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LIGATURE
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<tr>
<td>04.01.01 Staff Training: Identification of Patients at Risk for Harm.</td>
<td>Hospitals must provide the appropriate level of education and training to staff regarding: 1. The identification of patients at risk of harm to self or others, 2. The identification of environmental patient safety risk factors and 3. Mitigation strategies.</td>
<td>DOCUMENT REVIEW 1. Review documents to verify the requirement is included with new employee orientation. 2. Review documents to verify the requirement is included with annual training. 3. Review employee files to verify the new employee received this information during orientation and annually thereafter.</td>
<td>1 = Compliant 2 = Not Compliant</td>
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<tr>
<td>§482.13(c)(2)</td>
<td>Staff training is provided for: 1. Direct employees, 2. Volunteers, 3. Contractors providing clinical care, 4. Per diem staff and 5. Other individuals providing clinical care under arrangement.</td>
<td>This standard is not met as evidenced by:</td>
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<td>Hospitals have the flexibility to tailor the training to the particular services staff provide and the patient populations they serve.</td>
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<td>Hospitals are expected to provide education and training to: 1. All new staff initially upon orientation 2. Whenever policies and procedures change 3. Annually, thereafter.</td>
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### PHYSICAL ENVIRONMENT – REVISED STANDARD

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<tr>
<td>11.01.01 Periodic Monitoring for Safety Issues.</td>
<td>The physical environment of each facility used for treating or housing patients shall be inspected once every six months in patient care areas, and once every 12 months in non-patient care areas to identify safety related concerns and issues.</td>
<td><strong>DOCUMENT REVIEW, INTERVIEW AND OBSERVATION</strong></td>
<td>□ 1 = Compliant □ 2 = Not Compliant</td>
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<td>All patient care areas of the facility are inspected at least once every six months and all non-patient care areas are inspected at least once every 12 months to identify safety related concerns and issues. Special care is given to ensure compliance with applicable codes, standards and regulations related to the physical environment.</td>
<td></td>
<td>This standard is not met as evidenced by:</td>
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<td>The environmental risk assessment strategy for patient care in a safe setting shall be performed at least once every six-months.</td>
<td>- Verify that records have been maintained demonstrating safety inspections were conducted once every six months in patient care areas and once every 12 months for non-patient care areas.</td>
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<td>Inspections must be documented with date, initials or signatures of individuals participating in the inspection, and all deficiencies identified with the action item of said deficiencies.</td>
<td>- Verify the specific environmental risk assessment tool for a patient-safe care setting has been approved by the Safety Committee and contains a list of elements the hospital has identified are ligature risks, hazardous, or that provide accessible means for a patient to harm themselves or others.</td>
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<td>§482.13(c)(2)</td>
<td>- Additional facilities associated with the hospital, either owned or leased must also be monitored for safety. Records demonstrating correction of actions should be reviewed. All items identified in the report should be reviewed for corrective action.</td>
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# PHYSICAL ENVIRONMENT – REVISED STANDARD

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## 11.01.02 Building Safety
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, visitors, and staff is assured.

The hospital identifies hazards specific to weather on both interior and exterior locations.

The patient has the right to receive care in a safe setting. The hospital must implement environmental risk assessment strategies appropriate to the specific care environment and patient population served.

The risk assessment strategy shall address age, psychiatric, diminished capacity, and any other patient related factors the hospital identifies as applicable.

§482.41(a)  
§482.13(c)(2)

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, visitors and staff.

Review the environment based on elements which allow at-risk patients to cause intentional harm to self or others, including ligature risk, unattended hazardous items, windows that can be opened or broken, unprotected lighting fixtures, other unsecured objects considered dangerous, or other conditions identified by the hospital to be dangerous.

Hospitals are expected to address hazards and risk for age-related factors. Healthcare provided to neonatal, pediatric, and geriatric patients must be in accordance with nationally recognized standards.

Routine and preventative maintenance on medical equipment is scored under 11.05.01, and utility (plant) equipment is scored under 11.06.09.

### DOCUMENT REVIEW AND OBSERVATION
- Verify that the condition of the hospital is maintained in a manner to assure the safety and well-being of patients, visitors and staff.
- Review the interior and exterior for hazards related to weather conditions.
- 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.

