

## **F700**

(Rev. 211; Issued: 02-03-23; Effective: 10-21-22; Implementation: 10-24-22)

### **§483.25(n) Bed Rails.**

The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

**§483.25(n)(1) Assess the resident for risk of entrapment from bed rails prior to installation.**

**§483.25(n)(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.**

**§483.25(n)(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.**

**§483.25(n)(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.**

### **INTENT §483.25(n)**

The intent of this requirement is to ensure that prior to the installation or use of bed rails, the facility attempts to use alternatives. If the attempted alternatives were not adequate to meet the resident's needs, the resident is assessed for the use of bed rails, which includes a review of risks including entrapment; and informed consent is obtained from the resident or if applicable, the resident representative. The facility must ensure the bed is appropriate for the resident and that bed rails are properly installed and maintained.

### **DEFINITIONS §483.25(n)**

**"Entrapment"** is an event in which a resident is caught, trapped, or entangled in the space in or about the bed rail.

**"Bed rails"** are adjustable metal or rigid plastic bars that attach to the bed. They are available in a variety of types, shapes, and sizes ranging from full to one-half, one-quarter, or one-eighth lengths. Also, some bed rails are not designed as part of the bed by the manufacturer and may be installed on or used along the side of a bed.

Examples of bed rails include, but are not limited to:

- Side rails, bed side rails, and safety rails; and
- Grab bars and assist bars.

### **GUIDANCE §483.25(n)**

Even when bed rails are properly designed to reduce the risk of entrapment or falls, are compatible with the bed and mattress, and are used appropriately, they can present a

hazard to certain individuals, particularly to people with physical limitations or altered mental status, such as dementia or delirium.

### **Resident Assessment**

After a facility has first attempted to use appropriate alternatives to bed rails and determined that these alternatives do not meet the resident's needs, the facility must assess the resident for the risks of entrapment and review possible risks and benefits of bed rails prior to installation or use. In determining whether to use bed rails to meet the needs of a resident, the following components of the resident assessment should be considered including, but not limited to:

- Medical diagnosis, conditions, symptoms, and/or behavioral symptoms;
- Size and weight;
- Sleep habits;
- Medication(s);
- Acute medical or surgical interventions;
- Underlying medical conditions;
- Existence of delirium;
- Ability to toilet self safely;
- Cognition;
- Communication;
- Mobility (in and out of bed); and
- Risk of falling.

In addition, the resident assessment must include an evaluation of the alternatives that were attempted prior to the installation or use of a bed rail and how these alternatives failed to meet the resident's assessed needs.

The facility must also assess the resident's risk from using bed rails. The following includes examples of the potential risks with the use of bed rails, as identified by the Food and Drug Administration's Hospital Bed Safety Workgroup Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings (April 2003), and that have been adapted for surveyor guidance:

- Accident hazards
  - The resident could attempt to climb over, around, between, or through the rails, or over the foot board,
  - A resident or part of his/her body could be caught between rails, the openings of the rails, or between the bed rails and mattress.
- Barrier to residents from safely getting out of bed
  - A resident could crawl over rails and fall from greater heights increasing the risk for serious injury
  - A resident could attempt to get out of bed over the foot board
- Physical restraint

- Hinders residents from independently getting out of bed thereby confining them to their beds
- Creates a barrier to performing routine activities such as going to the bathroom or retrieving items in his/her room
- Other potential negative physical outcomes
  - Decline in resident function, such as muscle functioning/balance
  - Skin integrity issues
- Decline in other areas of activities of daily living such as using the bathroom, continence, eating, hydration, walking, and mobility
- Other potential negative psychosocial outcomes
  - Creates an undignified self-image and alter the resident's self-esteem
  - Contributes to feelings of isolation
  - Induces agitation or anxiety

These potential risks can be exacerbated by improper match of the bed rail to bed frame, improper installation and maintenance, and use with other devices or supports that remain when the bed rail is removed.

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Although not all bed rails create a risk for entrapment, injury may still occur and is varied depending on the resident. Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The untimeliness of assistance using the bathroom and inappropriate positioning or other care-related activities can contribute to the risk of entrapment.

### **Informed Consent**

- After appropriate alternatives have been attempted and prior to installation, the facility must obtain informed consent from the resident or the resident representative for the use of bed rails. The facility should maintain evidence that it has provided sufficient information so that the resident or resident representative could make an informed decision. Information that the facility should provide to the resident, or resident representative include, but are not limited to:
  - What assessed medical needs would be addressed by the use of bed rails;
  - The resident's benefits from the use of bed rails and the likelihood of these benefits;
  - The resident's risks from the use of bed rails and how these risks will be mitigated; and
  - Alternatives attempted that failed to meet the resident's needs and alternatives considered but not attempted because they were considered to be inappropriate.

The information should be presented to the resident or the resident representative, so that it could be understood and that consent can be given voluntarily, free from coercion.

