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BED RAIL SAFETY

2025

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Bed Rail
Policy & Procedure

Definition:

For the purpose of this document; the term “bed rail” will be adopted, although other names are often used, such as: assist bars, bedside rails, cot sides, grab bars, side rails, safety sides, repositioning devices, and bed guards.

Purpose:

The decision to use bed rails is complex and based on a person-centered approach utilizing clinical judgment, as well as physical, psychological, and environmental factors. The use of bed rails has been associated with an increased risk of injury and death related to entrapment where a resident becomes caught, trapped, or entangled in the space in or about the bed rail. Bed rails are intended solely to assist residents with independent repositioning. Bed rails should not be used as a restraint or for discipline and must solely be used for medical necessity. The purpose of this policy is to ensure that residents who use bed rails remain as safe as possible, through appropriate utilization, maintenance and supportive documentation of such devices.

Policy:

Each resident, or the resident's legal representative will understand both the risks and benefits to bed rail use and the alternatives. A Consent Form will be signed by the Resident, or the Legal Representative and a Physician Order will be in place, which corroborates the medical necessity of a bed rail for the resident before a bed rail will be implemented.

Procedure:

1. If a resident or a resident's legal representative expresses an interest in bed rail use, the staff member will educate them on the risks of devices attached to the bed and that most residents do not benefit from the use of bed rails.
2. The facility will attempt to use appropriate alternatives to bed rails (i.e., roll guards, foam bumpers, lowering the bed, concave mattresses, etc.). If it is determined that these alternatives do not meet the resident’s needs, the facility will assess the resident for the risks of entrapment and review possible risks and benefits of bed rails prior to installation or use. According to FDA 2023 and CMS F- Tag 700 “Bed Rails,” the facility will abide by the recommendations in determining whether to use bed rails, the following components of the resident assessment should be considered including, but not limited to:
    - Whether the resident is at risk of falling from bed.
    - Whether the resident’s medical diagnosis, conditions, symptoms, or surgical interventions create a risk.
    - Whether the resident’s height, size or weight creates a risk.

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- Whether the resident is agitated, confused, has delirium, or is affected by medication.
- Whether the resident needs to get out of bed during the night and sleep habits
- Whether the resident can get in and out of bed and toilet safely; and
- Whether the resident's head or body is small enough to pass through any gap between the bed rail and the side of the mattress.

3. A resident assessment will be completed before a bed rail is utilized, and when there is a change in the resident's: condition, bed, mattress, and/or bed rail. (Appendix A)
4. In the event a bed rail is determined to be beneficial to meet the resident's needs in accordance with the assessment above. The resident, resident's legal guardian, patient advocate, or other legal representative will be informed of the alternatives to bed rails, the risks involved, and the potential benefits.
5. The resident, resident's legal guardian, patient advocate, or other legal representative must sign a consent form for the use of bed rails, indicating that the potential risks, benefits, and alternatives have been discussed and agreed to. Please see attached "Resident Bed Rail Consent Form." (Appendix B)
6. The resident's attending physician must evaluate the resident and must sign an order verifying the medical necessity of the bed rail before it is implemented. The order must contain statement(s) and/or determination(s) regarding the medical necessity of the bed rail.
7. Before the bed rails are installed the facility will follow the recommendations according to FDA 2023 guidance and use only bed rails that conform with ASTM F3186-17: Standard specification for adult portable bed rails and related products for home care facilities and long-term care facilities.
8. The Facility will assess and document at least the following if appropriate, in the resident's chart if a bed rail is determined to be necessary: (Appendix C)
    - The outcome of each risk assessment;
    - Reason for appropriateness of bed rails and why alternatives will not be utilized;
    - Assessment of the resident's risk of entrapment (i.e., large openings or gaps) from the bed rails prior to installation;
    - Ensuring the bed's dimensions and mattress is properly fitted and are appropriate for the resident's size and weight;
    - Ensuring there are no areas that the resident could become injured by exposed metal, sharp, or damaged edges;
    - Resident behavioral issues, including known causes of restlessness;
    - Frequency of observation required;
    - Individuals involved in the decision-making process; and
    - Measurements of the resident's head, neck, and chest.
    - That the manufacturer's recommendations and specifications for installing and maintaining bed rails were followed. To ensure the bed rails, mattress, and bed frame are all compatible to verify safety in case the bed rails are purchased separately from the bed frame.

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- Assessment and documentation that the bed rails have been applied safely and that there are no areas in which the resident could become entrapped (i.e., large openings or gaps) or become injured such as exposed metal, sharp or damaged edges, per CMS- Accidents- Critical Element Pathways 2025. Assessment of gaps should include monitoring for compression of the mattress which can be caused by resident weight, movement, or bed position, or by using a specialty mattress, such as an air mattress or mattress pad.

9. The facility will implement an initial 5-day evaluation period for newly installed bed rails, per 2023 FDA recommendations. This evaluation will occur at least once each shift for the first 5 days, and will document within the resident's chart at least the following if appropriate:
    - Resident behavioral issues and adjustment to bed rail;
    - Any other issues related to the implementation of a bed rail;
    - Corrective action taken, if necessary; and
    - Proper fitting, including measurements at the top, bottom, and sides of the mattress. Please see the attached "Nursing 5 Day Bed Rail Monitoring" Form (Appendix D).
10. Ongoing Monitoring and Supervision. 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. A quarterly assessment will be documented in the resident's medical record to include but not limited to:
    - 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 the bed rail's use, such as for re-positioning, hydration, meals, use of the bathroom, and hygiene;
    - Ongoing assessment to ensure 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).
11. The resident care plan will reflect the use of bed rails, the rationale for use, and interventions to assist in preventing negative outcomes related to bed rail use. Identification of interventions to minimize or eliminate the use of bed rails.
12. The facility will initiate a review of each resident who uses a bed rail at least every sixty (60) days, per 2023 FDA recommendations. Please see the "Equipment and Device Safety Log" Form (Appendix E).

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FDA 2023 Bed Rails.pdf

SOM - Appendix PP (cms.gov)

Pathway

I have read, understand, and agree to adhere to the requirements outlined in this policy and procedure.

Administrator Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____

Review Dates:_____ _____ _____ _____

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Bed Rails Assessment

The purpose of performing this assessment is to identify the most appropriate assistive devices for each resident while promoting safety and independence.

Resident Name /Identifier		**Room Number**	
1	Is there a medical necessity for bed rails or assist devices? Describe	Y	N
2	Is the resident a paraplegic, L/E amputee, or have had recent surgery limiting the use of abdominals or L/Es?	Y	N
3	Is the resident non-ambulatory?	Y	N
4	Is the resident comatose, semi-comatose, obtunded, or have fluctuations in level of consciousness?	Y	N
5	Does the resident have alterations in safety awareness due to cognitive decline?	Y	N
6	Does the resident have a history of falls from bed?	Y	N
7	Has the resident demonstrated poor bed mobility or has difficulty moving to a sitting position on the side of the bed?	Y	N
8	Does the resident have difficulty with balance or poor trunk control?	Y	N
9	Does the resident have difficulty with postural hypotension?	Y	N
10	Is the resident on any medication that would require increased safety precautions?	Y	N
11	Does the resident exhibit behaviors (i.e., agitation, confusion) that increase the risk of injury related to the use of bed rail/assist devices?	Y	N
12	If bed rails/assist devices are utilized would the resident benefit from protective padding to decrease the risk of injury related to seizure activity, involuntary movement, etc.?	Y	N
13	Is the resident currently using a bed rail/assist device of any type for positioning or support?	Y	N
14	Is the resident cognitively aware and expresses a desire to have a bed rail/assist device up while in bed?	Y	N
15	If resident is cognitively impaired, is the responsible party/POA aware of risks associated with bed rails/assist devices?	Y	N
16	Does the resident need maximum assistance with ADL's including bed mobility and transfers?	Y	N

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17	Has the resident had any injuries related to bed rails/assist devices in the past?	Y	N
18	Does the resident have a history of attempting to climb over bed rails or rise from bed unassisted?	Y	N
19	Could the resident benefit from a trapeze or other assistive device to improve bed mobility?	Y	N
20	If bed rails/assist devices are utilized would pre-existing bedding, mattress, etc. require changing in an effort to increase safety?	Y	N
21	If bed rails/assist devices are utilized, do they meet the FDA measurement guidelines?	Y	N
22	If bed rails are used, are they applied securely and according to manufacturer's instructions?	Y	N
23	Are there areas in which the resident could become entrapped (i.e., large openings or gaps, or improperly fitting mattress)	Y	N
24	Are there areas in which the resident could be injured by exposed metal, sharp or damaged edges.	Y	N
If number **4, 5, 6, 13, 10, 11, 17, 18, 19, and 20** is yes consider alternatives to bed rails.			

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Past Interventions Attempted:		
_____ Bed rails/assist devices are indicated to promote independence. _____ Bed rails are not appropriate at this time.		
Consider Alternatives:		
❒ Trapeze ❒ Personal assist bar ❒ Firefighter pole ❒ 2 person assist for mobility ❒ Hip padding ❒ Low bed	❒ Verbal cueing to use the call light ❒ Arrange furniture for maximum space ❒ Obstacle free environment ❒ Toileting program ❒ Mats next to a mattress on the floor ❒ Motion detecting device	❒ Communication aids ❒ Bed and/or chair alarm ❒ Restorative Nursing ❒ Raised edge mattress ❒ Bed/chair alarm ❒ Other _____
Justification for bed rail use:		

Signature:	**Date:**
Physician Signature:	**Date:**
Review Date:	**Signature:**
Review Date:	**Signature:**
Review Date:	**Signature:**

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Resident Bed Rail Consent Form

(Per Michigan PA 437 of 2000, January 9, 2001, amending Michigan Public Health Code, PA 368 of 1978)

Resident's Name_____ Date of Request _____
(Last, First, MI) (Please Print)

Part 1. Please initial one of the following blocks indicating the responsible person requesting the use of bed rails.

_____ This request was prepared by the above-named resident while being mentally capable of participating in his/her own health care decisions.

_____ This request was prepared by the resident's legally appointed and appropriately empowered attorney-in-fact, as the resident has been determined to be incapable of participating in his/her own health care decisions by a team of physicians in a written Medical Determination.

_____ The resident's Probate Court-appointed guardian prepared this request.

Attorney-in-fact Surrogate's Name _____
(Last, First, MI) (Please Print)

Guardian_____
(Last, First, MI) (Please Print)

Part 2. General

I am responsible for medical treatment decisions of the above-named resident. I have been advised that I may request that bed rails be installed on this resident's bed. The risks and alternatives to using bed rails, as they apply to this resident's particular condition and circumstances, have been clearly explained to me.

I understand that, in addition to this signed consent form authorizing the use of bed rails for this resident, a written order from the resident's attending physician, specifying the medical rationale and circumstances for use, must be obtained prior to the installation of this medical treatment device.

It is also my understanding that the Facility will periodically review and re-evaluate the resident's need for bed rails and that the resident, responsible party, and attending physician will be consulted in this matter.

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With all of the above information in mind, I consent to the installation and utilization of bed rails for the care of the above-named resident, consistent with the written orders of the attending physician. I understand that this authorization is revocable, except to the extent of those actions already taken.

Signature: _____ Date:_____
(Resident, Attorney-in-fact, or Guardian)

Witness Signature: _____ Date: _____

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Formulario De Consentimiento Para Barandilla De Cama Del Residente
(Según Michigan PA 437 de 2000, 9 de enero de 2001, que modifica el Código de Salud Pública de Michigan, PA 368 de 1978)

Nombre del residente _____ Fecha de la solicitud _____
(Apellido, Nombre, IM) (En letra de imprenta)

Parte 1. Por favor, ponga sus iniciales en uno de los siguientes bloques indicando la persona responsable que solicita el uso de barandillas de cama.

_____ Esta solicitud fue preparada por el residente mencionado anteriormente mientras era mentalmente capaz de participar en sus propias decisiones de atención médica.

_____ Esta solicitud fue preparada por el apoderado legal y debidamente facultado del residente, ya que un equipo de médicos, en una Determinación Médica por escrito, ha determinado que el residente es incapaz de participar en sus propias decisiones de atención médica.

_____ El tutor designado por el tribunal testamentario del residente preparó esta solicitud..

Apoderado - Nombre del sustituto _____
(Apellido, Nombre, IM) (En letra de imprenta)

Tutor _____
(Apellido, Nombre, IM) (En letra de imprenta)

Parte 2. Aspectos generales

Soy responsable de las decisiones de tratamiento médico del residente mencionado anteriormente. Se me ha informado que puedo solicitar que se instalen barandillas de cama en la cama de este residente. Se me han explicado claramente los riesgos y las alternativas al uso de barandillas de cama, en lo que se refiere a la condición y las circunstancias particulares de este residente.

Entiendo que, además de este formulario de consentimiento firmado que autoriza el uso de barandillas de cama para este residente, se debe obtener una orden por escrito del médico tratante del residente, especificando la justificación médica y las circunstancias de uso, antes de la instalación de este dispositivo de tratamiento médico.