1 = Compliant  
2 = Not Compliant

This standard is not met as evidenced by:
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| **11.01.08**  **Review of Safety Policies / Procedures.**  
The Safety Committee is responsible to evaluate safety policies and procedures as conditions change within the organization or at least once every 36 months. | People, processes, and characteristics change; therefore, all safety policies and procedures shall be reviewed at least once every 36 months and approved for appropriateness by the Safety Committee.  
The chairperson of the Safety Committee shall sign and date the policies. | **DOCUMENT REVIEW**  
- Verify that an appraisal has been documented at least once in the past 36 months within the Safety Committee minutes  
- Verify that policies are current.  
- Review policy and procedures on what the hospital does to curtail contaminated materials and unsafe items that pose a safety risk to patients and staff. | ☐ 1 = Compliant  
☐ 2 = Not Compliant  
This standard is not met as evidenced by: |
### PHYSICAL ENVIRONMENT – REVISED STANDARD

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| **11.02.01 Building Security.** | The organization shall have policies and other measures in effect to identify and minimize security risks to patients, visitors, and staff. The organization must demonstrate security features are based on nationally recognized standards to ensure the safety of vulnerable patients. 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, and air conditioning (HVAC) rooms. §482.41(a) | **DOCUMENT REVIEW AND INTERVIEW**  
• Determine if policies, procedures and systems are in place. Review documents to determine if the security program is effective or if there are security concerns.  
• Review security risk assessments for frequency and thoroughness of assessments, and follow-through on recommended actions.  
• Interview staff to determine if security and safety is an issue.  
• Review policy and procedures on what the hospital does to curtail unwanted visitors that pose a safety or security risk to patients and staff.  
• Review 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. Security mechanisms must note references to nationally recognized standards of practice. | [ ] 1 = Compliant  
[ ] 2 = Not Compliant  
This standard is not met as evidenced by: |
13.00.01 Life Safety Code Compliance.
Except as otherwise provided in this section—

The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

§482.41(b)(1)(i)

Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

§482.41(b)(1)(ii)

The hospital must ensure that all buildings at all locations of the certified hospital meet State and Federal accessibility standards (e.g.

All hospitals, regardless of size or number of beds, must comply with the NFPA 101 Life Safety Code (2012 edition) requirements for all locations. All buildings and spaces owned, leased or rented which is used for hospital business must comply with the Life Safety Code.

The organization is responsible for developing a systematic process for assessing the compliance with the Life Safety Code of each building under its control.

While HFAP does not specify what process to Life Safety compliance the organization should use, the results must show that the facilities are in full compliance with the Life Safety Code, and other applicable standards.

Roller latches may not be used on corridor doors, with the exception of corridor doors that are not required to latch, such as doors to toilet rooms, bathrooms, shower rooms, sink closets and similar spaces that do not contain flammable or combustible materials.

Accessibility requirements apply to the interior and exterior of all buildings. This standard enacts additional assurance that individuals with physical challenges are not preventing from utilizing fire protection features required by the Life Safety Code for their safety and to prevent harm in a fire scenario.

- Determine that buildings are in compliance with the applicable occupancy chapters of the Life Safety Code and applicable codes, by direct observation.
- Provide findings for accessibility observations in the standards related to the individual element which is not in compliance with accessibility requirements.

This standard is not met as evidenced by:

1 = Compliant   2 = Not Compliant
Office of Civil Rights requirements).

§482.41(a)

The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

§482.41(b)(3)
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| **13.01.06 Exit Discharge.** | The exit discharge is the portion of means of egress from the exit door to the public way. The walking surface must be level and free of cracks and abrupt changes in elevation exceeding ¼ inch. Note that steps are permitted. Exit discharge must be maintained free from ice and snow and other weather-related hazards. An exit discharge across an unimproved area, such as a lawn, is not considered to be in compliance with this standard due to the uneven walking surface. Illumination of exit discharge must be by lighting fixtures with more than one lamp, or multiple lighting fixtures to ensure path is illuminated if one lamp fails. | OBSERVATION  
- During the building tour, observe all exit discharges to ensure they have level walking surfaces and illumination all the way to the public way. | 1 = Compliant  
2 = Not Compliant |
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**13.05.09 Utility Systems.**
Utility systems are properly installed and maintained to a fire-safe condition.

