

BED RAIL SAFETY



A Clinical Process Guideline

Laura Funsch, RN, BSN, MS – Director of Regulatory Strategy, LeadingAge Michigan
Karen Williams, RN, BA, CPHQ, CM – Health Care Surveyor, State of Michigan

Background

- Safety hazards related to bed rail use have been realized since 1990.
- Michigan's initial Bed Side Rail Clinical Process Guideline (CPG)
- Expected outcome for use of the revised Side Rail CPG



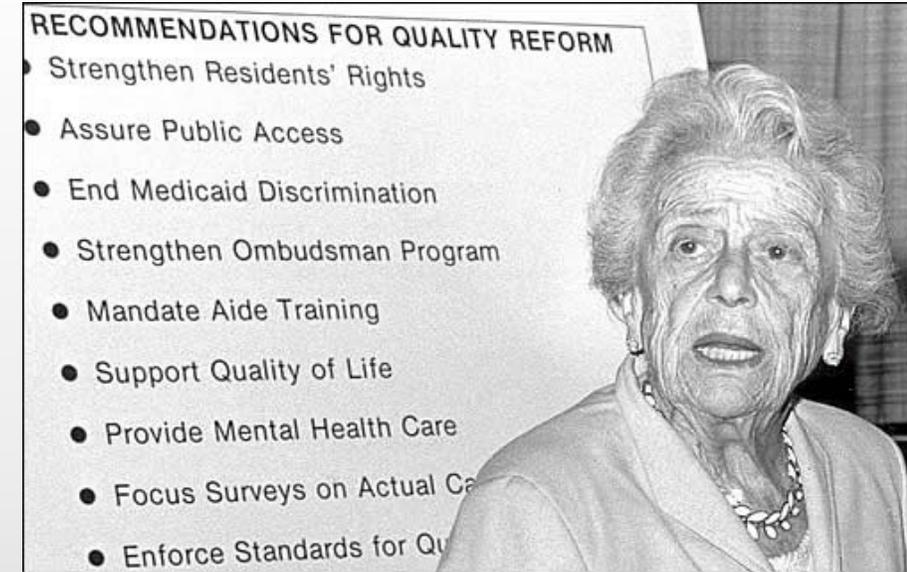
“Bed rails are used by many people to help create a supportive and assistive sleeping environment in homes, assisted living facilities and residential care facilities. This type of equipment has many commonly used names, including side rails, bed side rails, half rails, safety rails, bed handles, assist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

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/default.htm>

Federal Nursing Home Reform Act

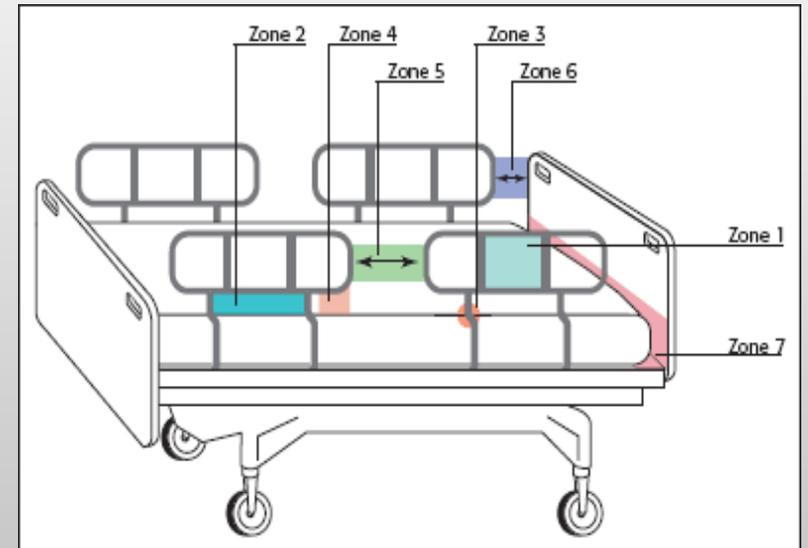
- **42 CFR 483.13(a)**, F221 applies to the use of physical restraints.