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También entiendo que el Centro revisará y reevaluará periódicamente la necesidad del residente de barandillas para la cama y que se consultará al residente, la parte responsable y el médico tratante sobre este asunto.

Con toda la información anterior en mente, doy mi consentimiento para la instalación y utilización de barandillas de cama para el cuidado del residente mencionado anteriormente, de conformidad con las órdenes escritas del médico tratante. Entiendo que esta autorización es revocable, excepto en la medida de las acciones ya tomadas.

Firma: _____ Fecha:_____
(Residente, Apoderado o Tutor)

Firma del testigo: _____ Fecha: _____

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Interim Guidelines For Use Of Bed Rails
Facility Checklist

_____ Modify Admissions Policy to include Provisions of PA 437

_____ Measurements of Residents

_____ Recorded in Medical Record

_____ Documentation of Measurements for Gaps

_____ Assessment of properly fitted mattress

_____ Equipment and Device Safety

_____ Bed rails are applied securely and according to manufacturer's instructions

_____ Resident and Bed Safety – To prevent injury by exposed metal, sharp, or damaged edges

_____ Documentation of Corrective Actions

_____ Resident Assessment for Bed Rail Use, including Risks and Alternatives

_____ Obtain Signatures on Consent Forms

_____ Written Physician Orders specifying Medical Determinations and Circumstances

_____ Conduct Staff Training

_____ Direct Care Staff

_____ Maintenance and Environmental Services Staff

_____ Modify Orientation of New Staff to include provisions of PA 437

_____ Initiate 5-day observation periods for newly installed bed rails

_____ Initiate Quarterly Care Plan Review of Bed Rails Use and Equipment

_____ Initiate Review of Bed and Device Safety at least every 60 days after the initial 5

_____ Maintenance log

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Interim Guidelines for Use of Bed Rails Facility Checklist (michigan.gov)

Accidents Critical Element Pathway (2/2025)

F689- Free of Accidents/Hazards/Supervision/Devices (2/2025

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NURSING 5 DAY BED RAIL MONITORING

Resident _____ Medical Record # _____

Room _____ Head Measurement _____ Type of Bed Rail _____

Device measurements are taken with the Resident in bed.

Please see back of form for picture of bed and exact areas to measure.

Bed# _____ **Mattress #** _____ **Bed Rail #** _____

	Day 1:			Day 2:			Day 3:			Day 4:			Day 5:		
	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd
#1-Left Side															
#1-Right Side															
#2-Head															
#2-Foot															
#3-Slats															
#4-Triangle															
Corrective Action, if necessary															
Signature															

Quarterly Review: _____

_____

_____

Quarterly Review: _____

_____

_____

Quarterly Review: _____

_____

_____

SAMPLE

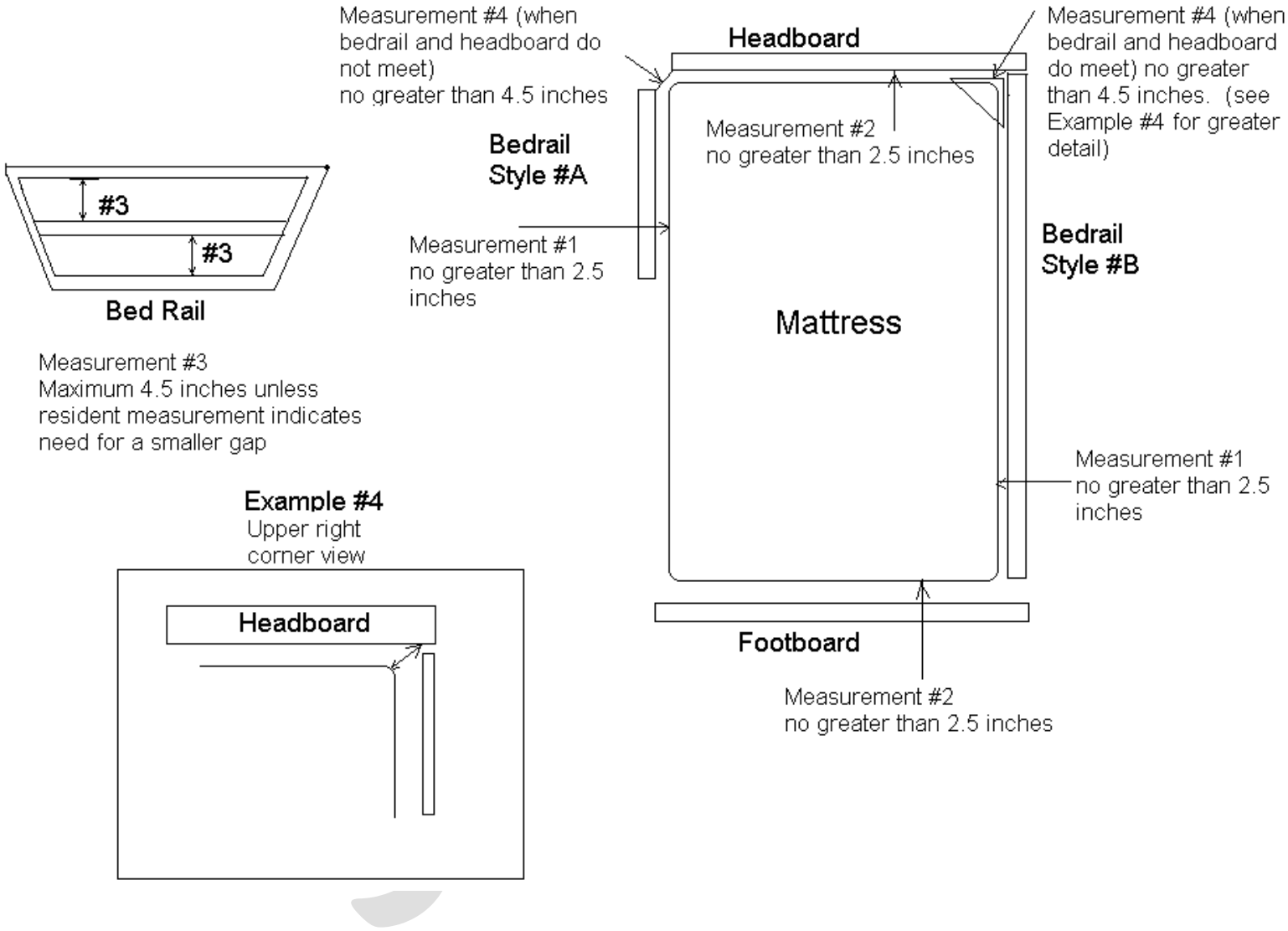
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Interim Guidelines Device Measurements

These are Interim Guidelines Measurements. These measurements may change with the Permanent Guidelines due out Fall 2001



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Resident Name _____

EQUIPMENT AND DEVICE SAFETY LOG

Complete upon initial use and at least every 60 days after the first 5 days following initial use or installation.

The gap between the slats of the bed rail and at the triangular space at the head of the bed can be no greater than 4.5 inches or _____ for this resident.
The gap between the mattress and the bed rail and between the mattress and the headboard or footboard can be no greater than 2.5 inches or _____ for this resident.
*These measurements are taken with the resident in bed. Gaps greater than those specified require **immediate** corrective action.*

Date	Bed Number	Mattress Number	Device Type	Space at Headboard	Space Beside Right Device	Space Beside Left Device	Space at Footboard	Mattress Affixed	Mechanically Sound Rail	Rail Firmly Attached	Mattress Condition	Bed Frame Condition	Bed Rail Condition	Latch Condition	Corrective Action	Signature

Posted on QIN Web Page 3/30/01

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Adult Portable Bed Rail Safety

Adult portable bed rails are used by many people to help create a supportive and assistive sleeping environment in homes, assisted living facilities and residential care facilities. This type of equipment has many commonly used names, including side rails, bed side rails, half rails, safety rails, bed handles, bed canes, assist bars, grab bars, and adult portable bed rails.

Many adult portable bed rails can be purchased by consumers on websites and in stores without a prescription and without the recommendation of a health care provider. Adult portable bed rails marketed for medical purposes such as those intended to assist individuals who are disabled, injured, or recovering from surgery or hospitalized with transfer in and out of bed or repositioning, intended to reduce risk of falling or fracture or mitigate the risk of falling due to the effects of balance disorders or other medical conditions are considered medical devices regulated by the U.S. Food and Drug Administration (FDA). See 21 CFR 890.5050 Daily activity assist device (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-890/subpart-F/section-890.5050), product code, QTC Adult Portable Bed Rails for Medical Purposes (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=QTC). Other adult portable bed rails that are not intended for medical purposes are considered consumer products and under the jurisdiction of the U.S. Consumer Product Safety Commission (CPSC). Many death and injury reports related to entrapment and falls for adult portable bed rail products and hospital bed rails have been reported to the FDA and the CPSC. All bed rails should be used with caution, especially with older adults and people with altered mental status, physical limitations, and certain medical conditions (for example, patients who are disabled, injured, or those post-surgery or hospitalized).

This webpage contains information about the risks of adult portable bed rails, recommendations for their safe use, alternatives to bed rails, and how to report a problem with medical devices to the FDA or consumer products to CPSC.

What are the different types of adult portable bed rails?



Example of a half-length adult portable bed rail



Example of a bed handle or grab bar adult portable bed rail.

Bed rails typically are divided into three distinct types: portable bed rails for adults, portable bed rails used for children (http://www.cpsc.gov/en/Newsroom/News-Releases/2012/CPSC-Adopts-New-Federal-Standard-for-Portable-Bed-Rails/), and hospital bed rails (/medical-devices/general-hospital-devices-and-supplies/hospital-beds) that are attached to a hospital or medical bed.

Adult Portable Bed Rails: An adult portable bed rail is a bed rail product or device that is attachable and removable from a bed, not designed as part of the bed by the manufacturer, and is installed on or used along the side of a bed. These rails are intended to provide assistance to the bed occupant in moving on the bed surface, or in entering or exiting the bed, to minimize the possibility of falling out of bed or for other similar purposes. Adult portable bed rails intended to assist individuals who are disabled, injured, or recovering from surgery or hospitalized with transfer in and out of bed or repositioning, intended to reduce risk of falling or fracture or mitigate the risk of falling due to the effects of balance disorders or other medical conditions are regulated as medical devices.

Adult portable bed rails are used in many different settings, including: the home, long-term care facilities, assisted living facilities and nursing homes. They are available in a variety of styles, shapes and sizes; some bed rails run along the full length of the bed, while others run a half, quarter or even shorter lengths of the bed.

Other Types of Bed Rails

Portable Bed Rails for Children: Portable bed rails intended for children (typically from 2 to 5 years of age) who can get in and out of an adult bed unassisted are considered consumer products. For more information, please see Portable Bed Rails | CPSC.gov (https://www.cpsc.gov/FAQ/Portable-Bed-Rails).

Hospital Bed Rails: Hospital bed rails are intended to be either part of or an accessory to a hospital bed or other FDA-regulated bed. They are considered medical devices. For more information on hospital bed safety, see A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts (/medical-devices/hospital-beds/guide-bed-safety-bed-rails-hospitals-nursing-homes-and-home-health-care-facts).

Additional Resources

- FDA: Hospital Beds (/medical-devices/general-hospital-devices-and-supplies/hospital-beds)
- Centers for Disease Control and Prevention: Older Adult Fall Prevention (https://www.cdc.gov/falls/about/)
- Centers for Disease Control and Prevention: STEADI (Stopping Elderly Accidents, Deaths & Injuries) STEADI—Older Adult Fall Prevention (https://www.cdc.gov/steadi/index.html)
- Consumer Product Safety Commission: Older Adults (https://www.cpsc.gov/safety-education/neighborhood-safety-network/toolkits/older-adults)
- Consumer Product Safety Commission: Safety Standard for Adult Portable Bed Rails (https://www.govinfo.gov/content/pkg/FR-2022-11-09/pdf/2022-22692.pdf)

Bedrail and Assistive Device Safety and Regulation

Health Regulation Division

Agenda

- Overall Risks and Considerations
- Use as a Restraint
- Assisted Living Facilities
- Home Health and Hospice
- Intermediate Care
- Nursing Homes

General Considerations

- Bed rails and similar assistive devices can be part of an effective and safe plan to support residents
- However, these devices create a risk of entanglement and strangulation, and can increase the severity of falls
- In addition, these devices can have the effect of being a restraint

Types of Devices

Bed rails are encountered in MDH-regulated settings in two ways:

- Hospital bed rails
- Consumer bed rails

Hospital Beds



Hospital beds are designed for use in health care settings. As a result, they are medical devices regulated by the Food and Drug Administration (FDA).