§482.41(a)

| | Utility systems must be installed and maintained to a fire-safe condition. |
| | Access to electrical control panels must not be obstructed. |
| | Circuits in electrical control panels must be properly labeled as to their use. |
| | Electrical junction box covers must be properly installed. |
| | Electrical wires and cables are not permitted to be tied to conduits. |

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

- UL 1363A or UL 60601-1 power strips would have to be a permanent component of a rack-, table-, pedestal-, or cart-mounted & tested medical equipment assembly and 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

**OBSERVATION**

- Determine if electrical control panels have proper clearance, and all circuits labeled.
- Determine if electrical junction boxes are properly covered.
- Determine if electrical conduits are free of attached wires and cables.
- Look for power strips in the facility and determine if they are UL compliant for the appropriate area of use.

[ ] 1 =Compliant  
[ ] 2 = Not Compliant

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<tr>
<td>• Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1</td>
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<td>• Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363</td>
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<td>• If line-operated medical equipment is not used in a patient care room/area, inside and outside the patient care vicinity</td>
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<tr>
<td>• 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</td>
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<td>• In non-patient care areas/rooms, other UL strips could be used with the general precautions.</td>
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### PATIENT RIGHTS – REVISED STANDARD

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<td>15.01.17 Privacy &amp; Safety: Safe Setting.</td>
<td>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.</td>
<td>DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION</td>
</tr>
<tr>
<td>§482.13(c)(2)</td>
<td>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 be components of an emotionally safe environment.</td>
<td>1. 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.</td>
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<td>2. Review QAPI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment.</td>
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<td>3. Review policy and procedures on what the facility does to curtail unwanted visitors, contaminated materials, or unsafe items that pose a safety risk to patients and staff.</td>
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**HOSPITAL MUST DEMONSTRATE**

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.

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This standard is not met as evidenced by:
2. Identify environmental safety risks for such patients, and

3. Provide education and training for staff and volunteers.

A. NON-PSYCHIATRIC SETTINGS OF ALL HOSPITALS

1. 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.

2. 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:

a. Providing 1:1 monitoring with continuous visual observation,

b. Removal of sharp objects from the room/area, or

c. Removal of equipment that can be used as a weapon.

B. Psychiatric Units Of Acute Care Hospitals:

- 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.
1. 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.

2. The focus for a ligature “resistant” or ligature “free” environment is that of psychiatric units of acute care hospitals and psychiatric hospitals.

3. A “ligature free” environment 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.
**15.01.19 Privacy & Safety: Identify Patients at Risk.**

The patient has the right to receive care in a safe setting.

§482.13(c)(2)

**IDENTIFY PATIENTS AT RISK**

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.

**PATIENT RISK ASSESSMENT TOOL**

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. The 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.

**POLICY**

The facility has a policy that evaluates the elements it uses to determine the patients at risk. For example, individuals at risk of suicide, demonstrating behavior that places self or others at risk, a history of violent behavior, expressions of self-harm, violence behavior toward others, and etc. in the emergency department, inpatient areas, or outpatient locations of the hospital.

**DOCUMENT REVIEW AND INTERVIEW**

1. 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.

2. Review policy and procedures and interview staff to determine the Patient Risk Assessment tools adopted by the hospital.

3. Ask staff how is the risk assessment tool is modified to ensure it is appropriate for the care area.

This standard is not met as evidenced by:
### STANDARD / ELEMENT

| 15.01.20 Privacy & Safety: Environmental Risk Assessment |  |  |  |

The patient has the right to receive care in a safe setting.

§482.13(c)(2)

#### EXPLANATION

**ENVIRONMENTAL RISK ASSESSMENT**

All hospitals must implement an environmental risk assessment strategy. The 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.

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. The use of such risk assessment 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:

1. 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.

2. Unattended items such as utility or

#### SCORING PROCEDURE

**DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW**

1. 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.

2. 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.

This standard is not met as evidenced by:

- [ ] ☐ 1 = Compliant
- [ ] ☐ 2 = Not Compliant
### PATIENT RIGHTS – NEW STANDARD

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<tr>
<td>1.</td>
<td>housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizer, etc.)</td>
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<td>2.</td>
<td>Unsafe items brought to patients by visitors in locked psychiatric units of hospitals and psychiatric hospitals.</td>
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<td>3.</td>
<td>Windows that can be opened or broken</td>
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<td>4.</td>
<td>Unprotected lighting fixtures</td>
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<td>5.</td>
<td>Inadequate staffing levels to provide appropriate patient observation and monitoring.</td>
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<tr>
<td>27.03.01 Privacy &amp; Safety: Identify Patients at Risk.</td>
<td>The patient has the right to receive care in a safe setting.</td>
<td>Refer to standard 15.01.19 for requirements.</td>
<td>Score at standard 15.01.19</td>
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<td>§482.13(c)(2)</td>
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<td>27.03.02 Privacy &amp; Safety: Environmental Risk Assessment.</td>
<td>The patient has the right to receive care in a safe setting.</td>
<td>Refer to standard 15.01.20 for requirements.</td>
<td>Score at standard 15.01.20</td>
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07.01.03 Reduce Risk of Legionella in Water Systems.
The infection control program includes processes to reduce the risk of growth and spread of Legionella and other opportunistic pathogens in building water systems including:

