for contracted arrangements. CHA requests confirmation of this interpretation.**

Emergency Services

Hospitals — even those without emergency departments — must provide basic emergency services to their patients. Such services include appraisal of emergencies and the provision of initial treatment. The draft guidance allows hospitals to contract with another hospital for appraisal and initial treatment only if the contracted staff are not simultaneously on shift at another hospital or entity.

The draft guidance calls into question whether one co-located hospital can contract with another co-located entity to provide "code team" or "rapid response team" services. **CHA urges CMS to allow hospitals to contract with their co-located hospital for specialized code teams to best address the needs of their patients. During the question and answer session of the national provider call hosted by CMS, we gleaned that the concern lies in the physical proximity or distance of the host and co-located hospitals. Such a one size fits all approach limiting the use of shared code teams is of concern. We strongly urge CMS to reconsider.**

For example, the emergency response care provided to adult patients in a children's hospital with an obstetrics/maternity unit co-located (often on the same campus, in the same building, or within a walkway) with an adult hospital benefits from experienced and highly competent staff. Many rapid response teams (RRTs) are comprised of highly specialized staff including a critical care registered nurse, respiratory care practitioner, phlebotomist, pharmacist, and a supervisor. The purpose behind use of this team, serving adult patients in the children's hospital, is to provide for timely assessment and

intervention of the adult obstetric inpatients when physiologic deterioration is recognized by the patient's primary nurse or family members. The adult RRT is trained in the critical competencies that respond effectively to the patient needs and provide education to the care team, as well as the patient and families. Members of the team complete a highly specialized and costly annual training to maintain their status as a member of this team. Having RRTs that specialize in providing this care makes sense from a patient safety perspective. Again, policies and procedures could be established to allay CMS' concerns about appropriate coverage. This is no different than a RRT response in an acute care hospital — there are back up teams also trained and ready to assist. With appropriate staffing and procedures in place, we believe RRTs should be permissible.

In addition, according to the draft guidance, hospitals that contract for emergency services with another entity's emergency department are considered to provide emergency services and must comply with the Emergency Medical Treatment and Labor Act (EMTALA). The language appears on page 7, but its intent is unclear. **We anticipate CMS has confused emergency services with emergency departments. EMTALA is not applicable to hospitals without emergency departments that contract for emergency services from another hospital. CHA urges CMS to remove any reference to EMTALA in the draft guidance.**

Survey Procedures

This revised guidance includes several changes to survey procedures, including surveying physical locations, reviewing floor plans, staff and service provider contracts, reviewing policy/procedures, and interviewing staff to determine adequate staffing levels, proper training, etc. **CHA urges CMS to develop, with stakeholder input, extensive surveyor education on this guidance to ensure requirements are consistently and effectively interpreted. Finally, we urge CMS to provide this education prior to the regulation's effective date and give state survey agencies time to adequately train staff. Additional oversight of compliance with surveyor training, similar to CMS' oversight of hospital employee training, should remain a priority.**

Other Considerations and Next Steps in Implementation

Due to the variation of interpretation of this guidance over time, and the current state of much of the construction underway in California, we ask the agency to consider the following as we prepare for implementation:

- 1. Absent a formal rulemaking process, CHA encourages CMS to consider a period of education and non-enforcement — at a minimum one year from release of the guidance.** We believe there are circumstances not fully contemplated in this guidance that would adversely impact hospitals' ability to continue to provide access to care for patients in our most vulnerable communities. Having a period of non-enforcement would allow any number of circumstances to be brought forward without fear of penalty, allowing the agency and providers time to work together on an agreed upon plan of correction. Further, and most importantly, this allows CMS the flexibility to "level set" across the country, as we believe the regional variation will be significant.
- 2. CMS established an LRER process in recent draft guidance for hospitals to request additional time to address ligature risks, with the goal of achieving compliance in a reasonable time frame. We strongly believe that a similar process will be needed for co-location arrangements to become compliant.** As outlined in the draft ligature risk guidance, the CMS regional office, state survey agency, or accrediting organization may — if, in their judgment, it is not reasonable to expect

compliance within 60 days — recommend the Secretary grant additional time in individual situations. For example, delays may be related to obtaining approval of the governing body, engaging in competitive bidding, applying for funding, obtaining permits for physical changes, and obtaining products and supplies needed for corrective actions. Co-location arrangements are complex, and similar issues arise. The process must include the hospital's accepted plan of correction, a risk mitigation plan ensuring patient safety, how the evaluation of the effectiveness of the mitigation plan will occur, and a rationale for why a 60-day compliance time frame is not reasonable. In addition, hospitals must submit monthly progress reports for all open LRERs.

