



Department of Health

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Date: June 13, 2025
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Subject: Entrapment Risk with Bed Systems
and Components

Dear Nursing Home Administrator:

Recent incident investigations by the Department of Health ("Department") have led to concerns regarding the use and safety of bed side rails, otherwise known as side rails, safety rails, grab bars, assist bars, and enabler bars. Please remind your staff to be especially diligent in evaluating the risk of entrapment with these types of devices on all beds in your nursing homes. Additionally, to ensure substantial compliance at your Nursing Home, please review the requirements at 42 CFR §483.25(n) which indicates:

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.

- 1) Assess the resident for risk of entrapment from bed rails prior to installation.
- 2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.
- 3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.
- 4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

In addition, please review the requirements at 42 CFR § 483.90(d)(3) regarding inspections of bed frames, mattresses, and bed rails as part of a regular maintenance program to identify areas of possible entrapment.

The State Operations Manual, at F700, reminds providers: "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." Additionally, the State Operations Manual also outlines several key areas that need to be addressed for consideration of bed rail use, including resident assessment; informed consent; appropriate alternatives, installation, and maintenance and ongoing monitoring and supervision.

It is recommended that the Nursing Home conduct initial and ongoing reviews of beds to ensure that no mattress, side rail, or enabler bar has gaps that are larger than recommended in the Food and Drug Administration (FDA) document "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" issued on March 10, 2006. The FDA document details seven potential zones for patient entrapment and provides detailed diagrams and instructions on how to measure the open spaces between bed system components.

A bed system manufacturer's or distributor's designation of "entrapment free,"

"entrapment proof," or "design does not allow entrapment" does not obviate the Nursing Home's responsibility to diligently monitor the system for the duration of each bed's use. The Department of Health encourages Nursing Homes to re-examine systems to ensure that adequate safeguards are in place for all aspects of bed safety encompassing the function of the bed's use. Special attention should be given to the following:

- Review and use as a resource the FDA's Assessment Guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment>.
- Review the FDA's Clinical Guidance at: <https://www.fda.gov/media/88765/download>.
- Review the FDA's Guide to Bed Safety FACTS at: <https://www.fda.gov/medical-devices/hospital-beds/guide-bed-safety-bed-rails-hospitals-nursing-homes-and-home-health-care-facts>.
- Assessing healthcare bed systems and components—bed frames, mattresses, and side rails/enablers. Those whose open spaces are larger than the dimensions advised by the FDA Safety Guidance are a potential safety hazard for patient and resident entrapment.
- Reviewing facility policies and procedures for assessing the function and safety of bed systems and their components for both new and used bed systems.

Additionally, it is equally important to assess bed systems already in use. Wear and tear can compromise the integrity and function of bed components, rendering them potentially unsafe. Over time, mattresses become soft and compressed, and side rails and enablers can become loose, wobbly, and improperly positioned.

Nursing Homes must also evaluate bed components based on the characteristics of their population. For example, tall and/or bariatric individuals need bed system equipment that is properly designed and intended to accommodate their unique physical characteristics, such as adequate length of bed and mattress and/or density of mattress to support their body weight adequately and comfortably.

It is important that your Nursing Home remain attentive to prevent negative resident outcomes associated with entrapment. All staff should be aware of the Nursing Home's systems, policies, and procedures for identifying, managing, preventing, and responding to entrapment risk. Please consider posting this letter at all nursing stations and staff rooms.

The Department acknowledges and appreciates the progress made in reducing entrapment risks for your residents. We encourage your efforts to provide our residents with a safe environment that allows them to enjoy a meaningful and satisfying quality of life. If you have any questions regarding this correspondence, please contact the Division of Nursing Home and ICF/IID Surveillance via email to nhinfo@health.ny.gov.

Sincerely,

Stephanie E. Paton, RN, Director
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