Consumer Bed Rails

- Numerous types of side rails, grab bars, and similar devices can be installed on any other type of bed
- As equipment, these are regulated by the Consumer Product Safety Commission (CPSC)
- **The same risks exist**

General Principles

In all provider types:

- For hospital beds: follow the FDA guidelines for bed rail safety, assess whether the device is appropriate for the individual, and educate the individual on the risks versus benefits of the device
- For other assistive devices attached to beds:
  - Know whether the device has been recalled by the CPSC and whether the device is installed according to manufacturer's guidelines
  - Assess whether the device is appropriate for the resident or client, considering cognitive and physical status
  - Educate the resident on the risks versus benefits of the device

Hospital Bed Guidance

- Hospital beds are medical devices regulated by the FDA and must be used in accordance with FDA guidelines:
  - Recommendations for Health Care Providers about Bed Rails | FDA
  - A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts | FDA
- This guidance contains a recommended assessment practice from the Hospital Bed Safety Workgroup, which includes measurement of seven potential zones of entrapment

Other Beds

- When devices are attached to other types of beds, the FDA guidance does not directly apply
- Several types of consumer bed rails and similar devices have been recalled by the CPSC
- Check for recalls at: Recalls | CPSC.gov



Manufacturer Guidelines

- The diversity of potential consumer devices makes it critical to know how the device was designed to be used
- You must be able to determine whether it was installed correctly, which means you need to have those instructions or guidelines
- If you do not have the manufacturer guidelines available to you, you cannot fully determine whether the device was installed correctly or what the risks may be in using it

Assessment

- For both hospital beds and consumer beds, documented assessments are critical
- Care planning about bed rails should start with the intended purpose of the device based on individual needs
  - Cognitive status
  - Physical strength and mobility, and fall history
  - Incontinence and toileting needs
- It must not have the effect of being an unordered restraint

Risks vs. Benefits

- Risks versus benefits:
  - Consider resident preferences and how they use the device
  - Individualized assessment of risks
- Document education of the resident and their family of the risks



Assessment, continued

- The assessment should include physical inspection of the stability and condition of the device, and potential areas for entanglement
  - The device must be securely attached to remain safe
  - Gaps between the mattress and the device are usually risks
  - Describe areas with openings large enough for a body part to be trapped

Assisted Living Laws

- An assisted living resident has the right to receive care according to accepted health care standards
  - Minnesota Statutes 144G.91, Subd. 4
- An assisted living facility must address mobility, including transfers and assistive devices, in their uniform assessment tool
  - Minnesota Rule 4659.0150
- This means the assessment must be documented upon installation of the device and on every subsequent 90-day or change of need assessment

Assisted Living Additional Considerations

- The resident has the right to make decisions about their living area, so it is possible a bed rail will be installed by the resident or their family without you knowing about it
  - Educate staff to ensure they inform the nurse when they see a new assistive device
  - You remain responsible for knowing whether the equipment is safe and appropriate
- If you conclude the device is not safe for the resident:
  - Offer alternatives, and discuss and offer interventions to mitigate safety risks
  - Document your assessment and all interventions discussed, offered, or attempted
  - If you use a negotiated risk agreement or similar, you must: maintain documentation of the offer of alternatives, implement interventions to mitigate safety risks, and conduct ongoing reassessment for the appropriate use of a bed rail

Bedrail Safety - Federal Providers

In addition to state licensing requirements, bedrail safety is reviewed for Federal providers, including but not limited to home health care (HHA), hospice, intermediate care facilities for individuals with intellectual disabilities (ICF/IDD), Nursing homes, etc.



Bedrail Safety Federal Providers - HHA

Under the federal HHA requirements, bed rail safety may be reviewed under one or more of the following conditions dependent on the nature of the concern identified:

- 484.55 - Comprehensive assessment of patient
- 484.50 - Patient rights
- 484.60 - Care planning/coordination of services/quality of care
- 484.75 - Skilled professional services.

Bedrail Safety Federal Providers - Hospice

Under the federal hospice requirements, bed rail safety may be reviewed under one or more of the following conditions:

- 418.52 - Patient rights
- 418.54 - Initial and comprehensive assessment of the patient
- 418.56 - Interdisciplinary group/care planning/coordination of services
- 418.110 - hospices that provide inpatient care directly

Bedrail Safety Federal Providers - ICF

Under the federal requirements for intermediate care facilities for individuals with intellectual disabilities (ICF/IID), bed rail safety may be reviewed under one of the following conditions:

- 483.470 - Physical environment
- 483.420 - Client protection
- 483.460 - Health care services

Bedrail Safety Federal Providers – FDA

- Providers should follow the standard of practice for Bed Rail safety FDA guidelines at Bed Rail Safety | FDA
- This site includes information on:
  - Safety concerns about bedrails
  - Recommendations before installing bedrails
  - Following manufacturer recommendation

Bedrail Safety Federal Providers - Assessments

Providers need to assess and reassess, as part of the comprehensive assessment, the patient/resident for safety and appropriateness for bedrail use.

- Refer to clinical guidance for the Assessment and Implementation of Bed rails in Hospitals, Long term Care settings and Home Care setting at Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings (fda.gov)
- Areas covered include; Guiding principles for bedrail use, patient assessment, patients at risk for entrapment, risk benefit assessment/education for the patient on the risks.

Bedrail Safety Federal Providers – Nursing Homes

- Under the federal Nursing Home requirements, bed rail safety is reviewed at 483.25(n) Bed Rails. This regulations provides detailed criteria when bedrails are used in a Nursing home setting
- SOM - Appendix PP (cms.gov)



483.25(n) - 483.25(n)(2)

- *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) - 483.25(n)(4)

- *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.*



Questions?

Thank You!

Clinical Guidance
For the Assessment and Implementation of Bed Rails
In Hospitals, Long Term Care Facilities, and Home Care Settings



Developed by the
Hospital Bed Safety Workgroup

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In April 1999, the Food and Drug Administration (FDA) in partnership with representatives from the hospital bed industry, national healthcare organizations, patient advocacy groups and other federal agencies formed the Hospital Bed Safety Workgroup. The workgroup's goal is to improve the safety of hospital beds for patients in all health care settings who are most vulnerable to the risk of entrapment. The workgroup is developing additional resources including dimensional guidelines, measurement tools, and educational materials to assist manufacturers, caregivers and consumers.

This clinical guidance is provided for discussion and educational purposes only and should not be used or in any way relied upon without consultation with and supervision of a qualified practitioner based on the case history and medical condition of a particular patient. The Hospital Bed Safety Workgroup, their heirs, executors, administrators, successors, and assigns hereby disclaim any and all liability for damages of whatever kind resulting from the use, negligent or otherwise, of this clinical guidance.

For information about the Hospital Bed Safety Workgroup, see the FDA's website at http://www.fda.gov/cdrh/beds/

Clinical Guidance
For The Assessment and Implementation of Bed Rails
In Hospitals, Long Term Care Facilities, and Home Care Settings

Introduction

Every patient, regardless of care setting, deserves a safe and comfortable sleeping and bed environment. The goal of this clinical guidance is the provision of such an environment to patients in hospitals, long term care facilities, and home care settings. (Note: The term *patient* as used in this document refers to patients in hospitals, residents in long term care facilities, and clients in home care settings.) The purpose of this guidance is to provide a uniform set of recommendations for caregivers in hospitals, long term care facilities, and home care settings to use when assessing their patients' need for and possible use of bed rails. The guidance is deliberately basic in design and content to allow each setting to adapt it to meet the unique needs of their respective patients and environments.

The guidance that follows is intended to assist caregivers in making decisions about the care for their patients. Its components are not intended to serve as clinical standards or requirements for care. They are not intended to serve as applicable federal, state or local regulations or guidelines governing care in respective settings. Likewise the recommendations should not be interpreted as the best or only options, professional standards of care, or legal protection for the users.

The term *bed rails* is used in this document. Commonly used synonymous terms are *side rails, bed side rails, and safety rails*. Bed rails are adjustable metal or rigid plastic bars that attach to the bed and are available in a variety of shapes and sizes from full to half, one-quarter, and one-eighth in lengths.[1] In the spectrum of care including hospital, long term care and home care settings, bed rails serve a variety of purposes, some of which are in the best interest of the patient's health and safety. Bed rails:

- are used on stretchers or beds while transporting patients following surgery or when relocating a patient to a new room or unit;
- can facilitate turning and repositioning within the bed or transferring in or out of a bed;
- may provide a feeling of comfort and security, or facilitate access to bed controls; and
- may be used as a physical barrier to remind the patient of the bed perimeters, to ask for nursing assistance, or to restrict voluntary movement out of bed.[2,3]

Achieving the goal of a safe and comfortable bed and sleeping environment may necessitate the reduction or elimination of bed rail use in cases in which the bed rail is not in the best interests of the patient's health and safety.

[1] Capezuti, E. & Lawson, WT III (1999). Falls and restraint liability issues. In P. Iyer (Ed.) Nursing Home Litigation: Investigation and Case Preparation. Tucson, AZ: Lawyers and Judges Publishing Company.
[2] Braun, J.A. & Capezuti, E. (2000). The legal and medical aspects of physical restraints and bed side rails and their relationships to falls and fall-related injuries in nursing homes. DePaul Journal of Healthcare Law, 3 (1) 1-72.
[3] Capezuti, E., Talerico, K.A., Cochran, I., Becker, H., Strumpf, N., & Evans, L. (1999). Individualized interventions to prevent bed-related falls and reduce side rail use. Journal of Gerontological Nursing, 25, 26-34.

Although various types may be used depending on a patient's medical and functional needs, bed rails may pose increased risk to patient safety. Clinical research suggests that bed rails may not be benign safety devices. For example, evidence indicates that half-rails pose a risk of entrapment and full rails pose a risk of entrapment as well as falls that occur when patients climb over the rails or footboards when the rails are in use.[4,5] Recognizing this risk, the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), have taken action aimed at reducing the likelihood of injuries related to bed rails. The FDA MedWatch Reporting Program receives reports of entrapment hazards.[6] In 1995 the FDA issued a Safety Alert entitled, "*Entrapment Hazards with Hospital Bed Side Rails*."[7] In 1997, the FDA authored an article, based on the reported hospital bed adverse events, that identified potential risk factors and entrapment locations about the hospital bed. The FDA continues to receive reports of patient deaths and injury that provide documentation of patient entrapment.[8]

CMS has imposed performance expectations on hospitals and nursing facilities. For example, in implementing federal regulations that apply to the use of physical restraints, CMS issued guidance in June 2000 for surveyors to determine hospitals' compliance with these regulations. One section of the guidance states, "*It is important to note that side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail. When attempting to exit the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised siderails."*[9]

In September 2000 CMS (then HCFA) issued revisions to surveyor guidance for determining nursing facilities' compliance with federal Medicare and Medicaid regulations governing the use of restraints, which similarly describes the potential risks of using bed rails.[10] For example, the guidance states, "*The same device may have the effect of restraining one individual, but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another."*

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[4]Parker, K., Miles, SH. (1997). Deaths caused by bed rails. Journal of the American Geriatrics Society 45:797-802.
[5] Feinsod, F.M., Moore, M., Levenson, S. (1997). Eliminating full-length bed rails from long term care facilities. Nursing Home Medicine 5:257-263.
[6] MedWatch, the U.S. Food and Drug Administration's medical products reporting program.
[7] Food and Drug Administration. FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails (Aug 23, 1995). U.S. Department of Health and Human Services.
[8] Todd, J., Ruhl, C., & Gross, T. (1997). Injury and Death Associated with Hospital Bed Side-Rails: Reports to the U.S. Food and Drug Administration from 1985 to 1995. American Journal of Public Health 87 (10): 1675-1677.
[9] Health Care Financing Administration guidance to surveyors in the implementation of 42 CFR Part 482 Medicare and Medicaid Programs. State Operations Manual Provider Certification Transmittal 17. June 2000. A-182-183.
[10]Health Care Financing Administration guidance to surveyors in the implementation of 42 CFR Part 483.13(a). Medicare and Medicaid Programs. State Operations Manual Provider Certification Transmittal 20. September 7, 2000. PP-45.

Guiding Principles

National surveys of patient deaths occurring in the bed environment demonstrate the risk of entrapment when a patient slips between the mattress and bed rail or when the patient becomes entrapped in the bed rail itself. The population at risk for entrapment are patients who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, and acute urinary retention that cause them to move about the bed or try to exit from the bed. The absence of timely toileting, position change, and nursing care are factors that may also contribute to the risk of entrapment. The risk may also increase due to technical issues such as the mis-sizing of mattresses, bed rails with winged edges, loose bed rails, or design elements such as wide spaces between vertical bars in the rails themselves.

The principles that follow are intended to guide the development of patients' care plans.

1. The automatic use of bed rails may pose unwarranted hazards to patient safety.
   When planning patient care the following should be considered:
   - The potential for serious injury is more likely to be related to a fall from a bed with raised bed rails when the patient attempts to climb over, around, between, or through the rails, or over the foot board, than from a bed without rails in use.
   - Evaluation is needed to assess the relative risk of using the bed rail compared with not using it for an individual patient.
   - Bed rails sometimes restrain patients. When used as restraints, bed rails can pose the same risk to patient safety as other types of physical restraints.
   - Patient safety is paramount. In an emergent situation the caregiver needs to do whatever is necessary in his or her professional judgment to secure the patient's safety. Consider that using a bed rail or other device to restrain the patient could place the patient's safety at risk.
   - Physical restraints such as vest/chest, waist, or leg/arm restraints used simultaneously with raised bed rails may be medically indicated in certain limited circumstances in the acute care environment. Consider that when physical restraints and bed rails are used simultaneously:
     - the risk to patient safety, e.g., suffocation or accidental suspension, may increase;
     - patients should be monitored closely;
     - appropriate care such as toileting should be provided; and
     - reassessment for medical necessity and removal is needed on a regular basis.
   - Strangling, suffocating, bodily injury, or death can occur when patients or parts of their bodies are caught between rails or between the bed rails and mattresses.

