HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

JULY 22, 2019

EVALUATING LIGATURE RISK PREVENTION REQUIREMENTS AND REGULATIONS: THE CHALLENGES OF PROTECTING PATIENTS WITHOUT RESTRICTING ACCESS

Effective July 1, 2019, The Joint Commission ("TJC") implemented new and revised requirements regarding suicide prevention for all TJC-accredited hospitals and behavioral health entities. The seven new and revised requirements, part of TJC's elements of performance ("EPs") under National Patient Safety Goal ("NPSG") 15.01.01, are designed to improve quality and safety of care for patients at risk for suicide. The requirements are intended to address environmental factors that may present ligature risk.[1] Separately, the Centers for Medicare & Medicaid Services ("CMS") issued draft interpretive guidelines incorporating TJC's requirements and developing additional guidance for maintaining standards related to ligature risk ("Interpretive Guidelines"). The finalized CMS guidance is forthcoming.

While safety and suicide prevention are undeniably worthy motivations for the heightened focus on ligature risk, the effect of the revised NPSG EPs may be to further restrict access to mental health care services, as psychiatric units and inpatient mental health facilities grapple with the high costs of operating under the revised requirements. Many psychiatric units and other inpatient mental health units are already struggling to comply with TJC's accreditation standards, and others may face additional strains once CMS issues the revisions to its Interpretive Guidelines.

Even prior to the revised NPSG EPs becoming effective, TJC's increased scrutiny on ligature risk during accreditation surveys has caused several psychiatric units to close temporarily to obtain funding or renovate their facilities to ensure compliance. In some instances, such units have closed permanently after determining they are unable, financially or otherwise, to meet the CMS and TJC requirements. This is a sensitive issue given the gravity of even a single self-inflicted patient death. However, if inpatient mental health units and facilities continue closing due to the increased costs of compliance, patients seeking mental health care services may face reduced access to needed care, particularly in rural and already underserved areas.

TJC REQUIREMENTS

TJC began developing the new and revised NPSG requirements after multiple health care entities experienced highly publicized ligature-related suicides following successful TJC accreditation surveys. Prompted by CMS, TJC sought to re-evaluate its NPSG standards to ensure diligent assessment of ligature risk. Shortly thereafter, TJC assembled an expert panel to review and present guidance on addressing ligature risk in health care settings. After multiple meetings in 2017 and 2018, TJC's expert panel presented recommendations to TJC on minimizing ligature risk.

In its recommendations, the panel used the term "ligature-resistant" rather than "ligature-free," concluding that it is not possible to completely remove all such risks. In inpatient psychiatric and general and acute care settings or settings with locked doors, the panel recommended that patient rooms, bathrooms, corridors and common areas use at least ligature-resistant materials in doors and hallways, transition zones between patient rooms and bathrooms, certain patient beds and ceilings. For residential, partial hospitalization, day treatment and intensive outpatient programming facilities, the panel did not recommend ligature-resistant requirements. The panel reasoned it would not be feasible to fully prevent suicide attempts or self-harming activity in unlocked units or facilities where patients have the ability to exit. However, the panel recommended that these facilities conduct a risk assessment to identify and remove items that present high ligature risk, transfer patients presenting a high suicide risk to facilities with a higher level of care and implement policies and procedures to manage patients deemed to be at risk for suicide in less restrictive levels of care.

The panel's recommendation ultimately resulted in TJC adopting the seven new and revised NPSG EPs, which generally require:

- Performance of an environmental risk assessment that identifies features in the physical environment presenting a suicide risk and taking steps to minimize such risk;
- Use of a validated suicidal ideation screening tool for all patients who are being evaluated or treated for behavioral health conditions as their primary reason for care;
- Use of an evidence-based suicide risk assessment for individuals who have screened positive for suicidal ideation;

- Documentation of each individuals' overall level of risk for suicide and the plan to mitigate the risk for suicide;
- Implementation of written policies and procedures addressing the care of patients identified as at risk for suicide, including staff training and competence assessment, guidelines for reassessment and monitoring of high risk patients;
- Implementation of written policies and procedures for counseling and follow-up care at discharge for patients identified as at risk for suicide; and
- Monitoring implementation and effectiveness of policies and procedures for screening, assessment and management of patients at risk for suicide and taking action as needed to improve compliance.

CMS REQUIREMENTS

For its part, CMS issued a memorandum clarifying its ligature risk policy in December 2017. Subsequently in July 2018, CMS announced that it would incorporate outcomes from TJC's panel recommendations into Interpretive Guidelines to assist providers in complying with the Medicare Conditions of Participation. CMS issued a draft policy memorandum on April 19, 2019 to update its December 2017 memorandum and request public comments for the draft guidance ("Draft Policy").

This Draft Policy includes the proposed revisions to the Interpretive Guidelines for the State Operations Manual ("SOM"), Appendix A and Chapter 2. These portions of the SOM, 42 C.F.R. § 482.13(c)(2) and 42 C.F.R. § 482.41(a), address a patient's right to receive care in a safe setting and requirements for physical environments of hospitals, respectively. CMS intends for the Draft Policy to address what constitutes a ligature risk and clarify the expectations for ligature-resistant environments within various facilities. Similar to TJC's new and revised NPSG EPs, the requirements proposed in the Draft Policy would not apply to non-psychiatric units of hospitals such as emergency departments and intensive care units. Additionally, the proposed revisions to Chapter 2 of the SOM outline a process for facilities to request additional time to address ligature risk.

The Draft Policy appears to recognize the challenges facing psychiatric units and other facilities that must comply with CMS and TJC requirements, but it is unclear whether the changes will strike an appropriate balance. While the new and revised TJC requirements became effective on July 1, 2019 and final guidance from CMS is forthcoming, several psychiatric units have already felt pressure to close temporarily or permanently in anticipation of the need to comply with the more stringent standards. Should additional units or facilities be forced to close either temporarily or permanently due to difficulties in complying with the TJC requirements or forthcoming CMS guidance, access to necessary mental health care services could be further compromised, particularly in rural or other underserved areas.

PRACTICAL TAKEAWAYS

Any loss of patient life due to self-harming activity is a tragedy, and a pattern of occurrences shortly following successful accreditation surveys supported CMS's and TJC's review of their own interpretation and enforcement standards to ensure that risks were properly addressed and patient suicides prevented. Actions by both CMS and TJC demonstrate the high priority placed on addressing ligature risk as a component of the Medicare Conditions of Participation regarding patient rights and the physical hospital environment. Although the Conditions of Participation themselves have not changed, actions by CMS and TJC suggest a more stringent interpretation and enforcement stance from both agencies moving forward.

Despite the laudable goals of CMS and TJC, the heightened requirements and their rigorous enforcement may create an environment in which it is increasingly difficult for inpatient mental health units to remain open. The new and revised NPSG EPs set forth by TJC are robust, and psychiatric units seeking to comply with the requirements may incur significant costs. According to the National Association for Behavioral Healthcare, the ligature risk regulations impose approximately $880.4 million in compliance costs nationwide per year. The issue then becomes whether these changes aimed at reducing ligature risk pose an insurmountable obstacle for mental health care providers due to the challenges and costs associated with compliance.

While navigating TJC requirements and other regulations is challenging, it is not impossible. Psychiatric hospitals, behavioral health care facilities and hospitals with inpatient mental health units should remain vigilant and aware of developments in the regulatory environment, including the forthcoming version of the Interpretive Guidelines issued by CMS. These facilities should also work closely with their quality departments, compliance teams and legal counsel to ensure compliance, and should collaborate with their advocacy and public affairs liaisons to advocate for policies that protect both individual patients and community access to mental health services. Ensuring the safety and availability of psychiatric services for patients is crucial, and all stakeholders, including TJC, CMS, manufacturers and suppliers of objects

that may pose a ligature risk, and others may have a role in the solution.

If you have any questions or would like additional information about this topic, please contact:

- Jennifer Skeels at 317-977-1497 or jskeels@hallrender.com;
- Lori Wink at 414-721-0456 or lwink@hallrender.com;
- Stephane Fabus at 414-721-0904 or sfabus@hallrender.com;
- Lindsey Croasdale at 414-721-0443 or lcroasdale@hallrender.com;
- Kristen Chang at 414-721-0923 or kchang@hallrender.com; or
- Your regular Hall Render attorney.

Special thanks to Jarrod Anderson, law clerk, for his assistance with the preparation of this article.

[1] A ligature risk is presented by any point or object that could be used to attached material for purposes of hanging or strangulation.