



Bedrail and Assistive Device Safety and Regulation

Health Regulation Division

- 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

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).

- 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**

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

- 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](https://www.cpsc.gov/Recalls)



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

- 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 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!