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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

Transmittal 216

Date: July 21, 2023

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**SUBJECT: Revision to State Operations Manual (SOM) Appendix A- Hospitals**

**I. SUMMARY OF CHANGES:** This transmittal includes updates of the interpretive guidance for §482.13(c)(2) - The patient has the right to receive care in a safe setting.

**NEW/REVISED MATERIAL - EFFECTIVE DATE\*: July 21, 2023**

**IMPLEMENTATION DATE: July 21, 2023**

*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/A-0144/§482.13(c)(2) - The patient has the right to receive care in a safe setting

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their 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
	One-Time Notification -Confidential
	Recurring Update Notification

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

**State Operations Manual**  
**Appendix A - Survey Protocol,**  
**Regulations and Interpretive Guidelines for**  
**Hospitals**

*(Rev. 216; Issued: 07-21-23)*

## A-0144

*(Rev. 216; Issued:07-21-23; Effective: 07-21-23; Implementation: 07-21-23)*

**§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, *similarly situated as the patient*, 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. *To* provide care in a safe setting, hospitals *should* 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 *who* exhibit violent behaviors toward others, receive healthcare services in both inpatient and outpatient locations of hospitals. Therefore, non-psychiatric settings of all hospitals where patients with psychiatric conditions may be cared for *should* 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 *evaluated, monitored, and cared for appropriately when* demonstrating suicidal ideation or *potential* harm to others. The *care could include, but not be limited to*, 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 *should be able* 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.

*Hospitals may find the recommendations and resources in the 2018 report, Recommended standard care for people with suicide risk: Making health care suicide safe, issued by the National Action Alliance for Suicide Prevention (Action Alliance), to be highly useful in developing the best practices for effective patient screening and assessment for those patients at risk for harm to themselves, as well as for improving the care of patients at risk of suicide.<sup>1</sup> The Action Alliance is the public-private partnership working to advance the National Strategy for Suicide Prevention and reduce the suicide rate 20 percent by 2025. Notably, the report advances two of the goals of the National Strategy for Suicide Prevention (National Strategy): (a) Promote suicide prevention as a core component of health care services; and (b) Promote and implement effective clinical and professional practices for assessing and treating those identified as being at risk for suicidal behaviors. (To download a copy of the National Strategy, please visit: [www.actionallianceforsuicideprevention.org](http://www.actionallianceforsuicideprevention.org)).*

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<sup>1</sup> National Action Alliance for Suicide Prevention: Transforming Health Systems Initiative Work Group. (2018). Recommended standard care for people with suicide risk: Making health care suicide safe. Washington, DC: Education Development Center, Inc. (accessed at: [https://theactionalliance.org/sites/default/files/action\\_alliance\\_recommended\\_standard\\_care\\_final.pdf](https://theactionalliance.org/sites/default/files/action_alliance_recommended_standard_care_final.pdf))

## 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 *should* implement a patient risk assessment strategy, but it is up to the *individual* 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 *should* implement a patient risk assessment strategy, all hospitals *should* implement an environmental risk assessment strategy. Environmental risk assessment strategies may not be the same in all hospitals or hospital units. The hospital implements environmental risk assessment strategies appropriate to *its* specific care environment and patient population. That does not mean that a unit which does not typically care for patients with psychiatric conditions *should not be* conducting 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 safety risks in all patient care environments 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 *such as handrails, doorknobs*, door hinges, shower curtains, exposed plumbing/pipes, soap, and paper towel dispensers on walls, power cords on medical equipment or call bell cords, light fixtures, or projections from ceilings, etc.
- Unattended items such as utility or housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizers, 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; *and*
- Inadequate staffing levels to provide appropriate patient observation and monitoring

Hospital staff *should* 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 *should* 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 *should* 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**

Cited *noncompliance that include* ligature risks, *which* 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, *should* be corrected *as soon as possible*, but within the *timeframe noted* by the CMS *Location, the SA, or the 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.

Interim patient safety measures to mitigate identified ligature or safety risks may include, *without limitation*, continuous visual observation or 1:1 observation based on the type of identified risk.

### **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.
- 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.
- 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 *are* based on nationally recognized standards of practice.