- **42 CFR 483.25(h)(2)**, F323 applies to assistive devices that create hazards (e.g., devices that are defective; not used properly or according to manufacturer's specifications; disabled or removed; not provided or do not meet the resident's needs (poor fit or not adapted); and/or used without adequate supervision when required).



483.25(d)(2) -To require that the facility ensure correct installation, use and maintenance of bed rails

- ✓ Including attempting to use alternatives prior to installing a side or bed rail,
- ✓ Assessing the resident for risk of entrapment from bed rails prior to installation,



483.25(d)(2) (cont)

- ✓ Reviewing the risks and benefits of bed rails with the resident and obtaining informed consent prior to installation,
- ✓ Ensuring that the resident's size and weight are appropriate for the bed's dimensions, and
- ✓ Following the manufacturers' recommendations and specifications for installing and maintaining bed rails.



MCL 333.21734

“...a nursing home shall give each resident who uses a hospital-type bed or the resident’s legal guardian, patient advocate, or other legal representative the **option of having bed rails**. A nursing home shall offer the option to new residents upon admission and to other residents upon request.....

A nursing home shall provide bed rails to a resident only upon receipt of a signed consent form authorizing bed rail use and a written order from the resident’s attending physician that contains statements and determinations regarding medical symptoms and that specifies the circumstance under which bed rails are to be used...”



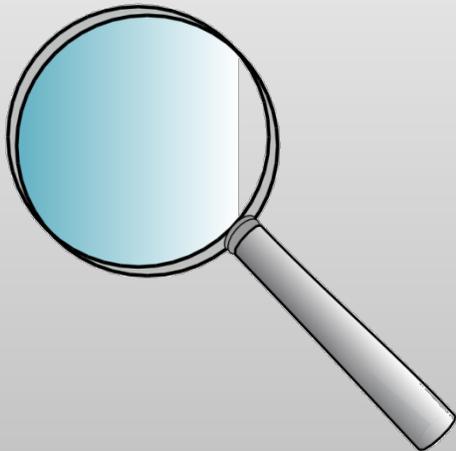
MCL 333.20201

“... resident is entitled to be free from mental and physical abuse and from physical and chemical restraints, except those restraints authorized in writing by the attending physician or a physician's assistant to whom the physician has delegated the performance of medical care services for a specified and limited time...”



Process Step 1: Assess

Evaluate all residents for safety needs
in relation to use of bed rails
on admission and reassessment –
identifying potential
medical needs/safety hazards



Assessment Guide Process Step

- Interdisciplinary Care Team (IDT) or representative discusses any concerns or indications of potential safety risks with resident to help determine if bed rails are needed.
- Reassure resident and family that in many cases residents can sleep safely without the use of side rails.
- Allow new residents a period of adjustment in determining safety risks and needs.



Assessment Guide Process Step



- Identify whether the resident experiences problems at night such as memory, visual or spatial perception issues, incontinence, pain, uncontrolled body movement, hypoxia, pressure ulcers and bed mobility, safe ambulation that may need to be addressed.
- Determine whether the resident's sleep is impacted by factors such as grieving, loneliness, boredom or other issues.
- Obtain/consider preferences/interventions individually designed for persons with life-long late night habits.

Assessment Guide Process Step

- Ensure that all underlying medical problems that affect resident symptoms are addressed and treated when appropriate. Treatments must also be evaluated for effect and impact on resident comfort and safety.
- Consider resident issues with esophageal reflux.
- Review resident's urinary and bowel elimination patterns if indicated.

Process Step 2: Implement

Implement and monitor effectiveness of least restrictive care plan interventions and work to mitigate environmental factors to reduce risk of injury



Implement Least Restrictive Intervention - Trials

Identify least restrictive interventions for any resident issues noted, such as but not limited to:

- ✓ Anticipate reasons residents get out of bed, such as hunger, thirst, need to go to the bathroom, restlessness and pain, need for skin care and hygiene.
- ✓ Frequent and scheduled monitoring/rounding of resident.
- ✓ Use transfer and mobility aids, such as trapeze as indicated.



Implement Least Restrictive Intervention - Trials

- ✓ Keep beds at lowest position with wheels locked while at same time, verify this lowest position does not have the same effect as a restraint.
- ✓ Consider use of floor mats for residents who are prone to rolling out of bed.
- ✓ Use beds that can be raised and lowered to assist in both resident and caregiver needs
- ✓ Consider the appropriateness of exercise or other therapeutic/restorative interventions to enhance ability to stand, transfer, or reposition self safely



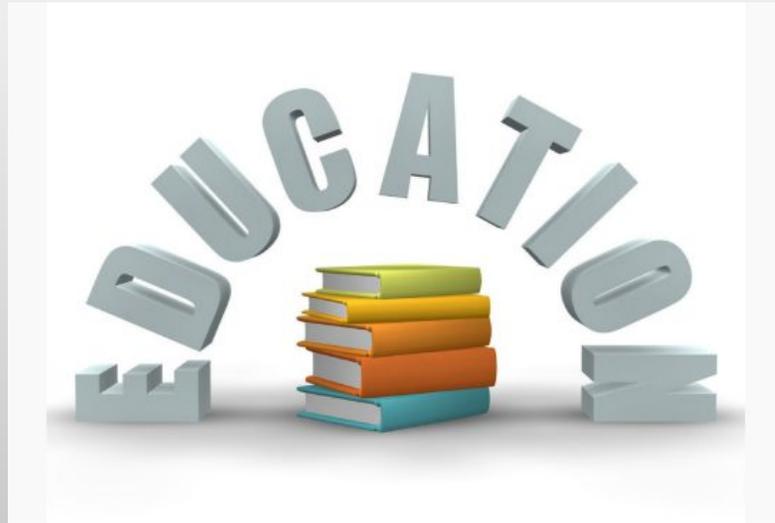
Implement Least Restrictive Intervention - Trials

- ✓ Evaluate and document the effect of interventions
- ✓ If the resident needs persist, conduct risk-benefit analysis for use of bed rails



Process Step 3: Education

Educate the resident/legal representative on the benefits and risks of bed rail use



The resident or legal representative has the 'right' to receive health-related information.

Resident/Legal Representative Education

- Resident issues that often result in side rail use includes memory disorders, impaired mobility, risk for injury, nocturia/incontinence, and sleep disturbances.
- Residents who are frail or elderly are at risk for entrapment.
- A resident with agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, and elimination issues are at risk for entrapment and/or suffer serious injury from a fall.



Resident/Legal Representative Education

- A resident may try to climb through/under or over rails or footboard which will greatly increase risk for injury.
- Strangling, suffocating, other bodily injury and death can occur when a resident is caught between rails or between rails and mattress.
- Ill fitted mattresses and rails increase the risk for injury to a resident.



Care Plan Check List

- ✓ Ensure the resident's care plan identify the specific medical symptom/indication for use of the bed rail.
- ✓ Ensure the resident's care plan have a 'time limit' for the bed rail use.
- ✓ Ensure the resident's care plan provide an explanation of how the use of a bed rail is intended to treat the specific resident's condition.
- ✓ Ensure the resident's care plan identify and address any underlying problems causing the medical symptom/indication for use.

