Department of Health & Human Services

Centers for Medicare & Medicaid Services

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**Center for Clinical Standards and Quality/Survey & Certification Group**

**S&C Memo: 18-06- Hospitals**

**DATE: December 08, 2017**

**TO:**  State Survey Agency Directors

**FROM:** Director

 Survey and Certification Group

**SUBJECT:** Clarification of Ligature Risk Policy

**Memorandum Summary**

* **Ligature Risks Compromise Psychiatric Patients’ Right to Receive Care in a Safe Setting:** The care and safety of psychiatric patients and the staff that provide that care are our primary concerns. The Centers for Medicare & Medicaid Services (CMS) is in the process of drafting comprehensive ligature risk interpretive guidance to provide direction and clarity for Regional offices (RO), State Survey Agencies (SAs), and accrediting organizations (AOs).
* **Definition of a Ligature Risk:** A ligature risk (point) is defined as anything which could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation. Ligature points include shower rails, coat hooks, pipes, and radiators, bedsteads, window and door frames, ceiling fittings, handles, hinges and closures.
* **Focus of Ligature Risks:** The focus for a ligature “resistant” or ligature “free” environment is primarily aimed at Psychiatric units/hospitals.
* **Interim Guidance:** Until CMS’ comprehensive ligature risk interpretive guidance is released, the ROs, SAs and AOs may use their judgment as to the identification of ligature and other safety risk deficiencies, the level of citation for those deficiencies, as well as the approval of the facility’s corrective action and mitigation plans to minimize risk to patient safety and remedy the identified deficiencies.
* **Timeframe for Correction of Ligature Risk Deficiencies: All** deficiencies are expected to be corrected within the timeframe designated by the CMS RO, SA or AO. In cases where it is determined that it is not reasonable to expect compliance within the designated timeframe, only CMS may grant additional time for correction.
* **Ligature Risk Deficiencies Do Not Qualify for Life Safety Code (LSC) Waivers:** Ligature risks are not LSC deficiencies. Therefore, a LSC waiver may not be granted.
* **Monitoring of Progress:** When additional time for correction is granted, the hospital is required to provide monthly electronic progress reports to the SA or AO, including substantiating evidence of progress towards compliance. The SA or AO will update the RO or Central Office (CO) monthly, respectively.

**Background**

A ligature risk (point) is defined as anything which could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation. Ligature points include shower rails, coat hooks, pipes, and radiators, bedsteads, window and door frames, ceiling fittings, handles, hinges and closures. (CQC Brief Guide: Ligature points – Review date: June 2017). The most common ligature points and ligatures are doors, hooks/handles, windows, and belts or sheets/towels. The use of shoelaces, doors, and windows increased over time. (Hunt et al 2012; Ligature points used by psych inpatients.)The presence of ligature risks in the physical environment of a psychiatric patient compromises the patient’s safety. This is particularly an issue for a patient with suicidal ideation. The hospital Patient’s Rights Condition of Participation (CoP) at § 482.13(c)(2) provides all patients with the right to care in a safe setting. Psychiatric patients receiving care and treatment in a hospital setting are particularly vulnerable. The presence of ligature risks in the psychiatric patient’s physical environment compromise their right to receive care in a safe setting. Safety risks in a psychiatric setting include but are not limited to furniture that can be easily moved or be thrown; sharp objects accessible by patients; areas out of the view of staff; access to plastic bags (for suffocation); oxygen tubing; equipment used for vital signs or IV Fluid administration; breakable windows; access to medications; access to harmful medications; accessible light fixtures; non-tamper proof screws; etc. The focus of this memo and the forthcoming guidance is care delivered in psychiatric units/hospitals and does not apply to other healthcare settings such as acute care hospitals. Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be protected when demonstrating suicidal ideation. The protection would be that of utilizing safety measures such as **1:1 monitoring with continuous visual observation**, removal of sharp objects from the room/area, or removal of equipment that can be used as a weapon.

CMS has identified the need for increased direction, clarity, and guidance regarding the definition of what constitutes a ligature risk and other safety risks involved in the care of patients requiring psychiatric care and treatment; how those risks should be surveyed; at what level these patient safety deficiencies should be cited; the elements required for an appropriate plan of correction (PoC); and what constitutes a suitable mitigation plan to minimize the risk to patients who are cared for in environments with identified patient safety deficiencies. The care and safety of this vulnerable patient population and the staff that provide that care are our primary concerns. To that end, CMS has begun the process of drafting guidance utilizing the skill and expertise of the Regional Offices, state survey agencies, accrediting bodies, providers, mental health clinicians, as well as other stakeholders central to this issue. CMS expects that this guidance will take approximately six months to complete. In the interim, the SAs and AOs may use their judgment as to the identification of ligature and safety risk deficiencies, the level of severity for those deficiencies, as well as the approval of the facility’s corrective action and mitigation plans to remedy the identified deficiencies in collaboration with CMS. The first portion of this guidance is attached. (See attachment A.)

Regulations at § 488.28 require that the deficiencies addressed in a PoC be corrected within 60 days from receipt of the deficiency report. Follow up surveys to verify correction of condition level deficiencies or the ability of the hospital to correct the ligature risk deficiencies, will be done according to the standards established by the surveying agency. The ability of facilities to comply with the limited number of days allotted for the correction of ligature risks has proven to be burdensome based on a number of variables, such as the severity and scope of the deficiencies, the need to obtain governing body approval, capital budget funding requirements, engage in competitive bidding, availability of the required materials, time for completion of repairs, and access to the unit/hospital areas. Ligature risks are not eligible for LSC waivers as they are not LSC deficiencies.

Cited ligature risks, that do not pose an immediate jeopardy situation or no longer pose an immediate jeopardy situation because the immediate threat to patient health and safety has been removed by the hospital, or has been mitigated through the implementation of appropriate interim patient safety measures, are expected to be corrected within the allotted number of days accorded by the CMS RO, SA or AO. Interim patient safety measures are expected to be implemented as part of an acceptable plan of correction to mitigate patient safety risks, as appropriate, until the ligature risks can be eliminated. Per § 488.28, the correction period begins the date the facility is notified of the deficiencies by the SA or AO. In cases where the SA or AO determine that it is not reasonable to expect compliance within the specified number of days, SA or AO may recommend additional time be granted by CMS in accordance with the regulations at § 488.28. The SAs and AOs do **not** have independent authority to grant additional time for the correction of deficiencies.

Hospital requests for the extension of timeframes for the correction of ligature risk deficiencies must include the hospital’s accepted PoC, mitigation plan, an evaluation of the effectiveness of the mitigation plan, and an update on the status of the PoC. The hospital request must also include a rationale for why it is not reasonable to meet the correction timeframe. Non-deemed hospitals submit the request electronically to the SA; deemed hospitals submit the request electronically to their AO. If the SA or AO rejects the request for an extended timeframe for correction, the submission is returned to the hospital with a rationale for denial. If the SA or AO supports the request, the submission is forwarded electronically to the appropriate RO or CO, as appropriate, with a recommendation of approval. For deemed facilities, the AO will also copy the appropriate RO. All request packages will be submitted electronically via designated RO and CO e-mailboxes. (See attachment B for e-mail addresses.)

For non-deemed hospitals, the RO will provide an electronic response to the hospital and copy the SA; for deemed hospitals, CO will provide a response and copy the AO and RO within ten business days. The facility is required to provide electronic progress reports to the SA or AO on a monthly basis that include, but are not limited to, copies of invoices, receipts, communications with vendors, etc. detailing ongoing progress correcting the ligature risks and other safety deficiencies. The facility is also required to provide ongoing electronic routine status updates on the effectiveness of mitigation strategies utilizing outcome and process measures to demonstrate the effectiveness of the plan. The SA and AO are required to monitor PoCs, progress reports and mitigation measures, on a monthly basis, and provide an updated report to CMS (RO or CO, as appropriate) on a monthly basis. The SAs and ROs may use the current process in place using the CMS form-539. AOs will provide reports in a format specified by CMS. (See attachment C for format.)

**Contact:** If you have any questions regarding this memorandum, please send inquiries to the hospital e-mailbox at hospitalscg@cms.hhs.gov .

**Effective Date:** Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

 /s/

David R. Wright

Attachment(s):

Attachment A- Advanced Guidance

Attachment B- Designated Email Addresses

Attachment C- Ligature Risk Extension Progress Report

cc: Survey and Certification Regional Office Management