1. Water management policies and procedures.

2. A facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens could grow and spread.

3. Implement a water management program that includes industry standard control measures.

Legionnaire’s disease, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium Legionella.

The Infection Control Coordinator collaborates with the Facilities Manager to reduce the risk of growth and spread of Legionella and other opportunistic pathogens in the water systems. (See also standard 07.01.03)

Outbreaks generally are linked to environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities. Transmission from these water systems to humans requires aerosol generation, as can occur from showerheads, cooling towers, hot tubs, and decorative fountains. Legionella is less commonly spread by aspiration of drinking water or ice.

In manmade water systems, Legionella can grow and spread to susceptible hosts, such as persons who are at least 50 years old, smokers, and those with underlying medical conditions such as chronic lung disease or immunosuppression. Legionella can grow in parts of building water systems that are continually wet, and certain devices can spread contaminated water droplets via aerosolization. Examples of these system components and devices include:

- Hot and cold water storage tanks
- Water heaters
- Water-hammer arrestors

DOCUMENT REVIEW
Those facilities unable to demonstrate measures to minimize the risk of Legionnaire’s disease are at risk of citation for non-compliance with the CMS Conditions of Participation.

Review policies, procedures, and reports documenting water management implementation results to verify that facilities:

1. Conduct a facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g. Pseudomonas, Acinetobacter, Burkholderia, Stenotrophomonas, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.

2. Implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

3. Specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.

DOCUMENT REVIEW
This standard is not met as evidenced by:
INFECTION CONTROL – NEW STANDARD

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<td>Pipes, valves, and fittings</td>
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<td>Expansion tanks</td>
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<td>Water filters</td>
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<td>Electronic and manual faucets</td>
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<td>Aerators</td>
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<td>Faucet flow restrictors</td>
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<td>Showerheads and hoses</td>
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<td>Centrally-installed misters, atomizers, air washers, and humidifiers</td>
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<td>Non-steam aerosol-generating humidifiers</td>
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<td>Eyewash stations</td>
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<td>Ice machines</td>
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<td>Hot tubs/saunas</td>
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<td>Decorative fountains</td>
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<td>Cooling towers</td>
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<td>Medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)</td>
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Healthcare facilities are expected to comply with CMS requirements to protect the health and safety of its patients. Those facilities unable to demonstrate measures to minimize the risk of Legionnaire’s disease are at risk of citation for non-compliance with the CMS Conditions of Participation. Accrediting organizations will be surveying healthcare facilities deemed to participate in Medicare for compliance with the requirements listed in this memorandum, as well, and will cite non-compliance accordingly.
TEXTING
10.00.00 Condition of Participation: Medical Record Services.  

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

The texting of patient orders is prohibited regardless of the platform utilized.

In order to be compliant with the CoPs, all providers must utilize and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the hospital and CAH CoPs.

It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized, in order to avoid negative outcomes that could compromise the care of patients. §482.24

The facility should have an organizational plan, which shows the responsible person for medical records (health information) of every individual treated at the facility.

The term “hospital” includes all locations of the hospital.

The hospital must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and outpatient records.

The hospital must create and maintain a medical record for every individual, both inpatient and outpatient, evaluated or treated in the hospital.

The term “medical records” includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

TEXTING

CMS does not permit the texting of orders by physicians or other health care providers. The practice of texting orders from a provider to a member of the care team is not in compliance with the Conditions of Participation (CoPs).

The texting of patient information among members of the health care team is permissible if accomplished through a secure platform.

DOCUMENT REVIEW AND INTERVIEW

1. Review the organizational structure and policy statements.

2. Interview the person responsible for the medical record (health information) service to determine that it is structured appropriately to meet the needs of the facility and the patients.

3. Verify the facility does not permit the texting of orders by physicians or other health care providers.

CHART REVIEW

Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and hospital policy.