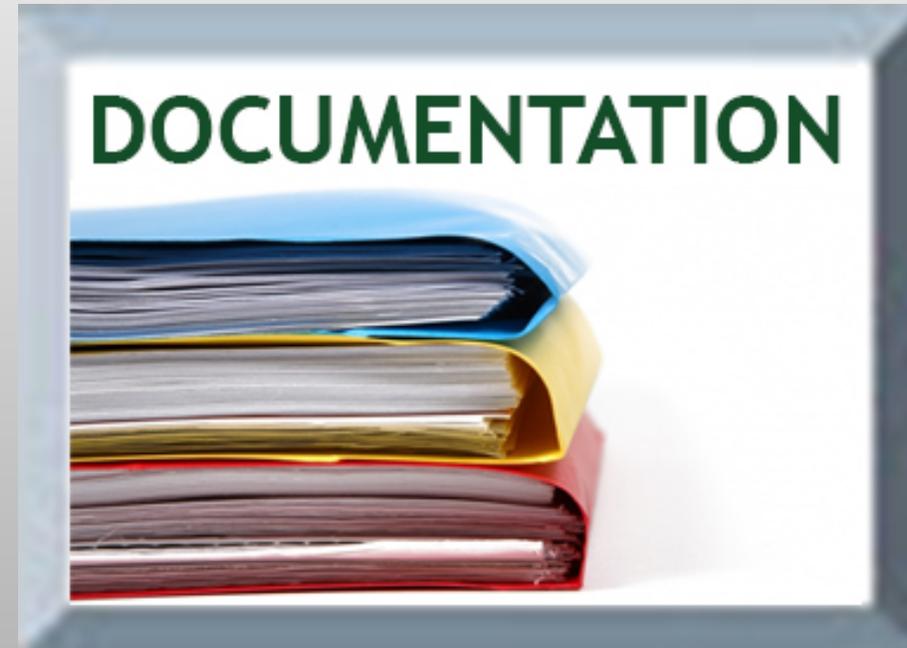
Care Plan Check List

- ✓ Ensure there care planned interventions identified to mitigate resident specific risks associated with the use of a bed rail, such as but not limited to:
 - Loss of autonomy, dignity and self-respect
 - Withdrawal, depression or reduced social contact
 - Reduced independence, functional capacity and quality of life



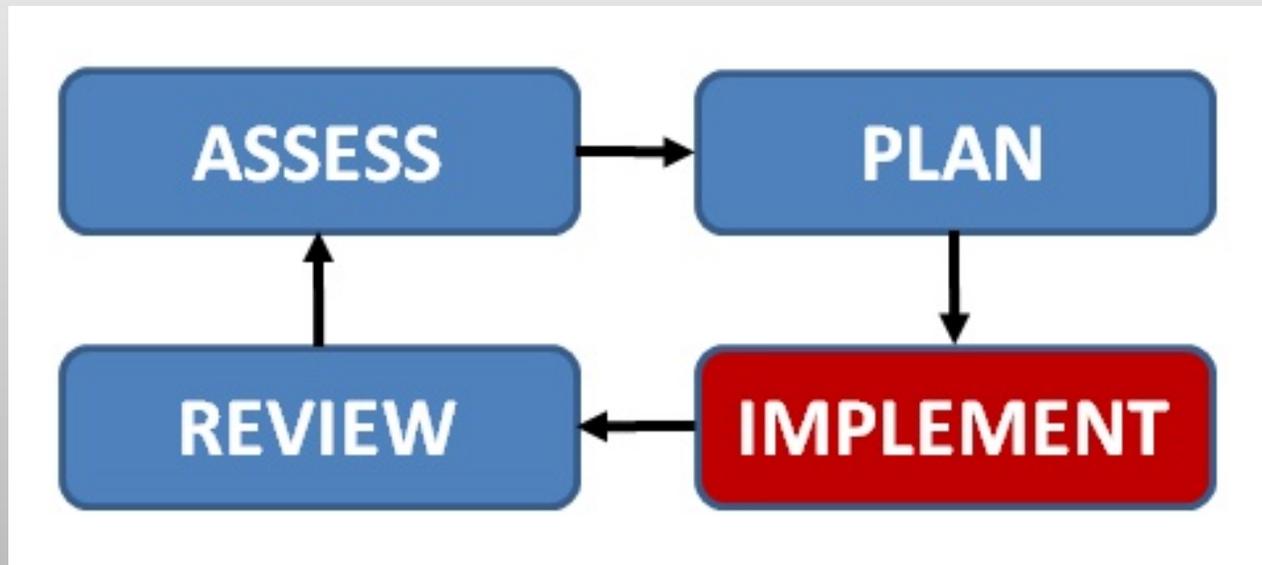
Care Plan Check List

- ✓ Ensure the resident's care plan identify the specific time periods for when the bed rail is to be used.
- ✓ Ensure there is documentation reflecting the plan of care has been consistently implemented.