2. Decisions to use or to discontinue the use of a bed rail should be made in the context of an individualized patient assessment using an interdisciplinary team with input from the patient and family or the patient's legal guardian.

3. The patient's right to participate in care planning and make choices should be balanced with caregivers' responsibility to provide care according to an individual assessment, professional standards of care, and any applicable state and federal laws and regulations.

Policy Considerations

1. Regardless of the purpose for which bed rails are being used or considered, a decision to utilize or remove those in current use should occur within the framework of an individual patient assessment**.**

2. Because individuals may differ in their sleeping and nighttime habits, creation of a safe bed environment that takes into account patients' medical needs, comfort, and freedom of movement should be based on individualized patient assessment by an interdisciplinary team.
   - The composition of the interdisciplinary team may vary depending upon the nature of the care and service setting and the patient's individual needs. Team members for consideration should include, but are not limited to: nursing, social services, and dietary personnel; physicians (or their designees); medical director; rehabilitation and occupational therapists; patient; family (or authorized representative); and medical equipment suppliers.
   - The patient and family (or authorized representative) play a key role in the creation of a safe and comfortable bed and sleeping environment. These individuals can provide information about the patient's previous sleeping habits and bed environment that caregivers need to design the bed environment. Their participation in discussions facilitates creation of a bed and sleeping environment that meets patients' needs.

3. Use of bed rails should be based on patients' assessed medical needs and should be documented clearly and approved by the interdisciplinary team.
   - Bed rail effectiveness should be reviewed on a regular basis.
   - The patient's chart should include a risk-benefit assessment that identifies why other care interventions are not appropriate or not effective if they were previously attempted and determined not to be the treatment of choice for the patient. (See Appendix 1: Glossary for patient/caregiver assist items.)

4. Bed rail use for treatment of a medical symptom or condition should be accompanied by a care plan (treatment program) designed for that symptom or condition.
   - The plan should present clear directions for further investigation of less restrictive care interventions.
   - The documentation should describe the attempts to use less restrictive care interventions and, if indicated, their failure to meet patients' assessed needs.

5. Bed rail use for patient's mobility and/or transferring, for example turning and positioning within the bed and providing a hand-hold for getting into or out of bed, should be accompanied by a care plan.
   - The patient should be encouraged to participate in care planning to help design a safe and comfortable bed environment.

- The care plan should:
  - include educating the patient about possible bed rail danger to enable the patient to make an informed decision; and
  - address options for reducing the risks of the rail use.

6. The process of reducing and/or eliminating existing use of bed rails should be undertaken incrementally using an individualized, systematic, and documented approach.

7. Creating a safe bed environment does not necessarily preclude the use of bed rails. However, a decision to use them should be based on a comprehensive assessment and identification of the patient's needs, which include comparing the potential for injury or death associated with use or non-use of bed rails to the benefits for an individual patient. In creating a safe bed environment, the following general principles should be applied:
   - Avoid the *automatic* use of bed rails of any size or shape.
   - Restrict the use of physical restraints, including chest, abdominal, wrist, or ankle restraints of any kind on individuals in bed.
   - Inspect, evaluate, maintain, and upgrade equipment (beds/mattresses/bed rails) to identify and remove potential fall and entrapment hazards and appropriately match the equipment to patient needs, considering all relevant risk factors.
   - Re-assess the patient's needs and re-evaluate the equipment if an episode of entrapment or near-entrapment occurs, with or without serious injury. This should be done immediately because fatal "repeat" events can occur within minutes of the first episode.

Process/Procedure Considerations

The items listed below are not meant to be all-inclusive. Caregivers may identify other concerns that need to be addressed.

1. Individualized Patient Assessment
   Any decision regarding bed rail use or removal from use should be made within the framework of an individual patient assessment. If a bed rail has been determined to be necessary, steps should be taken to reduce the known risks associated with its use. The individual patient assessment includes[11, 12, 13, 14, 15, 16, 17, 18]

[11] Capezuti, E., Talerico, K.A., Strumpf, N., & Evans, L. (1998). Individualized assessment and intervention in bilateral side rail use. Geriatric Nursing, 25, 26-34.
[12] *See* Capezuti et al., *supra* note 1.
[13] Donius, M. & Rader, J. (1994) Use of Side rails: Rethinking a Standard of Practice, Journal of Gerontological Nursing 23, 23-27.
[14] Rader, J. (1995). Creating a supportive environment for eliminating restraints. In Rader, J. & Tornquist, E.M. (Eds.) Individualized Dementia Care, New York: Springer Publishing Company.
[15] Donius, M., & Rader, J. (1996). Side rails: Rethinking a Standard Practice. In Burggraf, V. & Barry, R. (Eds.), Gerontological Nursing Current Practice and Research. Thorofare, NJ: Slack, Inc.
[16] O'Keeffe, S., Jack, C.I.A., & Lye, M. (1996). Use of restraints and bed rails in a British hospital. Journal of the American Geriatrics Society, 44, 1086-1088.
[17] Frengley, J.D. (1999), Bedrails: Do They Have A Benefit?, Journal of the American Geriatrics Society, 47(5): 627-628.
[18] Hammond, M., Levine, J.M. Bedrails: Choosing the Best Alternative. Geriatric Nursing. 20(6):297-300. 1999 Nov. – Dec.

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

2. Sleeping environment assessment
   This assessment includes elements or conditions that may affect the patient's ability to sleep and may be considered in evaluating areas to address in a patient's care plan.
   - Comfort
     - pain
     - hypoxia
     - grieving
     - loneliness
     - hunger, thirst
     - hydration
     - calorie intake and protein calories
     - boredom
     - amount of time spent in bed
     - light levels
     - temperature

   - Understanding of self and family
     - hobbies, interests, religion
     - pictures of family

   - Proximity to toilet
     - toilet within view
     - toilet accessible
     - strategy (patient with or without help from caregiver) for toileting

   - Appropriate bed
     - comfortable
     - safe
     - height
     - mattress/overlay
     - mattress edge definition (if necessary)
     - support for turning (if necessary)

- strategy for safe egress
- elevation for head of bed

- Support by Caregivers
  - individualized toileting schedule
  - routine comfort assessment
  - skin care and hygiene
  - emotional and physical support

- Medical Stabilization
  - treatment of underlying acute medical problems
  - dosages and types of medication
  - effects of long-term use of hypnotics
  - pain treatment strategy
  - caution with orthostatic medications (diuretics, short-acting antihypertensives)
  - diuretics (if indicated) not given at night
  - diabetic snack given at night
  - treatment for nocturnal esophageal reflux
  - bowel elimination plan for regularity

3. Treatment Programs/Care Plans
   - Address diagnoses, symptoms, conditions, and/or behavioral symptoms for which the use of a bed rail is being considered.
   - Identify nursing/medical and environmental interventions (e.g., for a patient with a life-long habit of staying up at night, provide nighttime activity).
   - If clinical and environmental interventions have proven to be unsuccessful in meeting the patient's assessed needs or a determination has been made that the risk of bed rail use is lower than that of other interventions or of not using them, bed rails may be used. Documentation of the risk-benefit assessment should be in the patient's medical chart.
   - The team should review the treatment program and determine its effects on the patient through an ongoing cycle of evaluation that includes assessment of outcomes and adverse effects.
   - When planning care for the patient for whom a low bed is selected, consideration should be given to potential effects on the patient such as restraining desired voluntary movement or creating an unwanted psychological effect by being placed close to the floor. The individualized care plan and risk benefit considerations should address these issues and the plan modified accordingly.
   - General guidance:
     a. A patient is assessed to be at low risk for injury, as defined by these factors:
        - transfers safely to and from the bed to a wheelchair without assistance;
        - ambulates without assistance to and from the toilet without falling;
        - has not fallen, or is unlikely to fall, out of bed; and
        - notifies staff appropriately using call system.

        Consider using a bed for this patient without a bed rail.

b. A patient is assessed to be unsafe in bed, or at high risk for injury, as defined by these factors:
   - inability to transfer safely to and from the bed to a wheelchair;
   - previous entrapment or near-entrapment episode;
   - inability to ambulate to and from the toilet without falling;
   - history of bed-related serious injury;
   - episodes of falling out of bed, or likelihood that such episodes will occur; or
   - inconsistent in notifying staff of needs or unable to access the call system.

   Consider placing this patient in an adjustable height bed that can go very low to the floor for sleeping and raised for transfers and activities of daily living care, or an alternative such as a concave mattress as determined by the interdisciplinary care team. Use a high-impact mat next to the bed.

c. A patient is assessed to require a bed in a low position but has difficulty getting into the low bed from the standing position:
   Consider an adjustable-height bed. If this is not available, consider adding a quarter rail or transfer device (See Appendix 1: Glossary) to a low bed for the patient to hold for support while entering the low bed. When selecting a support hold, consider:
   - Such rails should contain cross bars close enough to prevent the passage of the patient's head or body part through the rail and fit closely enough to the mattress to prevent entrapment.
   - Other interventions exist, such as secured vertical poles used for transferring in and out of bed. These poles, which are secured into the ceiling and floor, have weight limits. Tape applied to the pole may increase traction. They are generally used with more cognitively functional individuals.

d. A patient is assessed to need a low bed, but an assessment determines that the patient is in danger of hurting him/herself while exiting from the low bed or is in danger of an unstable transfer after standing up by grabbing onto a bed side table or sink:
   Consider using a bed alarm to alert nursing staff when patient is leaving the bed.
   - Base the decision on the individual patient's clinical condition and assessment.
   - Carefully consider the use of bed alarms for the patient who is agitated or confused.

e. Steps should be taken to reduce risk of injury to patients and caregivers. Keep the bed in the lowest position with the wheels locked when occupied, adjusting the level for activities such as administering care or for patient transfers in/out of bed:
   - Place a high impact mat next to the low bed to cushion falls from the low bed as long as this does not create a greater risk of accident to the patient or caregivers.
   - Raise the bed to give care and lower it when finished. If the bed is not adjustable, utilize body mechanics techniques such as kneeling on one or both knees on the high impact mat rather than bending over.
   - Store the high impact mat when it is not in use.
   - Assess area for objects that may cause injury.
   - Move furniture far enough away from the bed to avoid risk of injury.
   - Train caregivers on the proper use of low beds and proper body mechanics.

Risk Intervention

Assessment of risk should be part of the individual patient's assessment, and steps to address the risk should be incorporated into the patient's care plan. The following are examples of risk intervention approaches.

1. Nursing
   - Provide individually scheduled toileting.
   - Develop a schedule for turning and positioning.
   - Clean urine and/or feces promptly.
   - Elevate head of bed for patients with congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), reflux, and actively infusing enteral fluids.
   - Position patients to maximize comfort and change positions in a timely manner, maintaining comfort and reducing risk for skin breakdown.
   - Accommodate patients' preferred bedtime habits whenever possible.
   - Restrict use of physical restraints on patients in bed.
   - When medically indicated, use padded bed rails for individuals with an active seizure disorder or active movement disorder.
   - Provide distractions such as music, television, or food and fluids for patients who do not sleep through the night.
   - Provide calming interventions and pain relief.
   - Plan time during the day to provide periods of physical activity that help promote a restful sleep.
   - Re-evaluate and revise patient's treatment program as needed if an episode of entrapment or near-entrapment occurs with or without serious injury.

2. Medical
   - Minimize use of medications that alter mental status.
   - Use alternatives to sleeping medications.
   - Dispense diuretics before the late afternoon/evening.
   - Treat pain.
   - Screen and treat for hypoxia.
   - Assess the clinical status of delirious patients to rule out reversible etiologies.
   - Promote mobility and fitness, e.g., restorative care to enhance abilities to stand safely and to walk.

3. Patient and Family
   - Seek and utilize input about the patient from the patient and family (or authorized representative) to assist in identifying nursing and medical risk interventions.
   - If patients or family members ask about using bed rails, encourage them to talk to the health care team about whether bed rails are indicated.
   - Since the patient and family are integral members of the team, they should be encouraged to learn about bed safety and appropriate care options.

Individualized Environmental Changes

The environmental changes listed below are suggestions for consideration. Whether they will be used for an individual patient depends on the patient's assessment.

1. Use of low beds with adjacent mat on the floor (with consideration given to using mechanical lifts and proper lift technique training for caregiver staff).
2. Use of low beds that can be elevated electronically for transfer and activities of daily living (ADL) care.
3. Placement of the patient's call bell within easy reach and provision of visual and verbal reminders to use the call bell when necessary.
4. Use of bed alarms to warn of patients' attempts to exit from bed.
5. Use of "perimeter reminders" or "border definers" such as body pillow/cushions or mattresses with lipped/raised edges.
6. Use of a trapeze affixed to bed to increase patient's bed mobility. (For patients with shoulder conditions, trapeze use should be carefully scrutinized.)
7. Placement of inconspicuous signs, without patients' names, to inform caregivers of interdisciplinary care team recommendations.

Patient Choice

As with any other device that may be used as a restraint, if a patient, family member, or authorized representative requests the inappropriate use of side rails, then the interdisciplinary care team has a responsibility to discuss the risks involved, as well as the benefits of any clinical and/or environmental interventions that may be safer in meeting the patient's assessed needs, individual circumstances, and environment. The patient's right to participate in care planning and make choices should be balanced with caregivers' responsibility to provide care according to an individual assessment, professional standards of care, and any applicable state and federal laws and regulations.

Bed Rails as Restraints

When bed rails have the effect of keeping a patient from voluntarily getting out of bed, they fall under the definition of a physical restraint. If they are not necessary to treat medical symptoms, and less restrictive interventions have not been attempted and determined to be ineffective, bed rails used as restraints should be avoided.[19],[20] Bed rails used on the bed of a patient who is completely immobile do not serve as restraints, but may not be medically necessary. It is recommended that they be avoided.

Education /Training

Hospitals, long term care facilities, and home health care providers should provide education and training about bed rail use to assist in creating and implementing a safe and comfortable sleeping environment for their patients. It is recommended that the education and training be directed toward the following groups:

[19] *See* Health Care Financing Administration *supra* note 10.
[20] *See* Health Care Financing Administration *supra* note 7 at A-182.

- Staff
- Patient/family
- Physicians, including medical directors and physician extenders such as physician assistants and nurse practitioners
- Long term care ombudsman
- Regulatory agencies or representatives

Bed Rail Safety Guidelines

If it is determined that bed rails are required and that other environmental or treatment considerations may not meet the individual patient's assessed needs, or have been tried and were unsuccessful in meeting the patient's assessed needs, then close attention must be given to the design of the rails and the relationship between rails and other parts of the bed.

1. The bars within the bed rails should be closely spaced to prevent a patient's head from passing through the openings and becoming entrapped.
2. The mattress to bed rail interface should prevent an individual from falling between the mattress and bed rails and possibly smothering.
3. Care should be taken that the mattress does not shrink over time or after cleaning. Such shrinkage increases the potential space between the rails and the mattress.
4. Check for compression of the mattress' outside perimeter. Easily compressed perimeters can increase the gaps between the mattress and the bed rail.
5. Ensure that the mattress is appropriately sized for the selected bed frame, as not all beds and mattresses are interchangeable.
6. The space between the bed rails and the mattress and the headboard and the mattress should be filled either by an added firm inlay or a mattress that creates an interface with the bed rail that prevents an individual from falling between the mattress and bed rails.
7. Latches securing bed rails should be stable so that the bed rails will not fall when shaken.
8. Older bed rail designs that have tapered or winged ends are not appropriate for use with patients assessed to be at risk for entrapment.
9. Maintenance and monitoring of the bed, mattress, and accessories such as patient/caregiver assist items (See Appendix 1: Glossary) should be ongoing.

Appendix 1: Glossary

Adjustable height bed – A bed with "hi-low" function such that the height of the sleep surface can be adjusted.

Automatic contour - A feature of a bed where the thigh section of the sleep surface articulates upward as the head section travels upward thereby reducing the likelihood of patient/resident mattress from migrating toward the foot end of the bed.

Bed alarms – Alarms intended to notify caregivers of either an unwanted patient/resident egress or that the patient/resident is near the edge of the mattress.

Bed rail extender – A detachable device intended to bridge the space between the head and foot bed rail.

Bed rails –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. Synonymous terms are *side rails, bed side rails, and safety rails.* (See attached *Bed Side Rail Types* for illustrated definitions.)

Control bed rail – A bed rail that incorporates bed function controls for patient/staff activation.

Fireman's pole – A pole secured (floor and ceiling mooring) next to the bed that acts as a support for the patient to get into and out of the bed.

Handgrips – Devices attached to either side of the bed to provide the patient/resident the ability to reposition themselves while in bed as well as an aid to enter and leave the bed.

High-impact mat (bed-side mat) – A mat placed next to the bed that absorbs the shock if the patient falls from the bed.

Entrapment – An event in which a patient is caught, trapped, or entangled in the spaces in or about the bed rail, mattress, or hospital bed frame. Entrapment can result in serious injury or death.

Interdisciplinary team -- The interdisciplinary team may vary in constituency depending upon the nature of the care and service setting and the individual patients' needs. Members may include, but are not limited to: patient; family member (or patient's legal representative); nursing, social services, and dietary personnel; attending physician (or designee); medical director; rehabilitation and occupational therapists; and medical equipment suppliers.

Lifting pole – A device suspended above the bed intended to allow the patient to change position by gripping it.

Low bed – This bed is defined according to the patient: The bed is considered "low" if, when the patient is sitting on the side of the bed with feet on the floor, the angle of the patient's bent knees is 90 degrees or less.

Mattress with raised edges – A mattress that has a perimeter configured in a manner to allow the patient/resident to be "cradled" in the center of the mattress and reduces the likelihood of unwanted patient egress. It has a central area on either side of the mattress that is not raised and is used for egress.

Patient assessment – The assessment provides ongoing information necessary to develop a care plan, to provide the appropriate care and services for each patient, and to modify the care plan and care/services based on the patient's status. Details about the components of the assessment are found on pages 5 and 6 of this document.

Pediatric rail – A rail in which the bar spacing is no larger than two and three-eighths inches.

Pendant control – A means used by either the patient or the operator to control the drives that activate various bed functions and is attached to the bed by a cord.

Physical restraint – Any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's [patient's] body that the individual cannot remove easily that restricts freedom of movement or normal access to one's body. (Source: Health Care Financing Administration State Operations Manual, Rev. 274, Guidance to Surveyors at 42 CFR Subpart B, Requirements for Long Term Care Facilities, 483.13(a).)

Sleeping environment – Includes physical components such as the bed size and height and mattress, the accessibility of personal items and accessories such as a call bell, and the room temperature and noise or light levels. The environment also includes nonphysical aspects such as comfort and security. These aspects may be related to the physical features of the bed such as the degree of mattress firmness, or features that facilitate freedom from physical pain, or a feeling of safety and privacy.

Transfer device - Support for transfers such as half - or quarter-length upper bed rails, bed grab bars, bed handles attached to the bed frame, or fireman's transfer pole.

Treatment program (care plan) – The treatment program includes measurable objectives and timetables to meet the patient's medical, nursing, and mental and psychosocial needs that are identified through the assessment process. The effectiveness of the treatment program is evaluated and modified as necessary. The interdisciplinary team reviews, revises, and initiates changes to the program as needed in accordance with professional standards of practice after each assessment.

Seizure pads - Padded covers for bed rails that may be used to prevent unwanted patient/resident cuts and bruising from repeated contact with the bed rails. Also used to cover openings within the perimeter of the side rails and space between the head and foot rails.

Side rails – See *Bed rails*.

Stuff pads – Plastic covered pads used to obliterate open spaces between bed rails and mattresses, mattresses and head/foot boards.

Transfer bar – A one-piece device, attached to the bed frame on one or both sides of the bed, that is grasped to aid in bed entry and exit.

Appendix 2: Bed Rails - Intended Purpose and Potential Risks

Intended Purpose of Bed Rails

1. One of several methods utilized to prevent patient from falling out of bed.
   - Reminds patient not to get out of bed when medically contraindicated and/or medical equipment is attached to the patient.
   - Defines the bed edge.
   - Helps to protect patient from falling out of bed during transport.

2. May assist patient with movement.
   - Moving within the bed.
   - Getting in and out of bed.

3. One of several methods to provide the patient with easy access to bed controls.

4. One of several methods to provide a feeling of comfort and security.

Potential Risks of Bed Rails

1. Create a source of known morbidity and mortality such as:
   - Strangling, suffocation, serious bodily injury,* or death when patients or parts of their bodies are caught between rails, the openings of the rails, or between the bed rails and mattress.

2. Impede patients from safely getting out of bed:
   - Patients crawl over rails and fall from greater heights increasing the risk for serious injury.
   - Patients attempt to get out of bed over the foot board.

3. Restrain patients in many circumstances:
   - Hinder patients from independently getting out of bed thereby confining them to their beds.
   - Create a barrier to performing routine activities such as going to the bathroom.

4. Can create negative psychological effects:
   - Create undignified personal image.
   - Alter patient self-esteem.
   - Contribute to patient isolation.
   - Confinement can cause patients to be incontinent.

The potential risks can be exacerbated by:

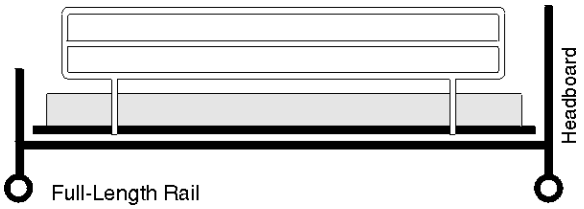
- Improper match of the bed rail to bed frame.
- Improper installation.
- Objects such as holders or supports that remain when the bed rail is removed.

* May include head trauma; bruising, contusions, and/or skin lacerations; and fractures and/or dislocations.

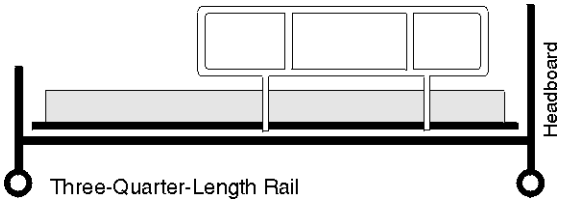
Appendix 3: Bed Side Rail Types

The drawings below are intended only to illustrate the design of bed rails. They are not intended to represent actual or recommended dimensions.

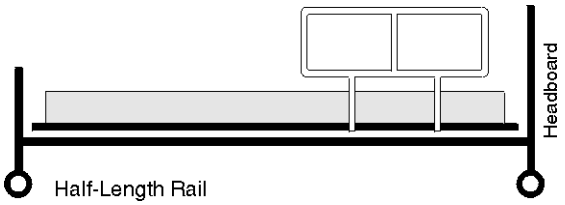
Full-Length Rail: A one-piece rail that extends along the side of the bed from the head to the foot section.



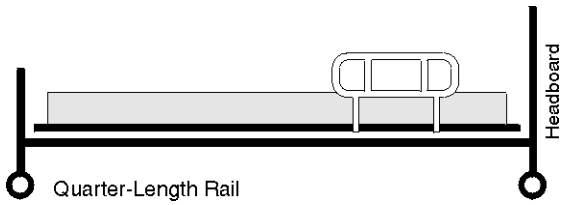
¾-Length Rail: A one-piece rail that extends along the side of the bed three-quarters of the way down from the head of the bed.



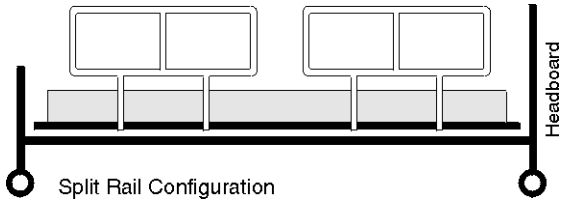
Half-Length Rail: A one-piece rail that extends along the side of the bed one-half the length of the bed from the head of the bed.

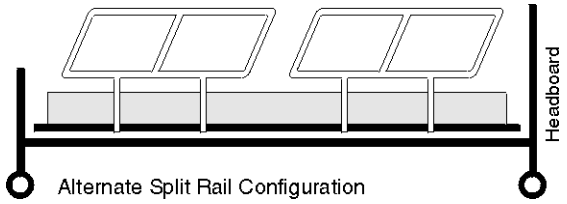


Quarter-Length Rail: A one-piece rail that extends along the side of the bed approximately ¼ the length of the bed from the head of the bed.

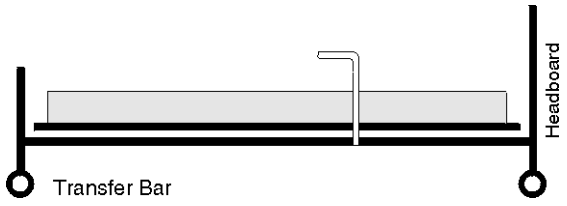


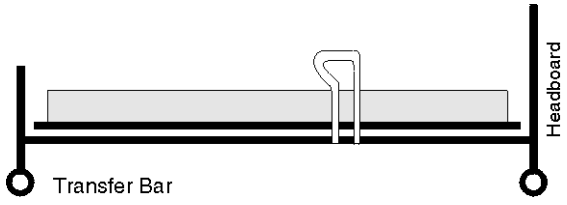
Split Rails: A pair of half rails. One set extends along the side of the bed from the head of the bed to the mid-section of the bed. The other set extends from the mid-section of the bed to the foot of the bed. Generally, there is a space between the two sets of rails.