- The sample should be 10 percent of the average daily census and be no less than 30 records.

- Additionally, select a sample of outpatient records in order to determine compliance in outpatient departments, services, and locations.
10.00.06 Security of Medical Information.
The hospital must have a procedure for ensuring the confidentiality of patient records.

Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

The texting of patient orders is prohibited regardless of the platform utilized.

The texting of patient information among members of the health care team is permissible if accomplished through a secure platform.

§482.24(b)(3)

RELEASE OF INFORMATION or COPIES OF RECORDS
The hospital must have a procedure to ensure the confidentiality of each patient’s medical record, whether it is in paper or electronic format, or a combination of the two, from unauthorized disclosure.

Confidentiality applies wherever the record or portions thereof are stored, including but not limited to central records, patient care locations, radiology, laboratories, record storage areas, etc.

A hospital is permitted to disclose medical record information, without a patient’s authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations.

1. Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual.

2. Health care operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to:
   - Quality assessment and improvement activities,
   - Case management and care coordination;

   DOCUMENT REVIEW, INTERVIEW AND OBSERVATION
1. Verify that policies are in place that limits access to, and disclosure of, medical records to permitted users and uses, and that require written authorization for other disclosures. Are the policies consistent with the regulatory requirements?

2. Observe whether patient records are secured from unauthorized access at all times and in all locations.

3. Ask the hospital to demonstrate what precautions are taken to prevent physical or electronic altering of content previously entered into a patient record, or to prevent unauthorized disposal of patient records.

4. Verify that patient medical record information is released only as permitted under the hospital’s policies and procedures.

5. Conduct observations and interview staff to determine what safeguards are in place or precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

6. If the hospital uses electronic patient records, is access to patient records controlled through standard measures, such as business

This standard is not met as evidenced by:
<table>
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<tr>
<td>• Competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs;</td>
<td>rules defining permitted access, passwords, etc.?</td>
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<td>• Business planning, development, management, and administration and certain hospital-specific fundraising activities.</td>
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<td><strong>POLICIES AND PROCEDURES</strong></td>
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<td>The hospital must develop policies and procedures that reasonably limit disclosures of information contained in the patient’s medical record to the minimum disclosure necessary, except when the disclosure is for treatment or payment purposes, or as otherwise required by State or Federal law.</td>
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<td>When the minimum necessary standard is applied, a hospital may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record is the disclosure amount reasonably required for the purpose.</td>
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<td>A hospital may disclose information from the medical record electronically, and may also share an electronic medical record system with other health care facilities, physicians and practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.</td>
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<td>The hospital must obtain written authorization from the patient or the patient’s representative for any other disclosure of medical record information.</td>
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<td>7. Do the hospital’s policies and procedures provide that “original” medical records are retained, unless their release is mandated under Federal or State law, court order or subpoena? Interview staff responsible for medical records to determine if they are aware of the limitations on release of “original” medical records.</td>
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<td>8. Observe the hospital’s security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurse’s stations, or on counters where unauthorized persons could gain access to patient records?</td>
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<td>9. Verify that there is an established system in place that addresses protecting the confidentiality of medical information.</td>
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<td>10. If the hospital uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?</td>
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<td>11. Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion / destruction of patient records or information in patient records.</td>
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PREVENTING UNAUTHORIZED ACCESS
The hospital must ensure that unauthorized individuals cannot gain access to patient records. This applies to records in electronic as well as hard copy formats.

Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

- For hard copy records, techniques such as locked cabinets or file rooms and limiting access to keys or pass codes may be employed.

- For electronic records technical safeguards, such as business rules that limit access based on need to know, passwords, or other control mechanisms must be in place.

When disposing of copies of medical records, physical safeguards might include first shredding documents containing confidential information, taking appropriate steps to erase information from media used to store electronic records, etc.

RELEASE OF ORIGINAL RECORDS
The hospital must not release the original of a medical record that exists in a hard copy, paper version only, unless it is required to do so in response to a court order, a subpoena, or Federal or State laws.

12. Verify the facility does not permit the texting of orders by physicians or other healthcare providers.

13. It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized, in order to avoid negative outcomes that could compromise the care of patients.
For electronic records, the hospital must ensure that the media or other mechanism by which the records are stored electronically is not removed in such a way that all or part of the record is deleted from the hospital’s medical record system.