### **Appropriate Alternatives**

Facilities must attempt to use appropriate alternatives prior to installing or using bed rails. CMS encourages facilities to refer to published information from recognized authorities such as the Food and Drug Administration, which has identified the following alternatives to bed rail use: “Alternatives include: roll guards, foam bumpers, lowering the bed and using concave mattresses that can help reduce rolling off the bed.” This and more information may be found at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362843.htm>. This webpage was last updated in December, 2017.

See also, Clinical Guidance for Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings:  
<https://www.fda.gov/media/88765/download>

Recommendations for Health Care Providers about bed rails;  
<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362848.htm>

Additionally, alternatives that are attempted should be appropriate for the resident, safe and address the medical conditions, symptoms or behavioral patterns for which a bed rail was considered. For example, a low bed or concave mattress may not be an appropriate alternative to enable movement in bed for a resident receiving therapy for hip-replacement. If no appropriate alternative was identified, the medical record would have to include evidence of the following:

- purpose for which the bed rail was intended and evidence that alternatives were tried and were not successful
- assessment of the resident, the bed, the mattress, and rail for entrapment risk (which would include ensuring bed dimensions are appropriate for resident size/weight), and
- risks and benefits were reviewed with the resident or resident representative, and informed consent was given before installation or use.

### **Installation and Maintenance of Bed Rails**

Assuring the correct installation and maintenance of bed rails is an essential component in reducing the risk of injury resulting from entrapment or falls. The FDA and the United States Consumer Product Safety Commission (CPSC) has recommended the following initial and ongoing actions to prevent deaths and injuries from entrapment and/or falls from bed rails:

- Before bed rails are installed, the facility should:
  - Check with the manufacturer(s) to make sure the bed rails, mattress, and bed frame are compatible, since most bed rails and mattresses are purchased separately from the bed frame.

**NOTE:** The FDA has published (1) the Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment as a resource to reduce entrapments resulting from hospital beds and (2) Practice Hospital Bed Safety as to the proper dimensions and distance of various parts of the beds (i.e., distance between bed frames and mattresses, bed rails and mattresses, etc.)

- Rails should be selected and placed to discourage climbing over rails, which could lead to falling over bed rails.
- When installing and using bed rails, the facility should:
  - Ensure that the bed's dimensions are appropriate for the resident.
    - Confirm that the bed rails to be installed are appropriate for the size and weight of the resident using the bed.
    - Install bed rails using the manufacturer's instructions and specifications to ensure a proper fit.
    - Inspect and regularly check the mattress and bed rails for areas of possible entrapment.
    - Regardless of mattress width, length, and/or depth, the bed frame, bed rail and mattress should leave no gap wide enough to entrap a resident's head or body. Gaps can be created by movement or compression of the mattress which may be caused by resident weight, resident movement or bed position, or by using a specialty mattress, such as an air mattress, mattress pad or water bed.
    - Check bed rails regularly to make sure they are still installed correctly as rails may shift or loosen over time.

In addition, ongoing precautions may include following manufacturer equipment alerts and recalls and increasing resident supervision.

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure injuries, facilities should also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.

Facilities must also conduct routine preventive maintenance of beds and bed rails to ensure they meet current safety standards and are not in need of repair.

CMS recognizes that there are many different types of beds, some with bed rails pre-installed, or bed rails with the call button and lights incorporated into the rail, and others without bed rails pre-installed for which a separate rail could be installed.

Facilities should have a process for determining whether beds, including mattresses and rails, are appropriate and safe for their residents. For beds with rails that are incorporated or pre-installed, the facility must determine whether or not disabling the bed rail poses a risk for the resident. Some considerations would include, but are not limited to, the following:

- Could the rail simply be moved to the down position and tucked under the bed frame?
- When in the down position, does it pose a tripping or entrapment hazard?
- Would it have to be physically removed to eliminate a tripping or entrapment hazard?

Facilities should follow manufacturers' recommendations/instructions regarding disabling or tying rails down. CMS regulations do not specify that bed rails must be removed or disabled when not in use. However, if bed rails are not appropriate for the resident and the facility chooses to keep the bed rail on the bed, but in the down position, raising the rail even for episodic use during care would be considered noncompliance if all of the requirements (assessment, informed consent, appropriateness of bed, and inspection and maintenance) are not met prior to the episodic bedrail use for the resident.

### **Ongoing Monitoring and Supervision**

Assuring the correct use of an installed bed rail and maintenance of bed rails is an essential component in reducing the risk of injury. After the installation of bed rails, it is expected that the facility will continue to provide necessary treatment and care to the resident in accordance with professional standards of practice and the resident's choices. This should be evidenced in the resident's records, including their care plan, including, but not limited to, the following information:

- The type of specific direct monitoring and supervision provided during the use of the bed rails, including documentation of the monitoring;
- The identification of how needs will be met during use of the bed rails, such as for re-positioning, hydration, meals, use of the bathroom and hygiene;
- Ongoing assessment to assure that the bed rail is used to meet the resident's needs;
- Ongoing evaluation of risks;
- The identification of who may determine when the bed rail will be discontinued; and
- The identification and interventions to address any residual effects of the bed rail (e.g., generalized weakness, skin breakdown).

### **KEY ELEMENTS OF NONCOMPLIANCE §483.25(n)**