Transfer Bar: A one-piece device, attached to the bed frame on one or both sides of the bed, that is grasped to aid in bed entry and exit.





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Appendix 4: Hospital Bed Safety Workgroup Member Organizations that Signed on to the Clinical Guidance

AARP
American Association of Homes and Services for the Aging
American Health Care Association
American Medical Directors Association
American Nurses Association
American Society of Healthcare Risk Management
Basic American Metal Products
Care Providers of Minnesota
Carroll Health Care
ECRI
Evangelical Lutheran Good Samaritan Society
Hard Manufacturing
Health Safe, Incorporated
Iona Senior Services
Kinetic Concepts Incorporated
Law Offices of Julie A. Braun
MC Healthcare
Medical Devices Bureau, Health Canada
National Association of Home Care
National Patient Safety Foundation
National Citizens Coalition for Nursing Home Reform
Orange Grove Habilitation Center
RN Systems +
Span American
Sunrise Medical
Tactilics, Inc.
Untie the Elderly, The Kendal Corporation
U.S. Food and Drug Administration
Vail Products, Incorporated
Veterans Administration National Center for Patient Safety

HBSW member, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has determined that the Clinical Guidance does not conflict with current standards in the JCAHO *Comprehensive Accreditation Manual for Hospitals 2002, 2002 Standards Manuals for Home Care*, or the *2002-2003 Comprehensive Accreditation Manual for Long Term Care*.

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Consumer Safety Alert: CPSC Issues Urgent Warning About Adult Portable Bed Rails; 9 Recalls in 3 Years; 18 Deaths Reported Since 2021

Release Date: November 14, 2024

WASHINGTON, D.C. – The U.S. Consumer Product Safety Commission (CPSC) announced today that it has recalled more than 200,000 adult portable bed rails manufactured by Medical King, of Brooklyn, New York, due to entrapment and asphyxia hazards. Today's announcement is the 9th recall of adult portable bed rails CPSC has issued since 2021. In total these recalls, along with two product warnings,* impacted more than 3 million units and are associated with serious injuries from head, neck, or chest entrapment and 18 reported deaths.

Adult portable bed rails are an important device used in assisted or residential care settings and private homes to help prevent falls or injuries for individuals with physical or mental limitations. They help individuals in standing or positioning on a bed, to assist mobility or to provide support when sleeping.

There are risks involved in using adult portable bed rails, however, including injuries from falls or entrapment, or death by asphyxiation. **CPSC data show that 92% of fatalities associated with adult portable bed rails are from entrapment usually of the head or neck.**

In January 2023, CPSC took steps to address this hazard by issuing new mandatory safety standards for adult portable bed rails. CPSC's rule builds on a voluntary industry standard and establishes requirements to reduce the risk of entrapment and other hazards associated with the use of adult portable bed rails. All APBRs sold in the United States and manufactured after the effective date must comply with the standard's performance and testing requirements.

“Those taking care of the elderly or individuals with mobility limitations or those with mental challenges shouldn’t have to worry that a critical piece of support equipment they rely on could lead to serious injuries or death,” said CPSC Chair Alex Hoehn-Saric. “During National Care at Home Month, we want to encourage all caregivers – whether in private homes or in institutional settings – to ensure that the adult portable bed rails they use are installed correctly, used properly and have not been previously recalled.”

CPSC offers the following safety tips for consumers purchasing or using adult portable bed rails. This and more information can be found on CPSC’s Adult Bed Rails Safety Education Center.

- **Make sure that your bedrail is not recalled by checking cpsc.gov/Recalls, and that it complies with the mandatory safety standard**
- **Prevent gaps between bed rail and mattress**
    - Make sure that bed rail is pressed firmly against the side of the mattress
    - Make sure that the retention device (ex: strap) is properly installed and secured
- **Prevent hazardous gaps between bed rail and surroundings**
    - Make sure that there is at least a 12.5” gap between the bed rail and headboard/footboard
    - Keep furniture (nightstands, dressers, etc.) away from bed rail
    - Do not install multiple bed rails next to each other
- **Read and follow all the provided warnings and instructions for assembly, installation, and use**
    - Do not climb or allow climbing over the bed rail
    - Do not modify the bed rail
    - Make sure the bed rail is compatible with your bed/mattress
- **Consider whether adult portable bedrails are an appropriate support for the situation.****
    - Carefully monitor those who may be at risk for entrapment, such as those with cognitive impairment**.**

Editor's Resources:

*In some instances where companies do not agree to recall a product, CPSC will issue a **product warning** to alert consumers to the hazard.

**Source: Food and Drug Administration

Previous CPSC Recalls and Safety Warnings for Adult Portable Bed Rails:

Bed Handles, Inc – April 2021 – 113,000 *(safety warning)*

CPSC Warns Consumers to Stop Use of Three Models of Adult Portable Bed Rails Manufactured by Bed Handles, Inc., Due to Entrapment, Asphyxia Hazard

Drive DeVilbiss – December 2021 – 496,000

Drive DeVilbiss Healthcare Recalls Adult Portable Bed Rails After Two Deaths; Entrapment and Asphyxiation Hazards

Essential Medical Supply – December 2021 – 272,000

Essential Medical Supply Recalls Adult Portable Bed Rails Due to Entrapment and Asphyxia Hazard; One Death Reported

Compass Health – December 2021 – 104,900

Compass Health Brands Recalls Carex Adult Portable Bed Rails After Three Deaths; Entrapment and Asphyxiation Hazards

Nova Medical Products – December 2022 – 20,000

Nova Medical Products Recalls Adult Bed Rails Due to Serious Entrapment and Asphyxia Hazards

Mobility Transfer Systems (MTS) – June 2022 – 285,000 *(safety warning)*

CPSC Urges Consumers to Immediately Stop Use of Mobility Transfer Systems Adult Portable Bed Rails Due to Entrapment and Asphyxia Hazard; Three Deaths Reported

Platinum Health – February 2023 – 53,000

Platinum Health Recalls LumaRail Adult Portable Bed Rails Due to Serious Entrapment and Asphyxia Hazard; One Death Reported

BeyondMedShop – March 2023 – 102,000

BeyondMedShop Recalls Vaunn Medical Adult Bed Rails Due to Serious Entrapment and Asphyxia Hazards

Essential Medical Supply – April 2024 – 272,000 *(recall reannouncement)*

Essential Medical Supply Reannounces Recall of Adult Portable Bed Rails Due to Entrapment and Asphyxia Hazards; Two Additional Deaths Reported After 2021 Recall

Medline – May 2024 – 1,500,000

Medline Industries Recalls 1.5 Million Adult Portable Bed Rails Due to Serious Entrapment and Asphyxia Hazards; Two Deaths Reported

Ceither – September 2024 – 1,170

Ceither Adult Portable Bed Rails Recalled Due to Serious Entrapment and Asphyxia Hazards

Medical King – November 2024 – 220,000

Medical King Recalls About 222,000 Adult Portable Bed Rails Due to Serious Entrapment and Asphyxia Hazards; One Death Reported

Individual Commissioners may have statements related to this topic. Please visit www.cpsc.gov/commissioners to search for statements related to this or other topics.

Release Number
25-047

About the U.S. CPSC
The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risk of injury associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product-related incidents cost the nation more than $1 trillion annually. Since the CPSC was established more than 50 years ago, it has worked to ensure the safety of consumer products, which has contributed to a decline in injuries associated with these products.

Federal law prohibits any person from selling products subject to a Commission ordered recall or a voluntary recall undertaken in consultation with the CPSC.

For lifesaving information:

- Visit CPSC.gov.

- Sign up to receive our email alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
- Report a dangerous product or a product-related injury on www.SaferProducts.gov.
- Call CPSC's Hotline at 800-638-2772 (TTY 800-638-8270).
- Contact a media specialist.

Media Contact	Please use the below phone number for all media requests. **Phone: (301) 504-7908** **Spanish: (301) 504-7800** View CPSC contacts for specific areas of expertise

United States
CONSUMER PRODUCT
SAFETY COMMISSION

CPSC Urges Consumers to Immediately Stop Use of Mobility Transfer Systems Adult Portable Bed Rails Due to Entrapment and Asphyxia Hazard; Three Deaths Reported

Release Date: June 02, 2022



Freedom Grip (model 501)

WASHINGTON, DC – The U.S. Consumer Product Safety Commission (CPSC) is warning consumers to immediately stop using 285,000 Mobility Transfer Systems adult portable bed rails. These products can create an entrapment hazard and pose a risk of serious injury or death to users. CPSC's warning applies to 10 models of bed rails.

The bed rails were manufactured and sold by Mobility Transfer Systems Inc. from 1992 to 2021, and by Metal Tubing USA Inc. in 2021 and 2022. Neither company has agreed to recall the bed rails and to offer a remedy to consumers. CPSC is assessing possible future action in this matter.

CPSC evaluated the bed rails and found that consumers can become entrapped between the bed rail and mattress, or within portions of the bed rail itself, leading to asphyxia.

At least three people have died after becoming entrapped in one model of the bed rails. They include a 78-year-old woman in a Michigan assisted living facility in 2006, an 85-year-old man in an Oklahoma nursing home in 2007, and a 90-year-old disabled woman in California in 2013.

The bed rails were sold at Walmart.com, Amazon.com, MTSMedicalSupply.com, VitalityMedical.com, Alimed.com, and other online retailers for between about $30 and $170. The products have also been found for sale on secondhand sites, such as eBay.com.

CPSC urges consumers to immediately stop use, disassemble, and dispose of the following bed rails and report any related incidents to the agency at www.SaferProducts.gov:

- Freedom Grip (model 501)
- Freedom Grip Plus (model 502)
- Freedom Grip Travel (model 505)
- Reversible Slant Rail (model 600)
- Transfer Handle (model 2025)
- Easy Adjustable (model 2500)
- 30-Inch Security Bed Rail, single-sided (model 5075)
- 30-Inch Security Bed Rail – Extra Tall, single-sided (model 5075T)
- 30-Inch Security Bed Rail, double-sided (model 5085)
- 30-Inch Security Bed Rail – Extra Tall, double-sided (model 5085T)

The name “Mobility Transfer Systems” and the model number are printed on a label located on the grip handle of the bed rails. The bed rails are made of white or chrome metal tubing.

Release Number

22-148

About the U.S. CPSC

The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risk of injury or death associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product-related incidents cost the nation more than $1 trillion annually. CPSC's work to ensure the safety of consumer products has contributed to a decline in the rate of injuries associated with consumer products over the past 50 years.

Federal law prohibits any person from selling products subject to a Commission ordered recall or a voluntary recall undertaken in consultation with the CPSC.

For lifesaving information:

- Visit CPSC.gov.
- Sign up to receive our e-mail alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
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- Contact a media specialist.

Media Contact	Please use the below phone number for all media requests. **Phone: (301) 504-7908** **Spanish: (301) 504-7800** View CPSC contacts for specific areas of expertise

NOTE OF CLARIFICATION, MARCH 20, 2003

This research was conducted in 2001 when the Hospital Bed Safety Workgroup (HBSW) dimensional guidelines were under development. The dimensional guidelines and measurement methodology used here do not necessarily reflect current recommendations neither of the HBSW nor of the guidance document that will eventually be released by the FDA.

For current information on the HBSW work, refer to:
www.fda.gov/cdrh/beds http://www.fda.gov/cdrh/beds

For information about the availability of the toolkit, refer to:
www.ecri.org/bedsafety <http://www.ecri.org/bedsafety>

HOSPITAL BED SAFETY EVALUATION IN HOSPITALS AND NURSING HOMES

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INTRODUCTION: The Veterans Health Administration is committed to improving patient safety. The VHA-funded center based in Tampa FL, The VISN 8 Patient Safety Center of Inquiry, focuses on safe patient mobility for frail elderly and the disabled. In 2000, our center partnered with the Food and Drug Administration (FDA) and representatives from the medical bed industry, national health care organizations, patient advocacy groups, and other federal agencies (Health Care Finance Administration; Consumer Product Safety Commission) to improve the safety of hospital beds for patients who are most vulnerable to the risk of side rail entrapment.

PROBLEM STATEMENT: Hospital bed systems can contribute to significant injury or death. Today there are about 2.5 million hospital and nursing home beds in use in the United States. Between 1985 and 1999, 371 incidents of patients caught, trapped, entangled, or strangled in beds with rails were reported to the U.S. Food and Drug Administration. Of these reports, 228 people died, 87 had a nonfatal injury, and 56 were not injured because staff intervened. Most of these patients were frail, elderly, or confused. Generally, it is assumed that most of these "close calls" are not reported. The FDA Hospital Bed Safety Workgroup developed a set of proposed guidelines that specify dimensional criteria for bed systems based on 15 anthropometric data sources and a retrospective validation based on a survey of past entrapment events.

RESEARCH OBJECTIVES: The goal of this six-month study using prospective observational and survey methods is to minimize risk of death and injury due to bed-related entrapment of patients. The purpose of the study is to (1) evaluate a facility-based approach for bed safety assessment (2) determine evidence-based recommendations for intervention (3) determine relative risk and cost benefit comparison of interventions. An observational descriptive design will be used in the proposed study. The following **immediate objectives** (O) will be addressed:

- **O1:** Determine the variability/frequency distribution/prevalence of bed systems (components of which include characteristics of rails, foot and head boards, beds and mattresses; models; manufacturers; bed modifications; bed rail alternatives) at six VA health care systems.
- **O2:** Evaluate each bed according to proposed safety criteria in seven critical "bed-safety zones".
- **O3:** Empirically refine the process for measuring beds according to the proposed safety criteria in each of the seven critical areas.
- **O4:** Estimate the incidence and etiology of bed-related adverse events including close calls, injuries, and deaths.
- **O5:** Evaluate the attributable risk of each bed system and its sub-components for each outcome using a decision analytic model.
- **O6:** Design a system for prioritizing interventions to improve bed safety based on risks, benefits (avoided cost of morbidity and mortality), and cost of interventions.
- **O7:** Develop a strategic plan to mitigate the bed-related patient risks identified in VISN 8.

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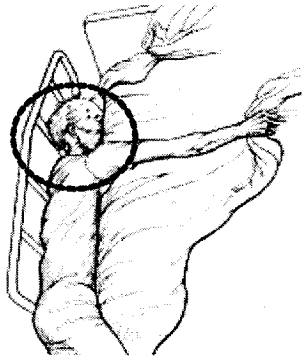
METHODS: OVERVIEW. Initially a pilot study for Objectives 1 through 3 will be conducted at the Tampa VAMC to finalize data collection processes and evaluate the surveys. Once methods are standardized similar data will be collected all VAMCs in VISN 8. Observational and survey methods will be used to address objectives 1-3. Trained data collectors will measure seven predetermined critical areas including gaps within side rails, distances between mattresses and side rails and between mattresses and head/footboards. To address objective 4 and 5, patient specific administrative information will be collected using the VHA's national Austin Automation Center (AAC) databases on all patients occupying a bed over the data collection period in long term care and medical/surgical units at Tampa VA only over a 45 day period. We will also review one year's worth of incident reports of bed-related entrapment from each VAMC in VISN 8 and VISN 16. During this period a standardized instrument will be used to collect data on all falls from bed, entrapments, and close calls. To address objectives 6 and 7 an expert panel will review results of the VISN-level data and determine evidence-based priorities and a strategic plan to mitigate risks in VISN 8.

ANTICIPATED IMPACT: The immediate outcome of this proposed Bed-Safety evaluation in VISN 8 pilot research is a reduction in patient risk of injury and entrapment related to bed systems. The result of this investigation will be an evidence-based decision making process on the replacement of bed systems. This process can be used to standardize purchasing through consolidated contracting based on an assessment of risk, benefit and cost. This proposed work extends the work of the FDA Bed Safety Working Group by validating and streamlining measurement procedures, providing the basis for training programs, and identifying processes for facilities to use in determining cost/benefits of mitigation strategies. Potential non-VHA users of data generated from this proposed study are the FDA, HCFA, JCAHO, and private industry.

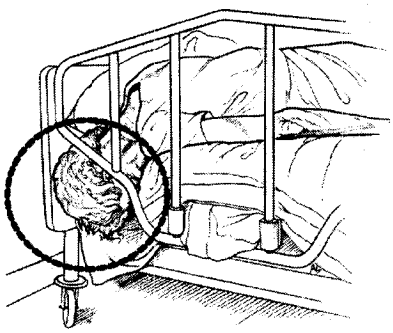
ATTACHMENT 1. SEVEN POTENTIAL ENTRAPMENT ZONES RELATED TO BEDRAILS

Bedrail use is a practice issue of growing concern to clinicians and administrators. Based on 102 incidents of head and body entrapment resulting in sixty-eight deaths and twenty-two injuries, the Food and Drug Administration (FDA) issued a Safety Alert in 1995 concerning hazards related to bedrails. All deaths involved entrapment of the head, neck, or thorax while most injuries involved fractures or lacerations of the extremities. Drs. Parker and Miles (1997) analyzed 74 bedrail-related deaths form the Unites States Consumer Project Commission files and found that 70% of victims were asphyxiated between the bedrail and the side of the mattress. Also, many bedrails have wide gaps within the rails that can lead to entrapment injuries (Capezuti, 2000). Several recently published newspaper articles have reported the risks associated with bedrails and have prompted public attention to this issue (Braun and Capezuti, 2000a; a refers to IBJ v. b refers to DePaul Jl of HC Law). Figure 1 shows the areas where bed rail entrapment is most likely to occur.

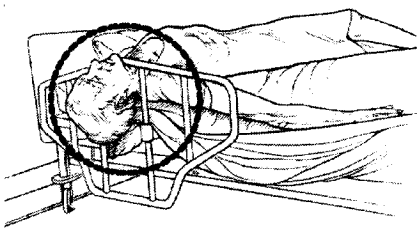
Entrapment Zone 1 (H)



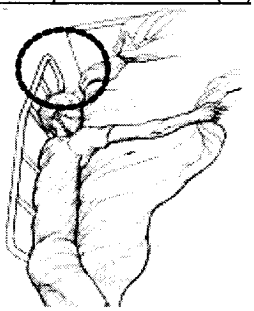
Entrapment Zone 2 (I)



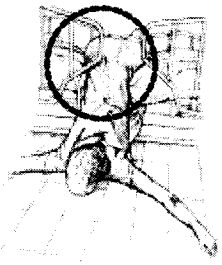
Entrapment Zone 3 (A)



Entrapment Zone 4 (D)



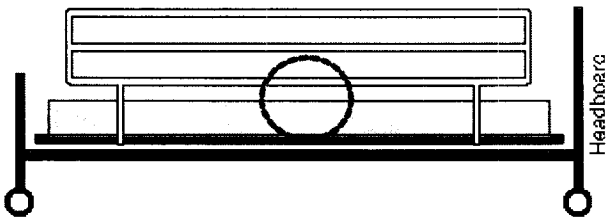
Entrapment Zone 5 (E)



Entrapment Zone 6 (F)



Entrapment Zone 7 (J)



ATTACHMENT II: BACKGROUND INFORMATION: THE HOSPITAL BED SAFETY WORKING GROUP

This workgroup was established in 1999 at the Department of Health and Human Services in Washington DC under the leadership of the Food and Drug Administration. The goal of the group is to reduce the risk of entrapment and injuries related to hospital beds, focusing on bed rails through standardization of definitions, standardization of the evaluation of beds, mattresses and side rails, and outreach to providers and patients. The working group is composed of representatives from government (including the VHA), professional and regulatory agencies (including HCFA, JCAHO), health care organizations, patient advocacy groups, and private industry. To date, the group has (1) reconciled regulatory definitions and requirements related to hospital beds; (2) authored "Universal Clinical Guidance for the Assessment for Use and Implementation of Hospital Bed Side rails in Hospitals, Long Term Care Facilities and Home Health Settings (not finalized as of April 2001); (3) developed a resident/family brochure on risks of side rails and alternatives to their use (posted on FDA website, (http://www.fda.gov/cdrh/beds/index.html) , and (4) proposed standards for seven bed system (bed/mattress/rail) measurements. These proposed measurement standards were systematically developed based on 1st and 5th percentiles for head, neck, chest measurements, then validated using actual entrapment data (Table 1).

It is expected that these measurement criteria will be submitted to the FDA in June 2001 for consideration as an FDA Guidance. The criteria were developed to be consistent with what the group believed will be international standards at a later date.

Table 1. Seven "Bed Safety Zones" and Recommended Measurement Criteria

BED-SAFETY ZONES	HEAD BREADTH < 120 mm	NECK DIAMETER < 60 mm	CHEST DEPTH > 318 mm
(1) Rail to mattress, horizontal measurement (H)		✍*	
(2) Board to mattress, horizontal measurement (I)		✍*	
(3) Within rail (A)	✍		
(4) Rail to bed end (board), both ends, 60 > D > 318 (D)		✍	✍
(5) Between split rails 60 > E > 318 (E)		✍	✍
(6) Top of compressed Mattress to bottom of rail, at ends of rail** (F)		✍	
(7) Top of compressed Mattress to bottom of rail, between rail supports (J)	✍		

Note: All dimensions are measured with bed in typical patient care positions except for Zones 1 and 4 which are measured in the flat bed position only

* allows for mattress compression by head

** End of rail is defined as the length of rail that extends beyond the rail support / post

ATTACHMENT III: PROCEDURE FOR MEASUREMENT OF ENTRAPMENT ZONES

A *Bed System Evaluation Toolkit* was developed by the FDA Bed Safety Working Group and includes a tape measure (to measure critical areas), a specially designed cone shaped device (to measure 2 1/3, 4 ¾, and 12 ½ inch spaces), a fish scale (to exert a predetermined force), and a weight to exert mattress compression that simulates the shoulder of a 170 pound adult.

Table 2. Evaluation Procedures for each Entrapment Zones

ENTRAPMENT ZONE	EVALUATION PROCEDURES	DEFINITION OF "PASS"
(1) Rail to mattress, horizontal measurement (H)	* Place bed in flat position, elevate side rails. (Elevate head end rails only for split rails.) * Push mattress against opposite side rails. * With tape measure, measure the horizontal distance between the side of the mattress and the inside surface of the side rail. * Repeat with head and knee elevated	Distance is less than 2 1/3 inches (60 mm)
(2) Board to mattress, horizontal measurement (I)	* Place bed in flat position. * Ensure bed ends are properly installed. * Push mattress to opposite end for each measurement * With tape measure, measure the horizontal distance between the end of the mattress and the inside surface of the bed end at head and foot end.	Distance is less than 2 1/3 inches (60 mm)
(3) Within rail (A)	* Place bed in flat position, elevate side rails * Insert cone in the maximum space within each rail. Attempt to pull cone through rail with 12 lbs of force	Pass: Cone does not pull past 4 ¾" (120 mm)
(4) Rail to bed end (board), both ends, 60 > D > 318 (D)	* Place bed in flat position, elevate side rails. * Insert cone between the side rail and bed end at the head and foot end. * Attempt to pull cone through the maximum space from the inside of the bed to the outside with 12 lbs. of force. OR * Alternatively, turn cone sideways and attempt to pull through minimum space	Cone does not pull past 2 1/3 " (60 mm) Cone passes freely through > 12.5" (318 mm)
(5) Between split rails 60 > E > 318 (E)	* Place bed in flat position, elevate side rails. * Insert cone at the maximum point between split rails. * Pull cone through from the inside of the bed to the outside with 12 lbs. of force. OR * Alternatively, turn cone sideways and attempt to pull through the minimum space. * Repeat with head and knee elevated	Cone does not pull past 2 1/3" (60 mm) Cone passes freely through > 12.5" (318 mm)
(6) Top of compressed Mattress to bottom of rail, at ends of rail** (F)	* Place bed in flat position, elevate side rails, push mattress towards opposite side. * Have 170 lbs person lie on his/her side on mattress at edge of mattress. Have person's shoulder positioned at end of rail. * With tape measure, measure the diagonal distance from the top of the compressed mattress to bottom of rail at the end of the rail. * Repeat with head elevated.	Distance is less than 2 1/3" (60 mm)
(7) Top of compressed Mattress to bottom of rail, between rail supports (J)	* Place bed in flat position, elevate side rails, push mattress towards opposite side. * Have 170 lbs person lie on his/her side on mattress at edge of mattress. Have person's shoulder positioned between rail supports. * With tape measure, measure the diagonal distance from the top of the compressed mattress to bottom of rail between rail supports. * Repeat with head elevated.	Distance is less than 4 ¾" (120 mm)

Before a side rail is utilized, a number of issues should be considered and addressed, such as:

What is the intended and functional purpose of the side rail?

- *Side rails have proven to be ineffective at keeping adult bed occupants from rolling or falling out of bed.*
- *Side rails are never to be used as a form of restraint - if they prevent the bed occupant from independently exiting the bed...they are acting as a restraint.*
- *The potential for serious injury is more likely to be related to a fall from a bed with raised side rails when the resident attempts to climb over, around, between, or through the rails, than from a bed without side rails in use.*
- *Side rails can be an effective device to assist with repositioning while in the bed or as an aid to getting into or out of the bed.*

Is the assisted living resident a safe "match" for a side rail?

- *The population at risk for entrapment are clients who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, and acute urinary retention that cause them to move about the bed or try to exit from the bed.*
- *Initial and ongoing evaluation and monitoring of the client and side rail should occur.*

Will the side rail be installed, utilized, and maintained in accordance to the manufacturer's recommendations?

- *Side rails must be designed to work with the bed "system", including the side rail, bed frame, and mattress.*
- *Loose or "wobbly" side rails should not be used.*
- *Side rails designed for youth or children are not meant to be used with adults and should not be used.*

Does the side rail being considered meet or exceed the FDA's dimensional guidance to reduce entrapments?

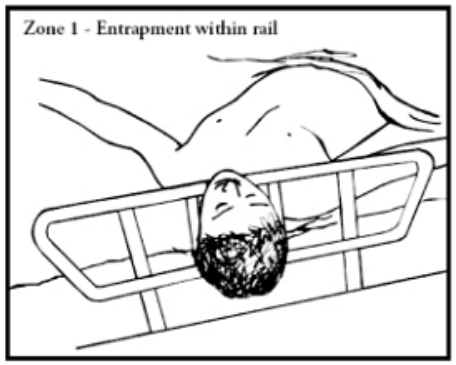
- *The Minnesota Department of Health has determined that in order to meet accepted health, medical, and nursing standards of practice, side rails known to be used by a client of a licensed home care provider must meet the FDA's dimensional guidance.*
- *To meet the FDA's dimensional guidance, each designated space in zones 1-3 must not exceed 4 3/4 inches and zone 4 must not exceed 2 3/8 inches (see front for zone pictorial).*
- *Many (not all) rental beds are sent with side rails that do not meet the FDA's dimensional guidance to reduce entrapment.*
- *When the design and use of a side rail is unsafe; strangulation, suffocation, bodily injury, or death can occur when clients or parts of their bodies are caught between side rails or between the side rails and mattresses. Refer to the drawings to the right.*

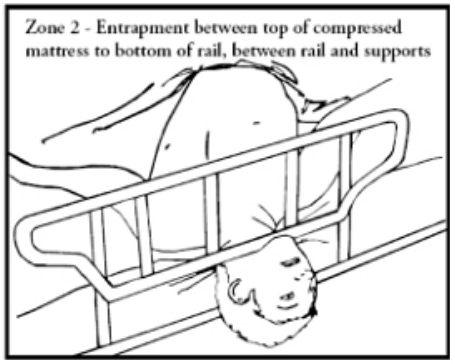
Based on the responses to these questions, an evaluation should be conducted to assess the relative risk of using the side rail compared with not using it for each individual resident.

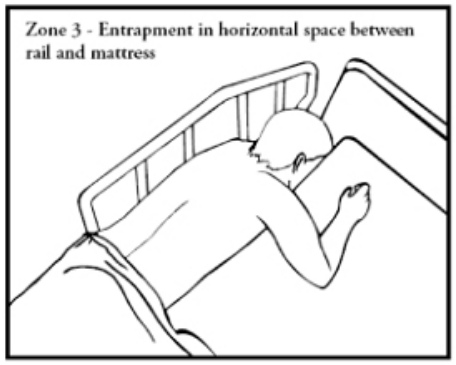
Residents and their family members should be educated about possible side rail danger to enable them to make an informed decision; including options for reducing the risks of side rail use.

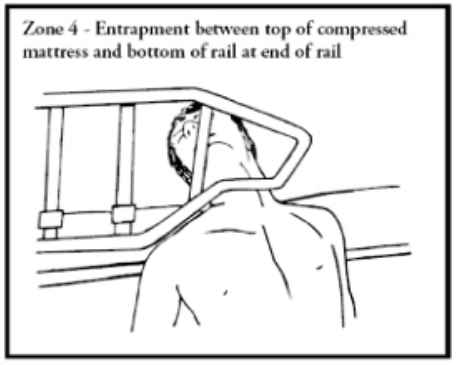
The resident's right to participate in care planning and make choices should be balanced with the assisted living's a responsibility to provide care according to an individual assessment, professional standards of care, and any applicable state and federal laws and regulations.

Drawings of Side Rail Entrapments









Between January 1, 1985 and January 1, 2013, the U.S. Food and Drug Administration (FDA) received 901 incidents of patients caught, trapped, entangled, or strangled in hospital-type beds. The reports included 531 deaths, 151 nonfatal injuries, and 220 cases where staff needed to intervene to prevent injuries.

Most patients were frail, elderly or confused.

Not all clients are at risk for side rail entrapment, and not all side rails and bed systems pose a risk of entrapment.

Side rails can prove very useful in certain limited situations. However, side rails can also function as a form of restraint, create a danger of the client falling to the floor from a greater height, create an entrapment danger, and even be a cause of death.

In response to continued reports of patient entrapments and deaths, the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau and representatives from national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers, formed a working group in 1999 known as the Hospital Bed Safety Workgroup (HBSW).

Using retrospective studies of side rail related deaths, the HBSW identified 7 potential entrapment zones in hospital beds and published side rail design dimensional guidance for bed manufacturers to minimize entrapments.

Unfortunately, many side rails in use around the world do not meet the recommended dimensional guidance, and entrapment injuries and deaths continue to occur.

This brochure was developed by Care Providers of Minnesota, a trade association representing assisted living facilities.

Care Providers of Minnesota

The intended purpose of this brochure includes:

- Elimination of preventable entrapments and injuries caused by the unsafe use of side rails
- Elimination of preventable deaths caused by the unsafe use of side rails
- Elimination of side rails acting as restraints
- Provide education to providers and consumers regarding side rail safety
- Provide a tool for assisted living facilities to use in educating residents and resident's representatives about the risks and benefits of side rails
- Decrease the frequency of side rail related assisted living deficiencies issued by the Minnesota Department of Health regarding side rail use

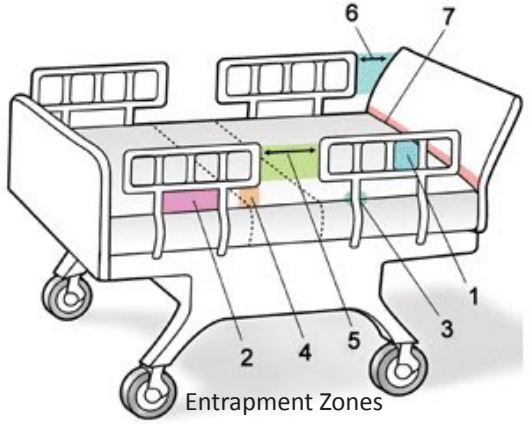
This brochure was provided by:

For more information:
http://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/hospitalbeds/default.htm

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2021

Using Bed Side Rails in Assisted Living Facilities



Entrapment Zones

Each year many assisted living residents and family members of residents request that a side rail be attached to a resident's bed. The basis of the request is generally to prevent a fall from the bed, provide assistance with transferring in or out of the bed, or providing assistance with repositioning while in the bed.

This brochure is designed to help assisted living facilities and their residents better understand the potential risks and benefits resulting from the use of side rails.

FEDERAL GUIDELINES FOR BED RAILS

Excerpted from State Operations Manual, Appendix PP - Guidance to Surveyors for Long Term Care Facilities. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ downloads/som107ap_pp_guidelines_ltcf.pdf.

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:

o 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)

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 https://ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center

Centers for Disease Control and Prevention at https://www.cdc.gov/falls/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhomeandrecreationalsafety%2Ffalls%2Findex.html

World Health Organization Fall Prevention in Older Age at https://www.who.int/publications/i/item/9789241563536

National Institute of Health- Senior Health at https://www.nia.nih.gov/health/topics/falls-and-falls-prevention.

Wandering and Elopement Resources
U.S. Department of Veterans Affairs VHA National Center for Patient Safety at https://patientsafety.va.gov/A_Toolkit_Patients_At_Risk_for_Wandering.asp

F710
(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.30 Physician Services
A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

§483.30(a) Physician Supervision.
The facility must ensure that—

§483.30(a)(1) The medical care of each resident is supervised by a physician;

§483.30(a)(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

INTENT §483.30(a)

The intent of this regulation is to ensure the medical supervision of the care of each resident by a physician and that orders for the resident's immediate care and needs are provided throughout the resident's stay.

DEFINITIONS §483.30(a)
"Attending physician" refers to the primary physician who is responsible for managing the resident's medical care. This does not include other physicians whom the resident may see periodically, such as specialists.

"Non-physician practitioner (NPP)" is a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).

"Nurse practitioner" is a registered professional nurse currently licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.

"Clinical nurse specialist" is a registered professional nurse currently licensed to practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

"Physician assistant" is a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians.

GUIDANCE §483.30(a)
A physician's personal approval of an admission recommendation must be in written form. The written recommendation for admission to the facility must be provided by a physician and cannot be provided by a NPP. This may be accomplished through a hospital transfer summary written by a physician, paperwork completed by the resident's physician in the community, or other written form by a physician. If a physician does not provide a written recommendation that the individual be admitted to the facility prior to the resident's admission, the physician's admission orders for the resident's immediate care as required in §483.20(a) will be accepted as "personal approval" of the admission **if** the orders are provided by a physician. Admission orders in lieu of a physician's written recommendation for admission to the facility cannot be provided by a NPP.

Generally, the term "attending physician" or "physician" may also include a NPP involved in the management of the resident's care, to the extent permitted by State law. However, when the regulation specifies a task to be completed "personally" by the physician, that task may not be delegated to a NPP.

Supervising the medical care of residents means participating in the resident's assessment and care planning, monitoring changes in resident's medical status, and providing consultation or treatment when contacted by the facility. It also includes, but is not limited to, prescribing medications and therapy, ordering a resident's transfer to the hospital, conducting required routine visits or delegating to and supervising follow-up visits by NPPs.

It is the responsibility of the facility to ensure that another physician supervises the care of residents when the attending physician is unavailable. The attending physician may designate another physician to act on his/her behalf when unavailable. If the attending physician is unavailable and does not designate another physician to act on his/her behalf, or the designated physician is unavailable, the facility must have a physician available who will supervise the care of the attending physician's residents.

There may be examples of physician orders in the medical record that would not impact a resident's medical care, such as instructions to contact a family member or providing date/time of an order; concerns related to these types of orders do not fall under the category of a physician's supervision of medical care and would not be cited here.

PROBES §483.30(a)

- Is there evidence that the attending physician supervises the resident's medical care? If not, what did the facility do?
- If the physician makes a change to the residents' plan of care, e.g. orders a new medication or changes a medication, is there evidence that the physician re-evaluated the effectiveness of the intervention and the resident's response? **NOTE**: the timing of the re-evaluation may vary depending upon the type of change, type of medication.
- If staff reported a change in medical status to the physician, how did the physician respond?
- If the attending physician was unavailable and could not respond, did the facility have a physician available to supervise the medical care of the resident? How did this physician respond?
- When a NPP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

The facility must ensure each resident has the right to designate an attending physician For potential concerns related to the resident having the choice of attending physician who is able and willing to meet the physician services requirements, see §483.10(d), F555, for additional guidance.

For concerns related to admission orders, see §483.20(a), F635. At the time each resident is admitted, the facility must have physician's orders for the resident's immediate care.

For concerns related to physician availability for emergencies 24 hours a day, see §483.30(d), F713.

DEFICIENCY CATEGORIZATION §483.30(a)

Examples of Level 4, immediate jeopardy to resident health and safety include, but are not limited to:

- The facility failed to ensure the physician conducted a medical evaluation of a resident with a new onset of seizures. As a result, anticonvulsant medications were prescribed, but the primary cause of the seizures was not evaluated to determine if it was neurological or secondary to another condition, such as infection or drug interaction. This placed the resident at risk for serious harm or death.
- The physician failed to provide laboratory orders for routine monitoring for a resident receiving anticoagulant medication, placing the resident at risk for significant adverse side effects including the risk for serious injury or death, such as gastrointestinal bleeding or stroke. The facility failed to follow up with the physician regarding the absence of laboratory orders and administered the anticoagulant medication as ordered.

An example of level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- The facility failed to ensure the physician supervised the resident's medical care, when the physician did not evaluate the effectiveness of treatments ordered for a skin condition, resulting in the development of a localized skin infection causing significant pain for the resident.

An example of Level 2, no actual harm, with potential for no more than minimal harm, that is not immediate jeopardy includes, but is not limited to:

- The facility failed to follow-up on recommendations from the dietitian for diet liberalization for a resident whose attending physician did not respond to phone calls. The facility then failed to contact another physician to assist with providing care for the resident when the facility was unable to reach the attending physician.

An example of Level 1, no actual harm with potential for no more than a minor negative impact on the resident includes, but is not limited to:

- The failure of the facility to ensure a resident's medical care is supervised by a physician or to ensure that the resident has orders for immediate care and needs always places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Other resources which may be useful:

National Council on Aging National Falls Prevention Resource Center at https://ncoa.org/professionals/health/center-for-healthy-aging/national-falls-prevention-resource-center

https://www.cdc.gov/falls/index.html?CDC_AA_refVal=https%3A%2Fwww.cdc.gov%2Fhomeandrecreationalsafety%2Ffalls%2Findex.html

World Health Organization Fall Prevention in Older Adults at https://www.who.int/publications/i/item/9789241563536

National Institute of Health-Senior Health at https://www.nia.nih.gov/health/topics/falls-and-falls-prevention

Wandering and Elopement Resources - U.S. Department of Veterans Affairs VHA National Center for Patient Safety at https://patientsafety.va.gov/A_Toolkit_Patients_At_Risk_for_Wandering.asp