The hospital must have policies and procedures that address how it assures that it retains its “original” medical records, unless their release is mandated by law/court order/subpoena.

Patient records must be secure at all times and in all locations. This includes patient records for patients who are currently inpatients in the hospital as well as outpatients in outpatient clinics.

Policies are in place that address the organization of the medical records service including:
- Confidentiality
- Release of information
- Retention
- Storage
- Security of medical records in all areas of the inpatient and outpatient areas of the organization.

**SECURE SYSTEMS/PLATFORMS**
In order to be compliant with the CoPs, all providers must utilize and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the hospital and CAH CoPs.
It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized, in order to avoid negative outcomes that could compromise the care of patients.
### Medical Records – Revised Standard

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| 10.01.03 **Legible & Complete.** | All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. | CHART REVIEW  
Review a sample of open and closed medical records.  
1. Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted?  
2. Determine whether orders, progress notes, nursing notes, or other entries in the medical record are complete.  
3. Does the medical record contain sufficient information to identify the patient;  
   - Support the diagnosis / condition  
   - Justify the care, treatment, and services  
   - Document the course and results of care, treatment, and services; and  
   - Promote continuity of care among providers?  
4. Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is responsible for ordering, providing, or evaluating the service provided.  
5. Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is responsible for ordering, providing, or evaluating the service provided. | ☐ 1 = Compliant  
☐ 2 = Not Compliant  
This standard is not met as evidenced by: |
the person responsible for providing or evaluating the service provided.

1. The time and date of each entry (orders, reports, notes, etc.) must be accurately documented.

Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care.

Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR §68687)

2. The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders / entries or computer entries.

3. The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins caring for the patient and who is authorized by hospital policy and in accordance with State law to write orders.

6. Determine whether the hospital has a means for verifying signatures, both written and electronic, written initials, codes, and stamps when such are used for authorship identification.

   • For electronic medical records, ask the hospital to demonstrate the security features that maintain the integrity of entries and verification of electronic signatures and authorizations.

   • Examine the hospital’s policies and procedures for using the system, and determine if documents are being authenticated after they are created.
processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated, and timed in the patient’s medical record.

**PRE-PRINTED ORDER SETS**

When a practitioner is using a preprinted order set, the ordering practitioner may be in compliance with the requirement at §482.24(c)(1) to date, time, and authenticate an order if the practitioner accomplishes the following:

1. **Last page:**
   - Sign, date, and time the last page of the orders, with the last page also identifying the total number of pages in the order set.

2. **Pages with Internal Selections:**
   - Sign or initial any other (internal) pages of the order set where selections or changes have been made.
     - The practitioner should initial / sign the top or bottom of the pertinent page(s); and
     - The practitioner should also initial each place in the preprinted order set where changes, such as additions, deletions, or strike-outs of components that do not apply, have been made.
     - It is not necessary to initial every preprinted box that is checked to indicate selection of an
order option, so long as there are no changes made to the option(s) selected.

**PRE-ESTABLISHED ELECTRONIC ORDER SET**
In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection / annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

1. Authentication of medical record entries may include written signatures, initials, computer key, or other code.
2. For authentication, in written or electronic form, a method must be established to identify the author.
3. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent.
4. There shall be no delegation of stamps or authentication codes to another individual. It should be noted that some insurers and other payers may have a policy prohibiting the use of rubber stamps as a means of authenticating the medical records that support a claim for payment.
5. Medicare payment policy, for example, no longer permits such use of rubber stamps. Thus, while the use of a rubber stamp for signature authentication is not prohibited under the CoPs and analysis of the rubber stamp method per se is not an element of the survey process, hospitals may wish to eliminate their usage in order to avoid denial of claims for payment.

**Electronic Medical Record**

Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the hospital.

**Countersignature**

When State law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address countersignature requirements and processes.

**Auto-authentication**

A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be
displayed, is not consistent with these requirements.

- There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created.

- In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature authenticating an entry, even though there may already be a date and time on the document, since the latter may not reflect when the entry was authenticated.

For certain electronically-generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

**Computerized Provider Order Entry (CPOE) is the preferred method of order entry by a provider. CMS**
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<td>has held to the long standing practice that a physician or Licensed Independent Practitioner (LIP) should enter orders into the medical record via a handwritten order or via CPOE. An order if entered via CPOE, with an immediate download into the provider’s electronic health records (EHR), is permitted as the order would be dated, timed, authenticated, and promptly placed in the medical record.</td>
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