American Hospital Association™
Advancing Health in America

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June 17, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: QSO-19-13-Hospital: DRAFT ONLY – Clarification of Ligature Risk Interpretive Guidelines – FOR ACTION

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Society for Health Care Engineering and American Society for Health Care Risk Management, our clinician partners and, especially, the 85 psychiatric hospitals and 1,039 hospitals with dedicated behavioral health beds, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed guidance on ligature risk. Specifically, our letter commends the agency for its work on this important issue and offers several recommendations aimed at providing increased clarity around these critical provisions.

We appreciate CMS's efforts to clarify guidance around ligature risk requirements in hospitals and health care systems. Caring for patients who pose a threat to themselves or others requires a careful and thoughtful approach focused on effectively assessing and caring for those patients while also taking into account the potential risk to health care workers. In its proposed guidance, **CMS has struck the appropriate balance, emphasizing safety for both patients and the providers who care for them while requiring meaningful assurances that hospitals are equipped to navigate these situations successfully**. In addition, we thank CMS for its recognition of the investment hospitals must make to meet a ligature-resistant standard.

Specifically, differentiating between locked and unlocked units will provide an important distinction and demonstrates the agency's commitment to ensuring patient safety, while also understanding the work required of hospitals. **Further, we support CMS's proposed ligature risk extension request process and encourage CMS to use a**

similar process for regulations and guidelines where construction or acquisition of additional resources requires additional time for compliance.

We also urge the agency to consider additional clarifying language around some of the proposed requirements in order to better direct and prepare hospitals for implementing the necessary changes. Specifically, we recommend additional clarification around behavioral health assessments, health care staff, surveyor education and training, and dedicated emergency department (ED) psychiatric beds. Our specific comments follow.

LOCKED VS. UNLOCKED PSYCHIATRIC UNITS

In its draft guidance, CMS proposes to require that locked psychiatric units be ligature resistant, while establishing that unlocked units need not meet the ligature-resistant standard but have proper mitigation procedures in place when treating patients at risk of suicide. **The AHA supports this approach and agrees that this differentiation appropriately balances the need to keep safe those patients at risk for suicide, while also understanding the investment and changes that hospitals and health systems will have to undertake to be compliant. Such a distinction places a reasonable expectation on hospitals and health systems to make changes to specific units within their clinical care areas as necessary.**

While the ligature-resistant requirement for locked units in psychiatric and acute care hospitals is clear for the most part, there is some ambiguity around requirements for dedicated psychiatric beds in EDs and what "locked unit" may mean. First, there is a variety of instances where ED beds serve multiple purposes, including, when necessary, treating psychiatric patients who pose a risk of suicide. For example, some EDs have beds capable of use for all types of patients but quickly convert into ligature resistant rooms when necessary by removing certain equipment or shuttering the windows and doors. We assume that those rooms capable of becoming ligature resistant when necessary are permissible under this guidance and would be expected to have a mitigation plan in place when treating patients at risk of suicide. Specifically, we ask the agency to confirm that these types of units will not be held to the ligature-resistant standard for "locked" units. Second, hospitals may have locked units for other reasons, such as providing care to incarcerated individuals who have a health care need. We assume that CMS does not intend to apply the ligature-resistant standard to those rooms, even if there are patients with suicidal ideation in those beds. We believe CMS intends to apply the standards for unlocked psychiatric units to these beds, not the locked unit standards, and we would appreciate a confirmation from the agency.

In the discussion of the application of guidance to unlocked units, CMS calls for a patient assessment, and, when necessary, assurance that patients determined to be at risk for suicide in unlocked units receive the proper care and appropriate level of monitoring. While the agency provides an example for the Department of Veterans Affairs, the AHA recommends it consider offering additional examples of appropriate assessments in order to better prepare hospitals when making these important determinations. In addition, multiple examples likely will help surveyors understand that

no one model is required, so long as the assessment appropriately meets the needs of the patient. Ultimately, more clarity will give hospitals a better understanding of the requirements for their unlocked units, while also ensuring surveyor objectiveness.

Lastly, we thank the agency for its proposed adoption of 1:1 video monitoring for at-risk patients in unlocked psychiatric beds, but we ask the agency to clarify further its intent relating to "immediately available to intervene." By its very nature, 1:1 video monitoring will require a certain amount of time for health care staff to enter the patient's room to intervene when an emergency presents itself. In such instances, staff will respond as quickly as possible, but we are concerned that the language, as proposed, places an unrealistic burden on those staff members responsible for video monitoring. We recommend that CMS clarify the term "immediately available to intervene" by adding language stating "*in a timely and effective manner*" to account for the matter-of-fact difference between video and 1:1 in-person monitoring.

LIGATURE RISK EXTENSION REQUESTS

In its proposed guidance, CMS establishes a ligature-risk extension request (LRER) process for those ligature findings that cannot be reasonably corrected within the required 60-day window. The AHA supports this proposal and commends CMS on its recognition of the potential scale and timing associated with certain changes that may be required to comply with this guidance. We appreciate the specific examples demonstrating when CMS deems LRER's to be appropriate and urge the agency to consider these requests on a case-by-case basis, understanding that no hospital presents the same set of circumstances or has the same resources available. We also ask that CMS confirm that those hospitals approved for an LRER and are in the process of mitigating the ligature finding will not be subject to unannounced surveys. We assume that so long as the required monthly progress updates are sufficient and timely, the agency will not survey for this specific issue until the correction is complete. In addition, we urge the agency to confirm that, when an LRER is approved, any "Immediate Jeopardy" designation will be removed, as such a designation would effectively over-penalize the hospital during the correction process.

Finally, because the LRER process is likely to provide significant benefit, we urge the agency to consider the implementation of similar extension request processes where warranted in future guidance when compliance within the allotted timeline is not achievable. Hospitals and health systems want to make the right decisions for their patients, and they want to follow through on those decisions in the right way. This process, when applicable, allows providers to make the critical changes necessary without rushing to meet impossible timelines, ultimately creating real and lasting benefits for all involved, especially the patients for whom we care.

EDUCATION AND TRAINING

Ensuring that our patients receive the highest quality of care requires that health care professionals receive the appropriate level of education and training. In its draft guidance, CMS proposes a series of education requirements for clinical staff, as well as hospital staff who work in clinical areas. Overall, we support the proposed requirements, but ask the agency to provide more clarity around requirements for contracted employees and those individuals who may be in clinical areas for a very limited period of time (i.e., a few days), like HVAC professionals or temporary staff substituting for permanent employees. In those situations, we recommend the agency allow an approved hospital employee to oversee these short-term contractors as necessary. In addition, we recommend that any short-term employment contracts include appropriate disclosures of the risks associated with work in these units. In the absence of adopting these suggested recommendations, we ask that CMS clearly state the level of training required for these types of contract workers, who is responsible for providing that training, and the length and substance of the training.

SURVEY PROCEDURES

We appreciate CMS's proposed changes to the survey process in order 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 may mean 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. In order 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 instance 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.

Again, thank you for the opportunity to comment on this proposed guidance. Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director, policy, at mhowell@aha.org or (202) 626-2274.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development