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June 17, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1718-P
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted electronically via the CMS Hospital Resource Mailbox: hospitalscg@cms.hhs.gov.

RE: QSO-19-12-Hospitals: Draft Only — Clarification of Ligature Risk Interpretive Guidelines

Dear Ms. Verma:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' draft policy memorandum clarifying its ligature risk policy.

HANYS shares CMS' goals of improving care and safety for all patients, especially our most vulnerable patients who are at risk of harming themselves or others. Limiting the risk of suicide is a top priority for every one of our hospital members that treats patients with psychiatric conditions. Hospitals are constantly applying best practices and the latest technology and data to ensure not only patient safety, but also the safety of those who provide care to these individuals. However, we have concerns about the increased, and often inconsistent, enforcement of ligature-point and other self-harm risk assessment citations.

We appreciate CMS' efforts to clarify guidance around ligature risk requirements in hospitals and healthcare systems and applaud the agency for providing stakeholders the opportunity to weigh in to help align our shared goals. We hope the agency will continue to use this approach with any additional ligature risk guidance.

Several of the proposed changes improve upon prior guidance; however, we believe additional clarity is still needed. CMS has made significant progress in adopting draft language that promotes a shared understanding of what constitutes ligature risk and the agency's expectations of what hospitals must do to achieve ligature-resistant environments. HANYS looks forward to working with CMS to continue to refine the language and improve the survey process.

Our detailed comments are below.

Locked vs. unlocked psychiatric units and application to emergency departments

Under the revised guidance, CMS proposes that locked psychiatric units within psychiatric hospitals and acute care hospitals be ligature-resistant. While unlocked, non-psychiatric units do not need to meet the ligature-resistant standard. Instead, those units must have proper mitigation procedures in place when treating patients at risk of suicide. HANYS appreciates this approach and believes that this differentiation strikes the appropriate balance.

Unfortunately, there is ambiguity around the requirements for dedicated psychiatric beds in emergency departments. It is unclear what CMS means by "locked unit" in terms of the ED. Emergency department beds serve a number of purposes, including, when necessary, treating psychiatric patients who pose a risk of suicide. While some New York hospitals have Comprehensive Psychiatric Emergency Programs, which would likely meet the definition for a locked unit, most hospitals do not have one. For those hospitals without a locked unit, they may have the capability to convert an ED bed into a ligature-resistant room when necessary, but we would expect them to be operating under the mitigation procedures for an unlocked unit versus the requirements for locked units.

HANYS is concerned about the unclear language regarding the applicability to EDs, when the previous language notes that ED are excluded from being ligature resistant (absent a locked unit within the ED). For comparison, The Joint Commission, under its *Revisions to the National Patient Safety Goal on Reducing the Risk for Suicide (NPSG.15.01.01),* issued Nov. 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 EDs.

HANYS requests that CMS limit the scope of the ligature-resistant requirements to locked psychiatric units within psychiatric and acute care hospitals, and remove references on pages 8 and 9 to the ED. A greater focus in the guidance on the patient's needs, rather than the care setting, will provide better clarity for surveyors and create clear expectations for providers.

Education and training

CMS proposes a series of education and training requirements 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. While HANYS supports the proposed requirements for clinical staff, we ask that CMS clarify the requirements around contracted employees versus those individuals who may be in clinical areas for limited periods. Temporary contract employees should not be subject to the same comprehensive staff and education requirements. HANYS is concerned it will be administratively burdensome, costly and will not have a direct impact on improving patient care.

Furthermore, we ask that CMS clarify the type of training required for non-patient care employees working in patient care areas. It is unclear if CMS is requiring the training to address general environmental patient safety risk factors or address suicide risk and risk to others.

Survey procedures

The revised guidance includes several changes to the surveyor process, including requiring them 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.

HANYS has heard from members that surveyors frequently disagree over what constitutes a ligature risk, as well as the minimally acceptable remediation measures. Some surveyors appear to be unofficially enforcing a "ligature-free" standard, notwithstanding CMS' recognition that such a standard is not possible. HANYS recommends that CMS develop, with stakeholder input, extensive surveyor education on this guidance to ensure that surveyors consistently and effectively interpret these new requirements. We urge CMS to provide increased specificity and direction concerning surveyor training to ensure that surveyors hold hospitals to an objective standard without the possibility for, or instance of, subjective treatment because of surveyor discretion.

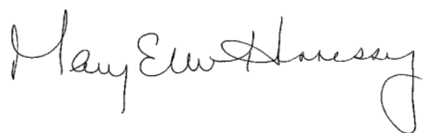
Ligature risk extension requests

In the proposed guidance, CMS establishes a ligature risk extension request process for when a hospital cannot reasonably correct a ligature finding within the required 60-day window. HANYS supports this proposal and commends the agency for recognizing the potential scale and timing associated with hospitals needing to make changes to be compliant. However, HANYS is disappointed that the ligature risk extension request must go through the state agency or accreditation organization before going to the CMS regional office.

HANYS recommends that CMS allow hospitals to go directly to the CMS regional office, especially since the state agencies and accredited organizations do not have the independent authority to grant additional time. This is of particular importance, because the guidance does not address what happens if the SA or AO misses its timeframe requirements. HANYS seeks clarification on whether the clock for the hospital would stop, once a hospital has shown it had a timely submission, but the SA or AO did not. HANYS also recommends that CMS create a process for appeal or reconsideration in the event the RO denies a ligature risk extension request.

HANYS appreciates the opportunity to provide feedback on the proposed clarification of ligature risk interpretive guidelines. If you have questions regarding our comments, please contact me at (518) 431-7624 or mehennes@hanys.org, or Victoria Aufiero, director, behavioral health, at (518) 431-7889 or vaufiero@hanys.org, or Kathy Rauch, director, quality and research initiatives, at (518) 431-7718 or krauch@hanys.org.

Sincerely,



Mary Ellen Hennessy
Vice President, Health Redesign and Regulatory Affairs