CHA commends CMS for including a process by which hospitals can seek sufficient time to comply when established time frames otherwise may not be feasible; we offered the following suggestions to clarify the LRER process and believe the same comments are applicable in this instance.

Broaden Examples of Situations That May Cause Delays

Additional examples of why it is not reasonable to expect compliance within 60 days are worth considering. **CHA requests that the introductory language reference the myriad situations in which it would be unreasonable to expect compliance within 60 days, simply by stating on page 4, “Examples causing delays may include, but not be limited to.” Further, we ask CMS to broaden the examples to account for differences in state and local requirements related to making physical changes to a hospital.** For example, not every physical change requires a “permit.” That terminology suggests an actual building permit — but in California, other approvals of physical changes (such as local fire clearance and state seismic safety approvals) may be required in addition to a local building “permit.” **The examples should be broadened to instead read, “obtaining approval of the governing body, engaging in competitive bidding, applying for securing funding, obtaining permits approvals for physical changes, and lack of or delays in obtaining products and supplies needed for corrective actions.”**

Clarify SA or AO Accountability for Timelines

Hospitals must submit an LRER to the SA or AO “as soon as the hospital identifies that more than 60 days are needed.” The SA or AO has 10 business days to review the request, which must then be received by the CMS Regional Office (RO) no later than 60 calendar days after the hospital is cited for a deficiency. **CHA appreciates the specific time frames, but seeks clarification on what happens if the SA or AO misses a timeline and whether the clock for the hospital would stop, given that it had done its due diligence.** For instance, due to the outer deadline of 60 days, a hospital could submit the LRER as soon as it finds out it cannot comply with the 60-day time frame but, due to a delay with the SA or AO, miss the LRER going to the RO within 60 days.

Similarly, the guidance states that, once corrective actions are completed, the SA is to conduct an unannounced focused survey within 30 business days. **CHA seeks clarification on the status of a hospital if the SA does not meet that time frame.** In that case, the hospital would have remedied the issue(s), but would lack certainty over its status due to inaction out of its control.

Define Criteria for Granting or Denying LRERs

The SA, AO, or RO would determine whether to grant or deny an LRER. **CHA urges CMS to note any explicit criteria for granting or denying the extension, and what the oversight will be to ensure that the interpretation is consistent across regions. We also ask that CMS outline a process for**

appeal or reconsideration in the event an LRER is denied. A clear and transparent process promotes accountability and still allows for flexibility on a case-by-case basis.

3. Consider a limited exceptions process or “grandfathering” of shared space arrangements.

CHA anticipates that CMS will encounter circumstances where long-standing and important co-location arrangements exist, where the remaining barrier is the shared space. We also believe that these circumstances are likely resolvable and that, rather than spend precious financial resources to immediately rectify the situation, there would be a recognition of the co-located hospital’s longer-term commitment to their design and layout of the space in future construction as planned for under states seismic law noted above. We urge the agency to allow, on a case-by-case basis, a temporary agreement for these arrangements to continue. While not grandfathered in perpetuity, there would be a recognized plan in place to ensure the issues are addressed on the timeline agreed to by CMS and the co-located entities. We anticipate similar provisions to the LRER process would be a part of this process.

Additional Areas for Consideration

CMS has not addressed the issue of visiting physician services, time-sharing arrangements, or physician leasing agreements in this guidance and, therefore, we ask CMS to confirm our assumption and provide language that these agreements are all expressly allowed.

Further, CMS has not addressed in this guidance the costly and evolving breakthrough medical technology that co-located entities may wish to obtain and share. For example, intraoperative magnetic resonance imaging (iMRI) technologies provide significant opportunities to improve surgical protocols and procedures. This advanced technology allows a surgeon to image and assess resection or any other needed or indicated surgical intervention while a patient is under anesthesia during the operative procedure. Currently, surgical procedures may be significantly improved through the use of iMRI for pediatric and adult patients requiring complicated neurosurgical interventions. Given the high cost of this technology and the unique location constraints to construct a surgical space with a dedicated iMRI device, co-located hospitals might wish to devote their limited capital resources to the purchase of a single iMRI to be housed in a surgical suite located in one hospital, rather than purchasing two. This is just one example of the needs of hospitals building for the future, and we ask CMS to revisit this guidance and articulate a pathway for consideration of such requests.

CHA appreciates that CMS is revisiting its co-location guidance, providing additional clarity. We urge the agency to establish a process to allow hospitals appropriate time to remediate any identified issues. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688, or Kiyomi Burchill, vice president, policy, at kburchill@calhospital.org or (916) 552-7575.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs