



**CALIFORNIA  
HOSPITAL  
ASSOCIATION**

*Providing Leadership in  
Health Policy and Advocacy*

June 17, 2019

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

***Subject: DRAFT-QSO-19-12-Hospitals - Clarification of Ligature Risk Interpretive Guidelines***

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 to update the CMS State Operations Manual (SOM) Appendix A for Hospitals and SOM Chapter 2, Section 2728G, both related to ligature risk.

CHA shares CMS' goals of improving care and safety for all patients, especially our most vulnerable psychiatric patients who are at risk of harming themselves or others. Inherent in that goal is ensuring the safety of those who provide care to these individuals. **We applaud CMS for revising Survey & Certification Memo: 18-06-Hospitals, and providing stakeholders an opportunity to share our perspectives. Gathering stakeholder input on draft guidance will only further align our shared goals and promote clear understanding and expectations by both regulators and providers.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.**

Several of the proposed changes are a step in the right direction, but additional clarity is needed. CMS has made great strides in adopting draft language that promotes shared understanding of not only what constitutes ligature risk, but also CMS' expectations of hospitals to achieve ligature-resistant environments. **Continued refinements to the language, as well as provider and state survey agency engagement and education, will be imperative for successful implementation.** We look forward to working with the agency in these endeavors.

In summary:

- CHA requests that CMS limit the scope of ligature resistant requirements to locked psychiatric units within psychiatric and acute care hospitals. This would establish a bright line between locked and unlocked units so hospitals can consistently and thoroughly comply. For emergency departments and other unlocked areas of hospitals, hospitals would still take steps to prevent patients from harming themselves or others, as outlined in the guidance and in accordance with nationally recognized standards and guidelines. Language in the guidance that focuses on the

patient's needs, rather than the setting in which care is provided, will provide greater clarity for surveyors and clear expectations for providers.

- CHA supports CMS' recognition that the current 60-day compliance time frame is not always reasonable and applauds the agency for establishing a ligature risk extension request (LRER) process by which hospitals can, on a case-by-case basis, request additional time to meet requirements. To further improve this process and to increase transparency and accountability, CHA urges CMS to consider a number of clarifications, including establishing criteria or a framework to approve or deny a request and identifying how regional offices (ROs), state agencies (SAs), or accreditation organizations (AOs) will be held accountable for meeting the deadlines by which they must respond to hospitals or submit requests to ROs.
- CHA urges CMS to put forward additional surveyor education on this guidance to ensure requirements are consistently and effectively interpreted. Such education should be required of surveyors prior to assessment of hospitals, mirroring CMS' request that hospitals train all employees on relevant policies and procedures. CHA also urges CMS to work with stakeholders to develop and publish a standardized surveyor tool to improve consistency in the standards' application.
- CHA requests additional examples and clarifications to assist surveyors and advise the field on measures that can be taken for protecting patient safety in areas not subject to the ligature resistant requirements.

Our detailed comments are below.

#### **CMS SOM APPENDIX A FOR HOSPITALS**

In its draft guidance, CMS clarifies existing 2017 ligature risk interpretive guidelines. This includes a differentiation between locked and unlocked psychiatric units, requiring education and training for hospital staff, and revising surveyor procedures.

##### *Clarify Application to Emergency Departments*

According to the revised guidance, the ligature resistant requirement applies to locked psychiatric units within psychiatric hospitals and acute care hospitals, including locked emergency department psychiatric units. The guidance further states that the ligature resistant requirements do not apply to non-psychiatric units of hospitals (e.g., emergency departments, intensive care units, medical-surgical units, and other inpatient and outpatient locations), even though these units may provide care to those at risk of harming themselves or others. However, the draft guidance's reference on page 9 to "emergency departments, with dedicated psychiatric beds or units, when within a locked area in which the patients may not move freely in and out of the unit/rooms" has created significant confusion in the field.

Data show that over a five-year period, hospital emergency department utilization in California increased by a staggering 47% for people with behavioral health conditions, while overall emergency department utilization increased by only 14%. This volume has necessitated that hospitals be flexible in where they place emergency department patients with a range of behavioral health needs, including alcohol, other substance use, and mental health needs. This ensures patients' medical and behavioral health care needs are assessed simultaneously. For example, some hospitals cohort psychiatric patients in the emergency department, rather than dedicating beds or designating units. The number, type, and location of these cohorts can change from day to day as the patient population varies. A hospital may place patients in different areas depending on the patient population they represent. For instance,

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hospitals may separate pediatric mental health patients from patients under the influence of alcohol or other substances who present a harm to themselves or others, as the latter population's mental health symptoms would be better addressed after the patient regains sobriety.

In addition, psychiatric patients within emergency departments may have personnel supervising them and restricting their movement in an unlocked unit. For example, there may be an area in which entrance is limited to those with an employee badge, but exit is unrestricted. As a result, the language about moving freely adds even greater confusion. Taken together, the language currently outlined is subjective and will result in significantly varied survey findings.

Including less than clear language regarding the applicability to emergency departments, when the previous language notes that emergency departments are excluded (absent a locked unit within the emergency department), is of great concern.

We ask the agency to reconsider this language, keeping in mind hospitals' current patient assessment processes that inform the mitigation of environmental risks. This process is used to ensure high-quality patient care not only within the emergency department, but also any other unlocked area of the hospital. In comparison, The Joint Commission — under its *Revisions to the National Patient Safety Goal on Reducing the Risk for Suicide (NPSG.15.01.01)*, issued November 26, 2018 and effective July 1, 2019 — states that it does not expect **non-psychiatric units in general hospitals** to be ligature-resistant environments. These would include emergency departments.

**CHA requests that CMS limit the scope of ligature resistant requirements to locked psychiatric units within psychiatric and acute care hospitals, and remove references to the emergency department, as noted, on pages 8 and 9.** Language in the guidance that focuses on the patient's needs, rather than the setting in which care is provided, will provide greater clarity for surveyors and clear expectations for providers. Further, this change would establish a bright line between locked and unlocked units, regardless of the location, so that hospitals can consistently and thoroughly comply. This would still require emergency departments and all other unlocked areas of hospitals, as outlined in the guidance, to take steps, in accordance with nationally recognized standards and guidelines, to protect patients who pose a threat of harm to themselves or others.

#### *Confirm Applicability to Detention Care Units*

Some of our acute care hospitals have dedicated detention care units that provide care only to incarcerated individuals. **Detention care units are not certified under Medicare. As such, we would not anticipate that they would be subject to these requirements. CHA would appreciate confirmation of this interpretation.** CHA recognizes that other accrediting organizations may set a standard higher than Medicare's, and appreciates CMS' consideration of additional language to promote clarity and understanding.

#### *Develop Surveyor Education on Changes to Surveyor Procedures*

This revised guidance includes several changes to surveyor procedures, including requiring surveyors to review hospital policy/procedures and interview staff on how the hospital initially and routinely trains staff, review policy/procedures and interview staff to determine how the hospital defines 1:1 video monitoring and continuous observation, and verify that a policy exists to assess and reassess patients who have been identified as being at risk for suicide or harm to self or others. **CHA urges CMS to**

**develop, with stakeholder input, extensive surveyor education on this guidance to ensure requirements are consistently and effectively interpreted.** CHA stands ready to work with CMS and other stakeholders to develop and pilot a standardized surveyor tool. **Finally, we urge CMS to provide this education prior to the regulations' effective date and give 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.**

#### *Safety Measures in a Non-Psychiatric and Unlocked Setting*

While ligature resistant requirements do not apply in non-psychiatric and unlocked settings, hospitals must take steps to minimize risks for patients identified at risk of harm to self or others, in accordance with nationally recognized standards and guidelines. The draft guidance provides examples of safety measures hospitals should take to ensure patients are protected. However, the list of examples is not exhaustive, and some are more specific than others. **CHA requests clarity that the listed examples are not the only measures that can be taken, as well as additional examples to assist surveyors and advise the field.**

Commonly, patients are risk-stratified, and appropriate evidence-based measures are taken. As a result, while 1:1 monitoring with continuous visual observation is one potentially appropriate measure, in-person or video monitoring with one personnel and multiple patients could be as well. **CHA requests that CMS modify the language on page 8 to read, "Safety measures that ensure these patients identified as being at risk are protected in a non-psychiatric and unlocked setting may include:**

- **~~1:1~~ monitoring with continuous visual observation, including ~~or~~ video monitoring, if appropriate;"**

Additional conforming changes to remove the references to 1:1 on pages 10, 11, and 12 would support communicating the range of patient safety steps that may be appropriate for a given patient. Further, outlining examples of nationally recognized standards that surveyors might consider using would be helpful in surveyor education.

The guidance also notes that while toilet seats may be a potential ligature point, evidence suggests the risk is minimal. The guidance explains that surveyors should not consider this one item as non-compliance in the absence of other factors. **CHA urges CMS to further clarify the "other factors" that could contribute to a non-compliance citation in relation to toilet seats.** For example, CMS should provide consistent guidance to surveyors on appropriate use of bathroom doors. Ligature resistant technology is an ever-evolving field, and CMS must determine how best to ensure that hospitals maintain flexibility in obtaining solutions that meet their facilities' needs, while not assuming a one-size-fits-all approach (e.g., only one brand of bathroom door).

#### *Clarify Education and Training of Hospital Staff*

Under this guidance, hospitals are expected to provide education and training related to screening and assessment of patients at risk of harm to self or others; identification of patient safety risk factors; and mitigation strategies for all new employees who work independently in patient care areas, including non-patient care employees who work in these areas. In addition, hospitals are expected to provide education and training to all staff when policies and procedures change. Based on the draft guidance, one may assume that CMS intends education and training to be required for temporary contract employees. **CHA believes that temporary, non-clinical contract employees should not be subject to the**

**same comprehensive staff education and training requirements, as we believe this will become administratively burdensome, costly, and not improve patient care.**

*Confirm That Voluntary or Involuntary Legal Status Is Irrelevant*

State laws govern mental health civil commitments. As such, application of ligature risk would not be dependent on whether a patient in a psychiatric hospital or acute care hospital is under an involuntary civil commitment or is there voluntarily. **CHA requests confirmation of its understanding that the ligature resistant requirements apply based on the clinical setting and not the patient's voluntary or involuntary legal status under state civil commitment laws. For example, for clarity, it would be helpful if CMS were to consider placing the following sentence on page 8 of the guidance: "Under state civil commitment laws, a psychiatric patient may be under an involuntary civil commitment or be there voluntarily. This legal status is irrelevant to the determination of whether a setting must be ligature resistant."**

**CHAPTER 2/SECTION 2728G/MAJOR DEFICIENCIES REQUIRING LONG-TERM CORRECTION IN PSYCHIATRIC HOSPITALS AND HOSPITAL PSYCHIATRIC UNITS, LRER**

CMS establishes a LRER process for hospitals to request additional time to address ligature risks with the goal of achieving compliance in a reasonable time frame. Specifically, the RO, SA, or AO may — if, in their judgement, 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. LRERs 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; below, we offer suggestions to clarify this new process. Moving forward, we encourage CMS to consider using a similar process with other requirements.** For instance, the pharmacy compounding chapters of the United States Pharmacopeia (USP)-National Formulary (USP 41-NF36), released May 31 and June 1, create a tight time frame that many hospitals will be challenged in meeting. With these and other regulatory requirements, even as we work in good faith, experience has shown that additional time will be needed for construction or acquiring additional resources.

*Broaden Examples of Situations That May Cause Delays*

There are other examples of why it is not reasonable to expect compliance within 60 days that would be 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**

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**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 a LRR 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 ROs 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 LRR 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 LRR 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 LRRs*

The SA, AO, or RO would determine whether to grant or deny a LRR. **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 LRR is denied.** A clear and transparent process promotes accountability and still allows for flexibility on a case-by-case basis.

CHA appreciates that CMS is revisiting its 2017 guidance, providing additional clarity, and establishing a process to allow hospitals appropriate time to take steps to remediate any identified issues. If you have any questions, please do not hesitate to contact me at [akeefe@calhospital.org](mailto:akeefe@calhospital.org) or (202) 488-4688, or Kiyomi Burchill, vice president, policy, at [kburchill@calhospital.org](mailto:kburchill@calhospital.org) or (916) 552-7575.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs