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President & CEO

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Ms. Karen Tritz, Acting Director  
Quality, Safety, and Oversight Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
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***SUBJECT: DRAFT-QSO-19-12-Hospitals; Clarification of Ligature Risk Interpretive Guidelines***

Dear Acting Director Tritz:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) Center for Clinical Standards and Quality, Quality, Safety, and Oversight Group, on the above referenced draft revisions to the State Operations Manual (SOM), issued to State Survey Agency directors in an April 19, 2019 Memorandum. The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute and ambulatory services.

As noted in the April 19, 2019 Memorandum, CMS's primary concern related to ligature risk is the care and safety of psychiatric patients at risk of harm to themselves or others and the staff providing care are the primary concerns. The FAH appreciates that the draft guidance offers clarity for hospitals in identifying patients who are at risk for intentionally harming themselves or others, identifying environmental safety risks for such patients, and providing environmental safety education and training for employees and volunteers. We agree that these components are important for contributing to a safer care setting, and offer the following comments related to the draft guidance.

## OVERALL COMMENTS

The FAH welcomes the additional guidance CMS proposes to help providers establish and maintain ligature-resistance in their operations. As these updates are finalized and then implemented, the process that CMS has outlined for allowing hospitals to request additional time to address ligature risks and achieve compliance will be helpful for hospitals. **In particular, the FAH supports the Agency's description of its expectations for hospitals to maintain ligature "resistant," rather than ligature "free" environments.** Although providers make good faith efforts to achieve the highest ligature resistant environment possible, a ligature free environment is not always feasible. Describing the Agency's expectation for providers to maintain a "ligature resistant" environment is more practical and creates a standard that is achievable for hospitals, while also protecting patients in these settings.

**Further, as CMS finalizes its ligature risk guidance, the FAH encourages CMS to consider the need for alignment between CMS ligature risk expectations and The Joint Commission (TJC) standards.** TJC requires inpatient psychiatric hospitals, inpatient psychiatric units in general acute care hospitals, and non-behavior health units designated for the treatment of psychiatric patients to establish and maintain safe and functional environments, which includes addressing ligature risks.<sup>1</sup> Failure to align CMS guidance with TJC standards could result in conflicting requirements and confusion among providers. In the alternative, if there are conflicts between CMS's final guidance and TJC standards, the FAH encourages CMS to identify these differences and then allow TJC and providers sufficient time to meet any new requirements that result from the final guidance.

We appreciate that CMS's draft revisions clarify that the ligature resistant requirements do not apply to "non-psychiatric units of hospitals" such as "emergency departments, intensive care units, medical-surgical units, and other inpatient and outpatient locations." The FAH also supports that the guidelines would not apply to unlocked psychiatric units where patients are able to move freely.

Finally, psychiatric partial hospitalization programs (PHPs) are outpatient locations where patients arrive in the morning for treatment and return home at the end of the day. Patients at risk of bringing harm to themselves or others are treated on an inpatient basis, not in a PHP where patients are able to move freely throughout the facility. Given that patients who pose a ligature risk are not treated in PHPs, it would not be appropriate to apply the ligature resistant requirements to a PHP. **Therefore, the FAH asks that the final guidance confirm that PHPs are outpatient facilities that are not subject to CMS's ligature risk guidelines.**

## SPECIFIC COMMENTS

The draft revisions to the SOM are generally helpful in guiding our member hospitals in implementing a ligature resistant environment. As discussed in more detail below, we offer targeted comments for certain components of the revisions.

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<sup>1</sup> The Joint Commission, Standards FAQ Details, Ligature Risks - Assessing and Mitigating Risk For Suicide and Self-Harm, [https://www.jointcommission.org/standards\\_information/jcfaqdetails.aspx?StandardsFAQId=1525](https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=1525).

## **Revisions to SOM Chapter 2 Certification Process**

### **2728G – Major Deficiencies Requiring Long-Term Correction in Psychiatric Hospitals and Hospital Psychiatric Units, Ligature Risk Extension Requests (LRER)**

As discussed in the guidance, ligature risks identified in psychiatric hospitals and hospital psychiatric units are cited under the Patient’s Rights Condition of Participation (CoP) (§482.13) and may also be cited under Physical Environment CoP (§482.41), depending upon the specific types of non-compliance identified. According to §488.28(d), a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of condition-level deficiencies.

The FAH recognizes the importance of addressing an identified condition-level deficiency in a timely manner. Nevertheless, under the draft guidance, the CMS Regional Office (RO), State Agency (SA), or Accreditation Organization (AO) may recommend additional time be granted in individual situations if judgment indicates that it is not reasonable to expect compliance within 60 days. The draft guidance provides examples where additional time may be needed, for example, when a provider is obtaining approval by a governing body; engaging in competitive bidding; applying for funding; obtaining permits for physical changes; or lack of or delays in obtaining products and supplies needed for corrective actions. The FAH appreciates CMS’s acknowledgment that these and other similar circumstances may require extra time to achieve compliance due to factors beyond a hospital’s control. **The FAH agrees with CMS that the 60-day period is burdensome in some scenarios and supports an allowance of additional time to achieve compliance, particularly when delays are beyond a provider's control, for example due to supply chain disruptions.**

### **2728G – Non-Deemed and Deemed Hospital LRERs**

**As discussed above, the FAH supports the granting of LRERs when appropriate.** While hospitals have invested, and continue to invest, significant resources to achieve a ligature resistant environment, in some instances additional time is needed to achieve that goal. As noted above, this can be especially true in circumstances beyond a hospital’s control, such as in the event of a shortage in the national supply chain for an item that is needed to achieve a ligature resistant environment. Once an item becomes available, providers need a reasonable amount of time to implement any new infrastructure related to the item. This need for flexibility and lead time gains greater importance in light of recent challenges faced by health care providers. For example, the national shortage of clinicians and other qualified staff available to provide psychiatric services can pose challenges to achieving a ligature resistant environment. In addition, converting operations to a ligature resistant environment can require significant capital investment. This is particularly true when existing hospital infrastructure was constructed decades ago for a different patient mix than is seen by hospitals today, where hospitals are overflowing with patients in need of psychiatric services.

**The FAH also supports the proposed requirement that the SA and RO must promptly respond to a LRER and appreciates CMS's clarification that the SA and CMS RO must review and make a determination within 10 business days of receipt of the LRER to allow a**

**facility adequate time to plan for corrective actions.** Prompt determinations in the case of an LRER are critical. If providers were to receive a LRER denial with little time left for corrective action, such as on day 58 before the 60-day deadline, it would be unreasonably difficult to comply with the deadline. Further, if the SA or CMS RO does not respond within the specified timeframe, providers should have a reasonable timeframe to implement corrective action. In addition, we urge that the draft guidance, in the case of a LRER denial, expressly permit providers to appeal the denial in the event that a provider's plan is appropriate and the rationale for the denial sent by the SA or AO to the provider is unwarranted.

The ligature risk guidelines also outline the process for an "unannounced focused survey" to be conducted within 30 business days to confirm that the ligature risk corrective actions have been completed and that the hospital is in compliance with §482.13 Patient's Rights (and §482.41 Physical Environment, if applicable). **The FAH urges CMS to clarify that the unannounced survey applies only to the deficiencies that were identified previously and that the surveyors may not conduct an entirely new survey when confirming the corrective actions have been taken.** The FAH believes that an additional full survey in such close time proximity to the previous survey would cause an unwarranted operational burden for hospitals.

#### 2728G – Re-Survey When Ligature Risks Deficiencies Are Cited

The draft guidance directs, that for both deemed and non-deemed hospitals, CMS may, at any time, request LRER information from the SA, AO, or hospital that may include, copies of invoices, receipts, communications with vendors, etc. that support ongoing progress in correcting the ligature risks and other safety deficiencies. The draft guidance stipulates that information related to ligature risk extension requests are expected to be responded to within two business days. The FAH appreciates the need for CMS to assess the progress of ligature risk corrective actions, but believes that two business days is a very short turn-around time. **It may not be feasible or may cause undue burden to provide the requested information during that time frame, especially if the project to bring the facility into compliance is expansive or the provider is a smaller entity and has limited administrative support. We, therefore, urge CMS to offer a longer timeframe for submitting the requested documentation, such as five business days.**

#### Revisions to SOM Appendix A Hospitals, A-0144; §482.13(c)(2)

As noted above, CMS has clarified that the ligature resistant requirements do not apply to non-psychiatric units of hospitals, even though these units may provide care to those at risk of harm to self or others, *e.g.*, emergency departments, intensive care units, medical-surgical units, and other inpatient and outpatient locations. **The FAH appreciates CMS's clarification that the ligature resistant requirements do not apply to non-psychiatric units of hospitals where patients with psychiatric conditions may receive care, with the understanding that the hospital must also identify patients at risk for intentional harm to self or others and mitigate environmental safety risks.** We encourage CMS to maintain this important distinction regarding the applicability of ligature risk requirements.

The FAH believes it is important to maintain the flexibility proposed in CMS's revisions outlining the safety measures that providers may use to ensure patients identified as being at risk are protected. **We also support allowing the use of video monitoring, if deemed appropriate via the hospital's assessment, and with the ability to intervene immediately if needed.** We further appreciate CMS's recognition that not all risks can be eliminated. In such cases, CMS expects hospitals to assess and then take steps to mitigate that risk. **In particular, the FAH supports CMS's acknowledgment that some medical supplies and equipment required for patient care may not be removed from the patient care setting, and a mitigation of risk standard applies in these situations, rather than total avoidance of that risk.**

Identifying Patients At Risk; Locked Versus Unlocked Psychiatric Units

**The FAH thanks CMS for recognizing the differences in ligature risk between clinical settings and proposing different standards depending on the patient population being treated in the clinical environment.** Recognizing the distinction between locked psychiatric units versus unlocked psychiatric units within psychiatric and acute care hospitals is especially important. Although it may make sense to apply ligature risk requirements to locked psychiatric units, the FAH believes that a lesser standard should apply in unlocked psychiatric units where patients are able to move freely with little or no supervision. We thank CMS for providing hospitals with the flexibility to make their own determinations for ligature resistance and treat patients accordingly.

Education and Training

The FAH agrees that an important element of an effective ligature resistant environment is ensuring that staff and volunteers receive the proper training and education. Informing personnel regarding screening and assessment of patients at risk of harm to self or others, the identification of environmental patient safety risk factors, and mitigation strategies is intended to keep staff and patients safe. The FAH supports CMS's proposal to allow hospitals the flexibility to tailor the training to the services provided by particular staff. Such flexibility would account for the differences in patient care responsibilities among different staff, such as the responsibilities of clinicians and patient sitters versus housekeeping services staff.

We are concerned, however, that CMS's proposal to require education and training "whenever applicable policies and procedures are revised or updated" is overly broad and could be burdensome and unnecessary. The FAH requests that CMS consider revising this so that re-training of personnel is not required every time minor changes are made to policies and procedures that do not *materially* affect a hospital's systems to ensure a ligature resistant environment. **We ask that CMS clarify in the final guidance that updates in training are required only when policies and procedures are "materially" revised or updated.**

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The FAH appreciates the opportunity to comment on the draft revisions to the ligature risk guidelines. We support CMS's efforts to provide additional clarity and flexibility for hospitals working to provide a safe care environment for all patients, which includes ligature resistant

environments. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

A handwritten signature in black ink, written in a cursive style. The signature is somewhat stylized and difficult to read precisely, but it appears to be a name with a last name ending in 'y'.