F700

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§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 attempt*s* 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/downloads/HospitalBeds/UCM397178.pdf.

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,* includ*ing*, *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)

To cite deficient practice at F700, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Identify and use appropriate alternative(s) prior to installing or *using* a *side or* bed rail;
- Assess the resident for risk of entrapment prior to installing or *using* a bed rail;

- Assess the risk versus benefits of using a bed rail and review them with the resident or the resident's representative;
- Obtain informed consent for the installation and use of bed rails prior to *use*.
- Ensure appropriate dimensions of the bed based on the resident's size and weight;
- Ensure correct installation of bed rails, including adherence to manufacturer's recommendations and/or specifications;
- Ensure correct use of an installed bed or side rail; and
- Ensure scheduled maintenance of any bed rail in use according to *the* manufacturer's recommendations and specifications.

NOTE:*If a facility is unable to identify the manufacturer and access the manufacturer information and guidance for bed rails that they use, they would not meet requirements to follow the manufacturers' recommendations and specifications for installing and maintaining bed rails at 483.25(n)(4).*

INVESTIGATIVE PROTOCOL §483.25(n)

Use this protocol for:

- A sampled resident who has MDS data that indicates a bed/side rail is used;
- Surveyor observation of the use of a bed/side rail for a resident; and/or
- An allegation of inappropriate use of a bed/side rail received by the State Survey Agency.

PROCEDURES §483.25(n)

Briefly review the assessment, care plan, and orders of the resident to identify facility interventions and to guide observations to be made. Corroborate observations by interview and record review.

Observation- Resident

During observations of a resident who has bed/side rails, determine:

- What type of bed rail is installed *or used* and for how long the bed rail has been in use;
- If the bed rail in good working order;
- Frequency of use of the bed rail;
- Any physical or psychosocial reaction to the bed rail, such as attempts to release/remove the bed rail, verbalizing anger/anxiety;
- Who *raises and lowers* the bed rail and how often monitoring is provided;
- How the resident is positioned in the bed relative to the bed rails and how the resident moves in bed;
- How the resident requests staff assistance (e.g., access to the call light);
- Whether the resident is toileted, ambulated or provided exercises or range of motion when the bed rails are released, who released the bed rails and for how long;

  NOTE: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not request that the resident

remove the bed rails, but rather request that staff ask the resident to demonstrate how he/she releases the bed rails.

Interview-Resident or Resident Representative
Interview the resident, or if applicable, the resident representative, to the degree possible to identify:

- Who requested the bed rail to be installed *or used*,
- Prior to the use of the bed rail, whether staff provided information regarding how the bed rail would address a resident need, the risks and benefits, and alternatives to bed rails, when and how long the bed rails were going to be used;
- Whether the interdisciplinary team provided interventions for monitoring and release of the bed rails for activities, such as use of the bathroom, walking and range of motion;
- Whether staff discussed mobility issues with the resident, or resident's representative, when the bed rail is in use and/or other impacts on activities of daily living and involvement in activities; and
- How the resident can request staff assistance when the bed rail is in use.

Interviews-Staff
Interview direct care and licensed nursing staff on various shifts who provide care to the resident to determine:

- Knowledge of specific interventions related to the use of the bed rails for the resident, including:
  - When use of the bed rail was initiated;
  - The rationale for selecting the bed rail for use;
  - Identifying the benefits and risks of using the bed rail;
- What is the resident's functional ability, such as bed mobility and ability to transfer between positions, to and from bed or chair, to toilet and to ability to stand;
- Whether there have been any physical and/or psychosocial changes related to the use of the bed rail, such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;
- Whether other interventions have been attempted to minimize or eliminate the use of the bed rails; and
- Whether there are facility guidelines/protocols for the use of bed rails.

Interview the charge nurse, to gather the following additional information:

- How the implementation of the use of bed rails is monitored and who is responsible for the monitoring;
- Who evaluates and assesses the resident to determine the ongoing need for bed rails;
- Whether bed rail use should be gradually decreased; and

- How the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rails.

Record Review

Review the MDS, assessments, physician orders, therapy and nursing notes and other progress notes that may have assessment information related to use of the bed rail. Determine whether identified decline can be attributed to a disease progression or use of bed rails. Determine whether the assessment information accurately and comprehensively reflects the status of the resident for:

- The identification of specific medical symptom(s) for which the bed rail is used;
- Functional ability, including strength and balance (such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and the ability to toilet);
- Identification of the resident's risks such as physical/functional decline and psychosocial changes, and benefits, if any, due to the use of the bed rails;
- Attempts at using alternatives to bed rails, including how the alternatives did not meet the resident's medical or safety need or were inappropriate;
- Identification of any injuries, or potential injuries, that occurred during the use of bed rails.

When the interdisciplinary team has determined that a resident may benefit from the use of a device for mobility or transfer, whether the assessment includes a review of the resident's:

- Bed mobility; and
- Ability to transfer between positions, to and from bed or chair, to stand and the ability to toilet.

Review the resident's care plan to determine if it is consistent with the resident's specific conditions, risks, needs, behaviors, preferences, current professional standards of practice, and included measurable objectives and timetables, with specific interventions/services for use of the bed rail. The care plan may include:

- Which medical need would be met through the use of bed rails;
- How often the bed rail is applied, duration of use, and the circumstances for when it is to be used;
- How monitoring is provided, and when and how often the bed rail is to be released and assistance provided for use of the bathroom, walking and range of motion;
- What the resident's functional ability is, such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and toilet and staff required for each function that requires assistance;
- Identification of interventions to address any potential complications such as physical and/or psychosocial changes related to the use of the bed rails, such as

increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression;

- Identification of interventions to minimize or eliminate the use of the bed rails; and
- Who monitors for the implementation of the use of the bed rails, and who evaluates and assesses the resident to determine the ongoing need for bed rails, whether the bed rail use should be gradually decreased, and how the modifications for the interventions are evaluated for effectiveness in discontinuing the use of the bed rail.

DEFICIENCY CATEGORIZATION §483.25(n)
Examples of Severity Level 4 Noncompliance Immediate Jeopardy to Resident Health or Safety include, but are not limited to:

- A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. The resident was assessed to be at risk of falls when she made repeated attempts to self-transfer off of her bed. All of the falls occurred when a half side rail was in use. According to a facility accident report, the resident was found on the floor with her back against the bed, holding onto one of the half side rails with both hands, with her neck wedged between the half side rails. The resident was able to remove herself from between the mattress and the bed rail, and did not sustain any injuries from the fall. After this incident, the facility performed a bed rail assessment, which did not indicate the risks/benefits of using bed rails. However, no changes were made to the resident's care plan, nor was there any documentation that the facility considered discontinuing use of the bed rails. Nine months later, the resident was found dead on the floor next to her bed, with her head wedged between the half side rail and the mattress. The resident's death certificate listed the cause to be asphyxiation-positional, extrinsic compression of the neck, and neck trapped under the bed rail.

- The facility failed to assess the resident for use of a bed rail, and failed to ensure that the bed rails did not pose a risk of entrapment or injury from falls. A moderately cognitively impaired resident was admitted to the facility who required extensive assistance with bed mobility and transfer, and was not ambulatory. The nursing assessment completed on admission indicated that the resident was at high risk for falls and full bed rails were used on all open sides of the bed. No assessment related to the use of bed rails was completed. A facility investigation report revealed that the resident crawled to the foot of his bed with the full bed rails in a raised position, tried to stand and ambulate, and fell off the right side of the bed. The resident sustained a femoral neck fracture and was hospitalized.

- A facility failed to attempt to use alternatives to bed rails and assess a resident for risk of entrapment. A bed rail assessment indicated that two half side rails would be used for the resident to promote independence. There was no evidence that the facility evaluated risks associated with bed rail use when the facility changed the

bed mattress to an air mattress. A facility accident report indicated that a nurse aide discovered the resident on the floor, with his/her head positioned between the side rail and the air mattress. The resident had visible bruising to the neck, had no pulse, or blood pressure.

Examples of Severity Level 3 Noncompliance Actual Harm that is Not Immediate Jeopardy include, but are not limited to:
An example of noncompliance that demonstrates severity at level three includes, but is not limited to:

- A facility failed to ensure the resident's bed dimensions were appropriate for the resident's size and weight. An extremely obese resident fell out of bed and sustained an injury while using the bed rail as an enabler to turn on his side. The bed was narrow and the bed rail could not sustain his weight and broke. The bed was meant to sustain the size and weight of a smaller person per manufacturer's directions.

Example of Severity Level 2 Noncompliance No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include, but are not limited to:

An example of noncompliance that demonstrates severity at level two includes, but is not limited to:

- The facility failed to inform a resident/representative of the risks and benefits of using side rails, prior to installing *or using* them on the resident's bed. The resident was cognitively impaired and was unable to comprehend, however, the staff did not contact the resident's representative to provide the information.

Examples of* Severity Level 1 Noncompliance No Actual Harm with Potential for Minimal Harm *include, but are not limited to: Facility failed to have a schedule for routine maintenance of its four beds with bed rails, which were newly installed two years ago. There is no evidence of incidents or injuries in those two years, the relevant resident care plans appear appropriate regarding bedrail usage, and the facility provides evidence of checks by staff on the impacted residents and appropriate use and installation of bed rails.

NOTE: References to non-CMS/HHS sources or sites on the Internet included above or later in this document are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Other resources which may be useful:
Falls

National Council on Aging National Falls Prevention Resource Center at
http://www.ncoa.org/center-for-healthy-aging/falls-resource-center

Centers for Disease Control and Prevention at
http://www.cdc.gov/homeandrecreationalsafety/falls/

World Health Organization Fall Prevention in Older Age at
http://www.who.int/ageing/projects/falls_prevention_older_age/en/

National Institute of Health- Senior Health at
http://nihseniorhealth.gov/falls/aboutfalls/01.html

Wandering and Elopement Resources

National Council of Certified Dementia Practitioners at http://www.nccdp.org