

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: Clarification of Ligature Risk Interpretive Guidelines

Dear Administrator Verma:

On behalf of our more than 200 member hospitals and nearly 50 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to submit comments on the on the Centers for Medicare & Medicaid Services' (CMS) [proposed guidance on ligature risk](#).

IHA commends CMS for its development of this proposed guidance to clarify interpretive guidelines from 2017 regarding what constitutes a ligature risk and expectations for different units of a hospital. Based on IHA member feedback, hospital surveys in this time period have resulted in inconsistent survey determinations between CMS and private accreditation organizations, so we support CMS' efforts to create further guidance. **IHA supports CMS' recognition of the importance of reducing environmental risks for patients that may cause harm to themselves or others, as well as recognizing the safety of healthcare workers in our hospitals.** However, IHA and our member hospitals have concerns with the operational aspects of several provisions, and subsequently, present the following for your consideration:

EXTENSION REQUESTS

In its proposed guidance, CMS establishes a ligature-risk extension request process for any findings that cannot be reasonably corrected within the current 60-day window permitted. IHA supports the extension request process, and **requests the agency clarify that unannounced surveys will be suspended for the specific issue approved for an extension until the correction has been completed, as long as all required updates are submitted in a timely manner.** We encourage the approval of an extension request on a case-by-case basis, as circumstances of the request, immediately available hospital resources, and the length of time that new hospital equipment may be on back order may all impact surveyor consideration.

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Given that CMS has proposed an extension request process in recognition of these variables, we urge the agency to designate hospitals with an alternative classification from Immediate Jeopardy (IJ), upon immediate approval of such requests, to clearly differentiate these situations from those that may involve IJ classification. Hospitals approved for a plan of action to address specific ligature risks identified by surveyors must have a mitigation plan to ensure patient safety following any extension request that is granted, so the continued use of IJ classification mischaracterizes hospital status and the risk to patient safety. This status puts hospitals at risk of losing all on-going contracts in negotiation, including those with Medicaid managed care contractors, private payers, and any vendors. Termination of these contracts could directly result in a hospital closing or reduction in behavioral health service line in order to maintain hospital access, prior to the completion of the CMS request.

HEALTHCARE INTEGRATION AND ACCESS

IHA supports the clarification provided requiring ligature-resistant locked units and mitigation procedures in unlocked units, when treating patients at risk of suicide. **For locked psychiatric units, IHA recommends clarification be provided around requirements for ligature resistant versus ligature-free environments, as those may be interpreted and viewed differently by any given surveyor.** Further clarity from CMS regarding what level of observation is required within each of those environments would also be appreciated.

Additionally, we request confirmation that emergency department (ED) beds shall not be held to locked unit standards, due to multipurpose use. Often, ED beds and rooms can transition to mitigate ligature risks with a pull-down door that locks medical equipment, or similar environmental protections. Requiring ED beds to follow locked unit requirements would result in hospitals choosing between using that bed for psychiatric or medical services, creating a direct access barrier for one of the populations served.

Hospitals have made important strides to integrate behavioral healthcare and medical care for patients with complex comorbidities and treat the person as a whole, but there is concern that this guidance may reverse these improvements to patient care. Requiring the ED and locked units with patients that have medical comorbidities to be ligature resistant is unrealistic, due to critical medical equipment like Continuous positive airway pressure (CPAP) machines, insulin pumps, and vacuum-assisted closure of wounds (i.e., wound VACs). Behavioral health patients are at risk of high comorbidities and conditions that may require a specialized medical bed for elevating the head of the bed, lower beds for patients to be able to get out safely, and physical disability requirements. Currently, there are no ligature resistant medical beds on the market. Since 2017, hospitals have reported that surveyors have indicated electronic or manual crank adjustable patient beds are not acceptable under new ligature risk requirements. However, the proposed alternative may create patient fall or injury risk that is unacceptable. **To ensure access to care for these patients, we strongly encourage greater flexibility around ligature risk requirements be afforded in locked units for patients with specific medical needs.**

Ligature resistant environments in locked units should have special consideration for shared spaces under observation, as the requirements remove items that are healthy outlets for patients to relieve stress and develop healthy coping mechanisms (e.g., exercise bikes, games). There is growing concern from patients and families that has been shared with healthcare workers that units have become very institutional looking in recent years, or concern that a patient's recovery may not be treated with dignity in such a sterile environment. Ligature risk determinations should prioritize patient safety, but also maintain an environment that fosters patient recovery.

IHA supports CMS' clarification on high-risk patients, but we recommend greater clarity on levels of suicide risk in unlocked units, especially with low-to-moderate risk patients. For low-to-moderate risk patients, requiring a general plan of action that follows organizational best practices provides flexibility for a patient's specific needs.

INCONSISTENT INTERPRETATION OF STANDARDS

Hospitals have reported that it is not uncommon for CMS surveyors to have substantial variation in their interpretation of rules, resulting in one surveyor making a costly recommendation for changes, only to be countered by another CMS surveyor who later comes to an opposite conclusion. The issue is further complicated between substantial differences in requirements between CMS and private hospital accreditation organizations. Hospitals have shared concern that their inpatient units, compliant with environmental standards before 2017 interpretive guidelines, now regularly require renovations that cost hundreds of thousands, and even millions of dollars. Since 2017, we have had reported instances of CMS surveyors requiring a hospital to purchase new furniture or environment-related equipment based on ligature risk, only to have a private accrediting agency determine the new equipment recommended by surveyors as a separate ligature risk that must be removed. These inconsistencies result in significant new equipment costs, but also substantial time and effort of staff that would be better spent on healthcare provider education, training and patient care. **Consistency and clarity in surveyor determinations and guidance to hospitals will be critical moving forward. We suggest CMS perform an audit not only of potential inconsistencies among CMS surveyors and recommendations to align determinations, but also identify and eliminate differences in CMS and private accreditation requirements.**

Similarly, IHA supports clarification on guidance regarding bolted or weighted furniture that can be easily moved or thrown in common areas. For example, some surveyor guidance since 2017 has indicated bolting furniture would be appropriate. However, when bolted down, chairs can be used as a fixed ligature point, either as a point from the back or across as an alligator roll. Likewise, depending on weight, furniture could be used as a weapon or projectile, and a heavier projectile creates alternative safety issues for patients and healthcare workers.

Finally, we support CMS' proposed adoption of video monitoring for at-risk patients in unlocked psychiatric beds, but ask for greater clarification around video monitoring ratios

and response. We recommend that CMS clarify the term “immediately available to intervene” to account for differences between video and in-person monitoring, by recognizing that interventions must take place in a timely and effective manner. Also, we recommend CMS expand the ratio of patients who may be monitored by one healthcare worker via video, as 1:1 monitoring may be considered limiting for an individual whose sole role is to monitor screens for patient safety and well-being.

Administrator Verma, thank you again for the opportunity to comment. If you or your staff has any questions on the comments, they should be addressed to Lia Daniels at (630) 276-5461 or ldaniels@team-iha.org.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association