
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 176

Date: December 29, 2017

SUBJECT: Revisions to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Revisions are being made to Appendix A for Hospitals by revising current interpretive guidelines regarding the assessment of ligature risks to patients.

NEW/REVISED MATERIAL - EFFECTIVE DATE:- December 29, 2017

IMPLEMENTATION DATE: December 29, 2017

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
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/ Tag 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.

Or

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

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

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

A-0144

(Rev. 176, Issued: 12-29-17, Effective: 12-29-17, Implementation: 12-29-17)

§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 would *also* be 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 education and training for staff and volunteers.*

*Patients at risk of suicide (or other forms of self-harm) or exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals. The focus for a ligature "resistant" or ligature "free" environment is that of psychiatric units of acute care hospitals and psychiatric hospitals and does not apply to non-psychiatric units of acute care hospitals that 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 a history of a psychiatric condition are cared for in psychiatric hospitals or psychiatric units of acute care hospitals. Therefore, non-psychiatric settings of all hospitals where patients with psychiatric conditions may be cared for 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 setting (medical inpatient units, ED, ICU, etc.) must be protected when demonstrating suicidal ideation or harm to others. 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.*

Although all risks cannot be eliminated, hospitals are expected to demonstrate how they identify patients at risk of self-harm or harm to 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, sharps, harmful substances, access to medications, breakable windows, accessible light fixtures, plastic bags (for suffocation), oxygen tubing, bell cords, etc.

Identifying Patients at Risk

There are numerous models and versions of patient risk assessment tools available to identify patients at risk for harm to self or others. No one size fits all tool is available. Therefore, the type of patient risk assessment tool used should be appropriate to the patient population, care

setting and staff competency. All hospitals are expected to implement a patient risk assessment strategy, but it is up to the hospital to implement the appropriate strategies. For example, a patient risk assessment strategy in a post-partum unit would most likely not be the same risk assessment strategy utilized in the emergency department.

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. That does not mean that a unit which does not typically care for patients with psychiatric conditions is not expected to conduct environmental risk assessments. It means that the risk assessment must be appropriate to the unit and should consider the possibility that the unit may sometimes care for patients at risk for harm to self or others. While CMS does not require the use of an Environmental Risk Assessment Tool (e.g. the Veteran's Administration Environmental Risk Assessment Tool), the use of such tools may be used as a way for the hospital to assess for safety risks in all patient care environments in order to minimize environmental risks and to document the assessment findings. Examples of Environmental Risk Assessment Tool content may include prompts for staff to assess items such as, but not limited to:

- Ligature risks include but are not limited to, 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.*
- 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*

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.*

Hospital staff must be trained to identify environmental safety risks regardless of whether or not the hospital has chosen to implement the use of an environmental risk assessment tool to identify potential or actual risks in the patient care environment.

Education and Training

Hospitals must provide the appropriate level of education and training to staff regarding the identification of patients at risk of harm to self or others, the identification of environmental patient safety risk factors and mitigation strategies. Staff includes direct employees, volunteers, contractors, per diem staff and any other individuals providing clinical care under arrangement. Hospitals have the flexibility to tailor the training to the particular services staff provide and the patient populations they serve. Hospitals are expected to provide education and training to all new staff initially upon orientation and whenever policies and procedures change. However, CMS recommends initial training and then ongoing training at least every two years thereafter.

Correction of Environmental Risks

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 life safety code (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.

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 recommended by the National Psychiatric Nursing Association (NPNA) at http://www.apna.org/files/public/Councils/PsychiatricNursingAvailabilityTool_021216.pdf. 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. Another interim safety measure may include locking rooms in which ligature risks have been identified to prevent patient access.

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.

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 working 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.

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 a problem with safe environment in the hospitals.
- *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.*
- *Interview staff in patient care areas to determine how the hospital has trained staff to identify risks in the care environment and if found, how staff report those findings.*
- *Review policy and procedures and interview staff to determine how the hospital defines continuous visual observation or 1:1 observation in which a staff member is assigned to observe only one patient at all times.*
- 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.*

A-0701

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§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. Although the following items are expected to be addressed when applicable, the list is not all-inclusive.

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 features

- 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 items such as security of inpatient and outpatient locations, access to medications, cleaning supplies and other hazardous materials, furniture and other medical equipment, and increased chance 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 psychiatric unit of a hospital is an immediate jeopardy situation. Additionally, this also includes any location where patients at risk of suicide are identified. 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.