



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: DRAFT-QSO-19-12-Hospitals

DATE: April 19, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: DRAFT ONLY-Clarification of Ligature Risk Interpretive Guidelines – FOR ACTION

Memorandum Summary

- **This draft policy memorandum would update S&C: 18-06-Hospitals released by the Centers for Medicare & Medicaid Services (CMS) on December 8, 2017.**
- **This Memo is Being Released in Draft:** We seek comment on these draft revised policies by June 17, 2019 (60 days from the date of this release).
- **Ligature Risks Compromise Patients’ Right to Receive Care in a Safe Setting:** The care and safety of psychiatric patients at risk of harm to themselves or others, and the staff providing care are our primary concerns. The comprehensive ligature risk interpretive guidance in the CMS State Operations Manual (SOM) Appendix A for Hospitals is being revised to provide direction and clarity for CMS Regional Offices, State Survey Agencies, accrediting organizations and hospitals.
- **Ligature Risk Extension Request Process Update:** The SOM Chapter 2, Section 2728G - Major Deficiencies Requiring Long-Term Correction in Psychiatric Hospitals and Hospital Psychiatric Units, Ligature Risk-Ligature Risk Extension Requests is also being updated. The section describes the process for deemed and non-deemed hospitals to request a ligature risk extension based on evidence of hardship and inability to complete necessary renovations within 60 days.

Background

The CMS hospital Condition of Participation, “Patient’s Rights” (42 C.F.R. §482.13(c)(2)) establishes the rights of all patients to receive care in a safe setting and is intended to provide protection for a patient’s emotional health and safety as well as his or her physical safety. Respect, dignity, and comfort are also components of an emotionally safe environment. In order to provide care in a safe setting, hospitals should identify patients who are at risk for intentionally harming themselves or others, identify environmental safety risks for such patients, and provide environmental safety education and training for employees (those directly employed and those providing services under contract) and volunteers.

Patients at risk of suicide (or other forms of self-harm) or those who exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals. The draft revised guidelines are intended to provide increased direction, clarity, and guidance regarding what constitutes a ligature risk and clarify the expectations that hospitals achieve a ligature “resistant” environment in psychiatric units of acute care hospitals, locked emergency department psychiatric units, and psychiatric hospitals. The requirements to create a ligature-resistant environment do not apply to non-psychiatric units of hospitals, even though these units might 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.

SOM Appendix A Revisions: In an effort to establish a ligature-resistant environment that is appropriate for each setting, CMS has developed additional guidance for establishing and maintaining this standard. CMS will take comments received during this review period into consideration and will issue a final version after comments have been analyzed.

Chapter 2 Revisions: Under 42 CFR §488.28, identified deficiencies addressed in an acceptable Plan of Correction are expected to be corrected within 60 days from receipt of the deficiency report. The ability of hospitals to achieve compliance of deficiencies related to ligature risks within the expected number of days allotted for the correction may 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, obtaining permits, engagement in competitive bidding, availability of the required materials, time for completion of repairs, and access to the unit/hospital areas. Therefore, CMS has outlined a process for hospitals to request additional time to address ligature risks with the goal of achieving compliance.

Please note, compliance with ligature risks requirements are not eligible for life safety code waivers as they are not life safety code deficiencies.

CMS SOM Chapter 2 Section 2728G addresses the process for Ligature Risk Extension Requests in non-deemed and deemed hospitals. Comments received regarding this Section will also be considered prior to issuing the final version.

Contact: We are seeking public comment. Comments and questions should be submitted to the CMS hospital resource mailbox: HospitalSCG@cms.hhs.gov.

Effective Date: CMS is seeking input on these drafts and requests comments by June 17, 2019. CMS will review submitted comments before issuing a final version of this policy memorandum, Appendix A and Chapter 2 of the SOM.

/s/
Karen Tritz
Acting Director

Attachment:
DRAFT- Advanced Copy SOM Chapter 2 and Appendix A Revisions – Ligature Risk

cc: Survey and Certification Regional Office Management

CMS Manual System
Pub. 100-07 State Operations
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal- **DRAFT**

DRAFT

Date:

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 2 Certification Process and Appendix A Hospitals

I. SUMMARY OF CHANGES: We are revising Chapter 2 and Appendix A of the SOM to incorporate new and revised language regarding ligature risk in hospitals and psychiatric hospitals and the Ligature Risk Extension Request process.

**NEW/REVISED MATERIAL - EFFECTIVE DATE*:
 IMPLEMENTATION DATE:**

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
 (R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Chapter 2/Section 2728G/Major Deficiencies Requiring Long-Term Correction in Psychiatric Hospitals and Hospital Psychiatric Units, Ligature Risk Extension Requests (LRER)
R	Appendix A/Tag A-0144/§482.13(c)(2) - The patient has the right to receive care in a safe setting
R	Appendix A/A-0701/§482.41(a) Standard: Buildings

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

DRAFT- This publication is currently in draft open for public comment. This is not final policy and does not replace existing regulations or policy.

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

Ligature risks identified in psychiatric hospitals and hospital psychiatric units must be cited under the Patient's Rights CoP (§482.13) and may also be cited under Physical Environment CoP (§482.41) in addition to citing under Patient's Rights CoP depending upon the specific types of non-compliance identified. Ligature risk non-compliance is not eligible for life safety code (LSC) waivers as they are not LSC deficiencies.

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 CMS Regional Office (RO), State Agency (SA) or Accreditation Organization (AO) may recommend additional time be granted by the Secretary in individual situations if judgment indicates it is not reasonable to expect compliance within 60 days. Examples causing delays may include:

- Obtaining approval of the governing body,*
- Engaging in competitive bidding,*
- Applying for funding,*
- Obtaining permits for physical changes, and*
- Lack of or delays in obtaining products and supplies needed for corrective actions.*

The expectation for hospitals and psychiatric hospitals to remedy identified ligature risks within the limited number of days available to achieve compliance may be overly burdensome to those providers. In cases where the SA or AO determine that it is not reasonable to expect compliance remedying identified ligature risks within the specified number of days, the SA or AO may recommend that a ligature risk extension request (LRER) 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 ligature risks deficiencies. Approval of a LRER must be granted by the CMS Regional Offices.

2728G Non-Deemed Hospital LRERs

Non-deemed hospitals must submit the LRER request to the SA as soon as the hospital identifies that more than 60 days are needed for necessary corrective actions. The LRER submission must occur prior to the date required for compliance. The LRER must include the hospital's accepted PoC, the risk mitigation plan that ensures patient safety, and how the evaluation of the effectiveness of the mitigation plan will occur. The LRER must also include a rationale for why it is not reasonable to meet the 60 day compliance timeframe. The SA must inform the hospital of the LRER submission process, including how the SA is to receive the LRER submission. The SA must review and make a determination within 10 business days of receipt of the LRER.

If the SA rejects the request for an extended timeframe for correction, the submission is returned to the hospital with a rationale for denial. The hospital will continue on the termination track for non-compliance (IJ or Condition level) until an acceptable LRER has been received.

If the SA approves the LRER, the SA will forward the LRER, including all documents submitted by the hospital, to their RO for final review and approval. The RO will provide a written response to the hospital with a copy to the SA within ten business days of its LRER decision. While renovations are underway, the hospital must have a detailed plan for monitoring and mitigating identified ligature risks until permanent changes are complete to ensure patient safety throughout the LRER process.

Once the SA receives CMS approval of the hospital's LRER, the hospital is required to provide progress reports to the SA on a monthly basis of all open LRERs. The SA must review the LRER monthly progress update reports and provide the RO with a quarterly update on all open LRERs. Minimally, the progress reports must include evidence of monitoring the effectiveness of the mitigation plan, untoward patient events related to identified ligature risk non-compliance, status of corrective actions, barriers to meeting approved timeline, and other information the SA or RO deems necessary. LRERs may be approved for timeframes not to exceed one year. The RO may, on a case by case basis, grant an extension beyond one year if evidence of continued hardship to the hospital is provided and accepted by the RO.

When the SA is notified that all corrective actions have been completed, it will conduct an unannounced focused survey 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 SA will document in the 2567 that all ligature risk corrective actions have been completed, or if appropriate, cite additional observations of noncompliance.

When the RO receives the 2567 documenting that all LRER corrective actions have been completed, the RO will send a written response to the hospital and the SA confirming that the LRER is closed.

Upon resurvey, if the corrective actions do not achieve compliance, the LRER will remain open. Surveyors must verify the hospital has short term strategies in place to mitigate any remaining ligature risks. The hospital will be required to submit a new POC for the 2567 that identifies continued noncompliance. If the hospital requests to extend the completion date of the LRER, the process for 2728G Non-Deemed Hospital LRERs must be followed. The RO will determine whether or not to grant a new completion date for the existing LRER.

Upon resurvey, when new findings of noncompliance are cited, the hospital will be required to follow the 2728G Non-Deemed Hospital LRERs process that addresses all findings of noncompliance. The RO has the ability to grant a second extension based on an approved POC and new LRER that the SA recommends for approval. If the SA/RO determines that the POC is unacceptable, the hospital will continue on the termination track for noncompliance (IJ or Condition level) until an acceptable POC has been received.

2728G Deemed Hospital LRERs

Deemed hospitals must submit the LRER request to the AO as soon as the hospital identifies that more than 60 days are needed for necessary changes. The LRER must include the PoC, mitigation plan that ensures patient safety, and how the evaluation of the effectiveness of the mitigation plan will occur. The LRER must also include a rationale for why it is not reasonable

to meet the required compliance timeframe. The AO must inform the hospital of the LRER submission process, including how the AO is to receive the LRER submission. AOs will provide reports to the RO in a format specified by CMS.

If the AO rejects the request for an extended timeframe for correction, the submission is returned to the hospital with a rationale for denial. The AO may not recommend deemed status until all deficiencies have either been resolved and/or an acceptable LRER is received, reviewed, and accepted by the AO for submission to CMS.

Once the AO supports the LRER, the AO will forward the LRER, including all documents submitted by the hospital, to their RO for final review and approval. All LRERs must be submitted to the RO prior to the 60th calendar day from the end survey date. The RO will provide a written response to the AO and SA within ten business days of the LRER receipt of its decision. LRERs may be approved for timeframes not to exceed one year. The RO may, on a case by case basis, grant an extension beyond one year if the evidence of hardship to the hospital is provided and accepted by the RO. The AO will notify the hospitals that CMS has granted approval of the LRER and will explain to the hospital the process of monthly progress monitoring. While renovations are underway, the hospital must have a detailed plan for monitoring and mitigating identified ligature risks until permanent changes are complete to ensure patient safety throughout the LRER process.

Once the AO receives CMS approval of the hospital's LRER, the hospital is required to provide progress reports to the AO on a monthly basis of all open LRERs. The AO must review the LRER monthly progress update reports and provide the RO with a monthly progress update on all open LRERs. Minimally, the progress reports must include evidence of monitoring the effectiveness of the mitigation plan, untoward patient events related to identified ligature risk non-compliance, status of corrective actions, barriers to meeting approved timeline, and other information the AO or RO deems necessary.

When the AO is notified that all corrective actions have been completed, it will conduct an unannounced focused survey within 30 business days to confirm the ligature risk corrective actions have been completed and that the hospital is in compliance with §482.13 Patient's Rights. The AO will document in their survey report that all identified ligature risk corrective actions have been completed or if appropriate, cite additional observations of noncompliance. Upon receipt of the AO's survey report confirming that all corrective actions have been completed, the RO will send a written response to the AO confirming that the LRER is closed.

Upon resurvey, if the corrective actions do not achieve compliance, the LRER will remain open. Surveyors must verify the hospital has short term strategies in place to mitigate any remaining ligature risks. The AO will require the hospital to submit a new POC for the identified noncompliance. If the hospital requests to extend the completion date of the LRER, the process for 2728G Deemed Hospital LRERs must be followed. Based on AO recommendation and supporting documentation, the RO will determine whether or not to grant a new completion date for the existing LRER.

Upon resurvey, when new findings of noncompliance are cited, the hospital will be required to follow the 2728G Deemed Hospital LRERs process to address all findings of noncompliance if a timeframe for corrective actions will take greater than 60 days to complete. The RO has the

ability to grant a second extension based on AO recommendation and evidence submitted to support the LRER.

2728G Deemed Hospitals when Ligature Risk Non-Compliance is cited by SA

When ligature risk noncompliance is identified in a deemed hospital by the SA, the SA must cite all observations of non-compliance on the 2567. The RO should be alerted by the SA that ligature risks deficiencies have been cited at the condition level. The RO must confirm whether or not the AO has an outstanding LRER for the hospital and if so, determine if the same observations of non-compliance were documented by the AO and SA. When the identical ligature risk deficiencies have been cited, the approved LRER remains with the AO for monthly progress monitoring.

When the AO has an open LRER for the hospital and the SA cites ligature risk deficiencies that are different, or in addition to the deficiencies listed in the approved LRER, deemed status will be removed and the SA will follow the non-deemed LRER process.

2728G Re-Survey when Ligature Risks Deficiencies are cited

The SA and AO may postpone the re-survey for ligature risk non-compliance when ligature risk non-compliance is the only condition level finding and resulted in a LRER approved by CMS. The re-survey will take place within 30 days of the approved completion date in the LRER.

When condition level findings in addition to ligature risks are cited, the resurvey must take place according to Chapter 3- 3010B - Processing of Immediate Jeopardy Terminations or 3012 - Termination Procedures Substantial Noncompliance; No Immediate Jeopardy.

NOTE: *If the originating survey cited noncompliance with one or more CoPs, including ligature risks, the revisit survey must occur according to the Schedule of Termination Procedures - Noncompliance with One or More CoPs. The progress of the ligature risk corrective actions should be assessed during the follow-up survey to ensure the hospital is compliant with their approved mitigation plan.*

For both deemed and non-deemed hospitals, the 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. CMS requests for information related to ligature risk extension requests are expected to be responded to within two business days.

DRAFT- This publication is currently in draft open for public comment. This is not final policy and does not replace existing regulations or policy.

A-0144

(Rev.)

§482.13(c)(2) - The patient has the right to receive care in a safe setting.

Interpretive Guidelines §482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. The hospital must protect vulnerable patients, including newborns and children. Additionally, this standard is intended to provide protection for the patient’s emotional health and safety as well as his/her physical safety. Respect, dignity, and comfort *are also* components of an emotionally safe environment. In order to provide care in a safe setting, hospitals must identify patients at risk for intentional harm to self or others, identify environmental safety risks for such patients, and provide *environmental safety* education and training for staff and volunteers.

Patients at risk of suicide (or other forms of self-harm) or *those who* exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals. The focus *to achieve* a ligature “resistant” environment is *required in locked* psychiatric units of acute care hospitals, *including locked emergency department psychiatric units*, and psychiatric hospitals. *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.

It is important to note that not all patients with psychiatric conditions or *with* a history of a psychiatric condition are cared for *solely* in psychiatric *units of acute care* hospitals or psychiatric hospitals. Therefore, non-psychiatric settings of hospitals where patients with psychiatric conditions may *receive care* must also identify patients at risk for intentional harm to self or others and mitigate environmental safety risks.

Psychiatric patients requiring medical care in a non-psychiatric *and unlocked* setting must be protected when demonstrating suicidal ideation or *threat of* harm to *self or* others. Although all risks cannot be eliminated, hospitals are expected to demonstrate how they identify patients at risk of harm to self or others and steps they are taking to minimize those risks in accordance with nationally recognized standards and guidelines. *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 *or video monitoring, if appropriate;*
- Removal of sharp objects;
- Removal of equipment that can be used as a weapon *or to inflict harm;*
- *Securing personal belongings; and*
- *Removal of any other item(s) that may contribute to harmful behavior.*

Although all risks cannot be eliminated, hospitals are expected to demonstrate how they identify patients at risk of harm to self or others and steps they are taking to minimize those risks in accordance with nationally recognized standards and guidelines. The potential risks include but are not limited to those from ligatures, sharp *objects*, harmful substances, access to medications, *easily* breakable windows, *readily* accessible light fixtures, plastic bags (for suffocation), oxygen tubing, *staff-call* cords, *electrical equipment cords*, and *others*. *Staff must mitigate the risk for medical supplies and equipment required for the provision of patient care and unable to be removed from the patient care setting.*

Note: Although toilet seats may be a potential ligature point, as noted by the Facility Guidelines Institute (FGI) and others, the evidence suggests the risk is minimal. Surveyors are encouraged to review the patient care environment in its entirety (to include a thorough review of any risk assessments completed) and not consider this one item as non-compliance in the absence of other factors.

Identifying Patients at Risk

There are numerous models and versions of patient *screening and assessment tools to identify risk of harm to self or others*. *CMS does not endorse or require the use of any particular tool*. Therefore, the type of patient *screening or assessment tool used to determine risk of harm to self or others* should be appropriate to the patient population *served*, care setting, and staff competency. Hospitals are expected to implement a patient *screening and risk assessment strategy that is appropriate to the patient population*. *For example, a patient screening and risk assessment strategy in a post-partum unit would most likely not be the same screening and risk assessment strategy utilized in the emergency department.*

All patients in psychiatric hospitals and psychiatric units must be screened for suicidal ideation. In acute care hospitals, patients being evaluated and treated for behavioral health conditions as their primary reason for care must be screened for suicidal ideation. Hospital policy should address any other circumstances where suicidal screening is required.

Locked versus Unlocked Psychiatric Units

Locked psychiatric units within psychiatric hospitals and acute care hospitals are expected to achieve a ligature resistant environment. In addition, 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, are also expected to achieve a ligature resistant environment. This does not mean that hospitals with locked psychiatric units that are not ligature resistant may convert to unlocked units merely to avoid making the environment ligature resistant.

Unlocked psychiatric units within psychiatric hospitals and acute care hospitals in which the patient population is able to move freely throughout hallways and other areas of the hospital with little or no supervision, such as the cafeteria, do not have the same expectation to be ligature resistant. However, patients that have been identified as being at risk for suicide or harm to self or others that are receiving care in unlocked psychiatric units must be screened and assessed, per hospital policy and according to nationally accepted standards of practice, to ensure these patients do not harm themselves in the non-ligature resistant environment.

Environmental Safety Risks

Just as all hospitals must implement a patient risk assessment strategy, all hospitals must implement an environmental risk assessment strategy. Environmental risk assessment strategies may not be the same in all hospitals or hospital units. The hospital must implement environmental risk assessment strategies appropriate to the specific care environment and patient population. *Risk assessments* must be appropriate to *each* unit and should consider the possibility that the unit may sometimes care for patients at risk for *threat of* harm to self or others.

Although CMS does not *endorse or* require the use of an *environmental risk assessment tool* (e.g. the Veteran’s Administration *Mental Health Environment of Care Checklist (MHEOCC)*) the use of such tools may be *helpful* for hospitals to assess safety risks in patient care environments. *Following the assessment process will identify environmental risks leading to staff’s ability to minimize those risks and document assessment findings.* Examples of *environmental risk assessment tool* content includes prompts for staff to assess items such as *the following*:

- Hand rails, door knobs, door hinges, shower curtains, exposed plumbing/pipes, soap and paper towel dispensers on walls, power cords on medical equipment or call bell cords, and light fixtures or projections from ceilings, etc.
- *Solid versus drop ceilings.*
- Unattended items such as utility or housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizer, etc.)
- Unsafe items brought to patients by visitors in locked psychiatric units of hospitals and psychiatric hospitals.
- Windows that can be opened or broken.
- Unprotected lighting fixtures.
- Inadequate staffing levels to provide appropriate patient observation and monitoring *as required by the physical layout of the patient care environment.*

A ligature risk (point) *may include anything* which could be used to *create a sustainable attachment point such as* a cord, rope, or other material for the purpose of hanging or strangulation. Ligature points include shower rails, coat hooks, pipes and radiators, window and door frames, ceiling fittings, handles, hinges and closures. *Common ligature points and ligatures* are doors, hooks/handles, windows *frames*, belts, sheets, towels *and* shoelaces.

Additional safety risks to psychiatric patients and patients at risk for harm to self or others may 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 cleaning chemicals; accessible light fixtures; non-tamper proof screws; etc.

Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be protected when *screened and assessed as high risk for suicidal or homicidal ideation and intent or demonstrating other violent or aggressive behavior.* The protection *may* be that of utilizing safety measures such as 1:1 monitoring with continuous visual observation *in which staff may immediately intervene when necessary,* removal of sharp objects from the room/area, removal of equipment that can be used as a weapon, *or protection from windows that are able to be broken.*

Interim patient safety measures to mitigate identified ligature or safety risks may include continuous visual observation or 1:1 observation in which a staff member is assigned to observe only one patient at all times, including while the patient sleeps, toilets or bathes, to prevent harm directed toward self or others as well as other alternative nursing protocols. The level of constant visual observation may be determined based on the type of identified risk.

For example, a suicidal patient that is placed in a room with windows that may be opened or with breakable glass, would require constant 1:1 visual observation that would allow the staff member to immediately intervene should the patient attempt to jump or break through the window. The use of video monitoring would not be acceptable because staff would not be immediately available to intervene. Another interim safety measure may include locking rooms in which ligature risks have been identified to prevent patient access.

For high risk patients, video monitoring should only be used in place of direct line-of-sight monitoring when it is unsafe for a staff member to be physically located in the patient's room. In addition, for both direct line-of-sight and video monitoring of high risk patients, the monitoring should be 1:1 and the monitoring must be linked to the provision of immediate intervention by a qualified staff member when requested.

Note: State law may restrict visualization of the patient during toileting, bathing or other acts of personal hygiene. Hospital staff as well as surveyors when assessing compliance with these requirements, must be aware of their State requirements and potential impact on the provision of care to patients in need of 1:1 visual observation.

Hospitals are expected to maintain documentation of their environmental risk assessments and mitigation plans.

Education and Training

Hospitals are expected to provide education and training regarding the screening and assessment of patients at risk of harm to self or others, the identification of environmental patient safety risk factors, and mitigation strategies to all new patient care employees (employed or contracted) upon hire and prior to providing patient care independently. Hospitals are expected to provide education and training regarding the identification and reporting of environmental patient safety risk factors to new non-patient care employees (employed or contracted) who may work in patient care areas upon hire and prior to working independently in patient care areas. This might include employees such as security, dietary, maintenance, housekeeping, and other ancillary support services.

In addition, hospitals are expected to provide education and training to all staff whenever applicable policies and procedures are revised or updated. While hospitals have the flexibility to tailor the training to the particular services staff provide, hospitals are expected to demonstrate how the education and training keep staff current in order to meet the needs of the patient population served.

Survey Procedures §482.13(c)(2)

- Review and analyze patient and staff incident and accident reports to identify any

incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect *more widespread or pervasive* problems with safe environment *issues* in the hospital.

- Observe patient care environments for unattended items such as utility or housekeeping carts that contain hazardous items that may pose a safety risk to patients, visitors and staff. Examples of these items could include cleaning agents, disinfectant solutions, mops, brooms, tools, etc.
- *Review policy and procedures and* interview staff in patient care areas to determine how the hospital *initially and routinely* trains staff *to keep them current on meeting the needs of the patient population served*, to *identify risks in the care environment*, and if *risk is* found, how staff report those findings.
- Review policy and procedures and interview staff to determine how the hospital defines *1:1 monitoring or continuous visual observation* in which a staff member is assigned to observe only one patient at all times. The policy should *include the ability of the assigned staff member to immediately intervene when patient safety may be at risk*.
- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?
- Review policy and procedures on what the hospital does to curtail unwanted visitors, contaminated materials, or unsafe items that pose a safety risk to patients and staff.
- Access the hospital's security efforts to protect vulnerable patients including newborns, children and patients at risk of suicide or intentional harm to self or others. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients? Security mechanisms must be based on nationally recognized standards of practice.
- *Verify the hospital has a policy for assessing and reassessing patients that have been identified as being at risk for suicide or harm to self or others, according to nationally accepted standards of practice.*

NOTE: Waivers for Ligature Risk findings are not permissible. See Chapter 2 (identify section when written) for ligature risk extension request guidelines.

A-0701

(Rev.)

§482.41(a) Standard: Buildings

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

Interpretive Guidelines §482.41(a)

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and well-being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the hospital's QAPI plan.

The hospital must be constructed and maintained to ensure risks are minimized for patients as well as for employees and visitors. Hospitals are expected to demonstrate how they are addressing important safety features in accordance with nationally recognized standards.

Important safety features are expected to be addressed when applicable, *including but not limited to the following:*

Accessibility

- The hospital must ensure all buildings at all locations of the certified hospital meet State and Federal accessibility standards (e.g. Office of Civil Rights requirements). The requirements apply to the interior and exterior of all buildings.

Age-related safety *considerations*

- Hospitals are expected to address safety hazards and risks related to age-related factors. Healthcare provided to neonatal, pediatric, and geriatric patients must be in accordance with nationally recognized standards. Age-related risks may include *factors* such as security of inpatient and outpatient locations, access to medications, cleaning supplies and other hazardous materials, furniture and other medical equipment, *and* increased *risk* of falls.

Security

- To minimize the risk of unauthorized access to or inappropriate departure from secured healthcare units, hospitals must demonstrate security features in accordance with nationally recognized standards to ensure the safety of vulnerable patients. This includes, but is not limited to, patients such as newborn (e.g. infant abduction), pediatric, behavioral health, those with diminished capacity and dementia/Alzheimer's.

Access to non-clinical rooms identified as hazardous locations must be secured to prevent patient and visitor entry. Examples include electrical rooms and heat, ventilation, air conditioning (HVAC) rooms.

Ligature risk

- The presence of unmitigated ligature risks in a psychiatric hospital or a psychiatric unit of a hospital *may be* an immediate jeopardy situation. *Please refer to Appendix Q for guidance on immediate jeopardy.* Ligature risk findings must be referred to the health and safety surveyors for further evaluation and possible citation under Patients' Rights.

Weather-related exterior issues

- Although hospitals cannot address all weather-related issues, they are expected to address potential safety hazards specific to weather on both the exterior and interior locations in accordance of nationally recognized standards. Areas of risk include driveways, garages, entry points, walkways, etc.

Life Safety Code surveyors assess the use of power strips in healthcare facilities. However, the following guidance is provided as reference for healthcare surveyors as they survey physical environment along with other CoP requirements. Any observed power strip deficiencies should be conveyed to the LSC surveyors for citation.

If line-operated medical equipment is used in a patient care room/area, inside the patient care vicinity:

- UL power strips would have to be a permanent component of a rack-, table-, pedestal-, or cart-mounted & tested medical equipment assembly.
- Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1.
- Power strips cannot be used for non-medical equipment.

If line-operated medical equipment is used in a patient care room/area, outside the patient care vicinity:

- UL power strips could be used for medical & non-medical equipment with precautions as described in the memo.
- Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1.
- Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363.

If line-operated medical equipment is not used in a patient care room/area, inside and outside the patient care vicinity:

- UL power strips could be used with precautions.

Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363. In non-patient care areas/rooms, other UL strips could be used with the general precautions.

Survey Procedures §482.41(a)

- Verify that the condition of the hospital is maintained in a manner to assure the safety and

well-being of patients (e.g., condition *of* ceilings, walls, and floors, presence of patient hazards, etc.).

- Review the hospital’s routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.
- Review a copy of the most recent environmental risk assessment to determine if the hospital has identified any accessibility, age-related, security, suicide and/or weather related risks or concerns. If environmental safety concerns have been identified in this assessment, what plans have been implemented by the hospital to ensure patient/staff safety?
- Refer any potential power strip use deficiencies to Life Safety Code surveyors.
- Communicate findings with health and safety surveyors as appropriate. *Ligature risks when identified and which have not been appropriately mitigated, must be cited under Patient Rights §482.13(c)(2) and may be cited under Physical Environment §482.41(a). For example, in follow-up to a suicide by hanging it was determined there was lack of screening and assessment of a patient at risk as well as hazards in the physical environment (presence of drop ceilings or ligature points in unmonitored areas), surveyors may consider citing Physical Environment in addition to Patient Rights.*

NOTE: Waivers for Ligature Risk findings are not permissible. See Chapter 2 Section 2728G for ligature risk extension request guidelines.

DRAFT- This publication is currently in draft open for public comment. This is not final policy and does not replace existing regulations or policy.