Process Step 5: Implement When Indicated

Implement and monitor resident response to bed rails when indicated and ordered by the physician



Implement Bed Rails When Indicated

The use of bed rails should only be utilized for the purpose(s) intended and when they assist the resident to attain/maintain their highest practicable level of physical or psychological well-being.

Implement Bed Rails When Indicated

- Determine that the benefits of bed rail use outweigh the risks:
 - ✓ aiding in turning and positioning in bed,
 - ✓ providing a hand hold to get into and out of bed,
 - ✓ providing a feeling of comfort and safety,
 - ✓ reduce the risk of falling when being transported,
 - ✓ providing easy access to bed controls

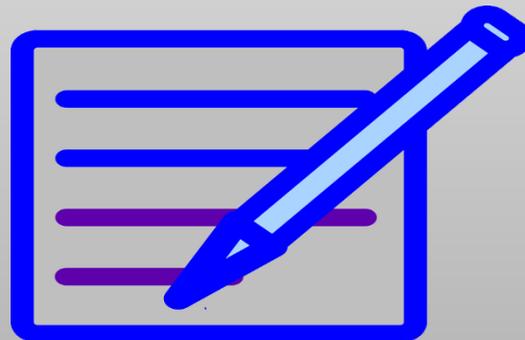
Implement Bed Rails When Indicated

- Assess the appropriateness of the bed and rails for safety (see assessment/evaluation for conformance to the Food and Drug Administration's (FDA) bed system entrapment zones).
- Utilization of consistent evaluators of beds and entrapment zones provides less variance in evaluations.



Implement Bed Rails When Indicated

- Document and log for the first four days following initial use or changes to equipment tests to determine appropriate fit and usage of the bedrail.
- Document and log monthly compliance with bed and rail specifications, resident outcomes, and attempts to move to lesser restrictive devices and then quarterly thereafter until discontinued.



Implement Bed Rails When Indicated

- Take corrective actions for any variances identified and/or update care plan as indicated.
- When evaluating the safe use of a hospital bed, component or accessory, caregivers should recognize that the risk for entrapment may increase if a hospital bed system is used for purposes, or used in a care setting, not intended by the manufacturer.

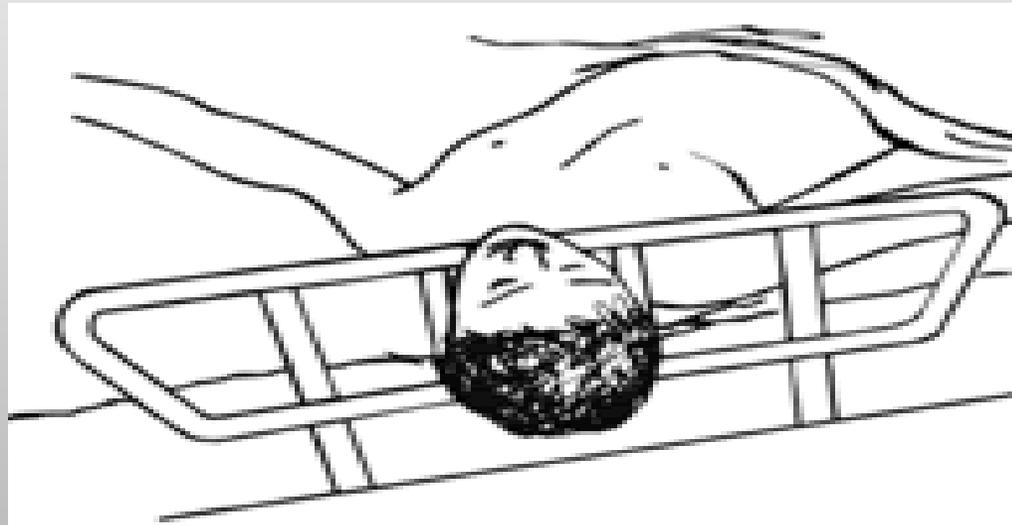
Assessment/evaluation for conformance to FDA's bed system entrapment zones

- Has a member from a select interdisciplinary group measured existing bed frame, mattress/overlays/specialty mattresses etc., bed rails and other accessories to ensure that they are compatible with each other?
- Evaluate resident's bed according to safety criteria in seven critical "bed-safety zones".

Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 1 – Within the Rail

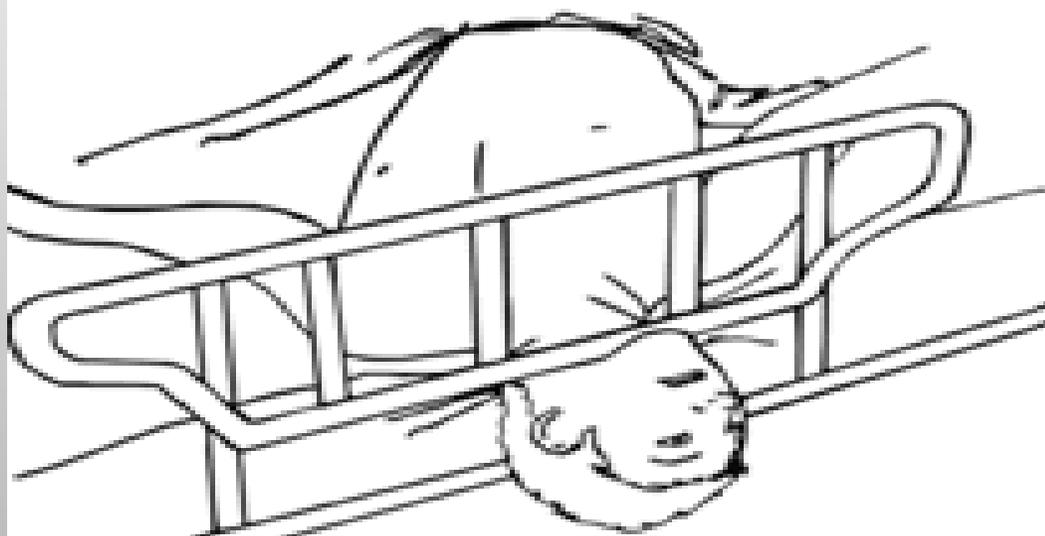
This space should be less than 4 3/4 inches, representing head breadth.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 2 - Under the Rail, Between the Rail Supports or Next to a Single Rail Support

The dimensional limit of 4 3/4 inches is recommended to prevent head entrapment.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 3 – Between the Rail and the Mattress

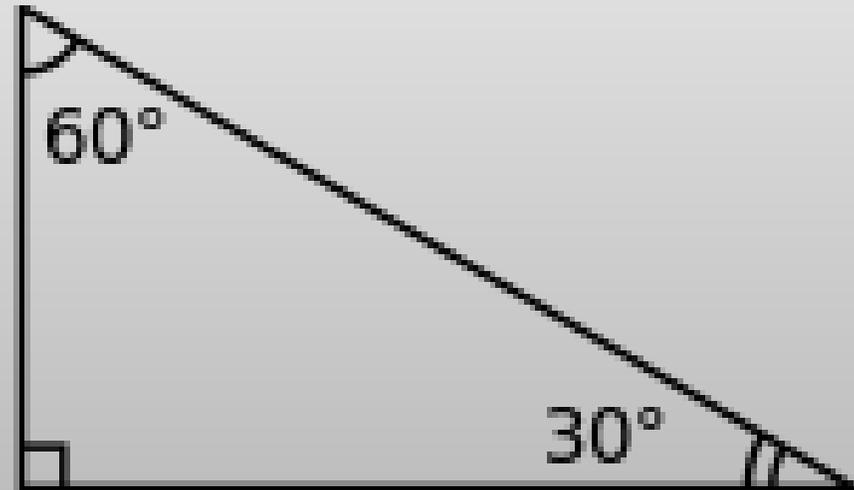
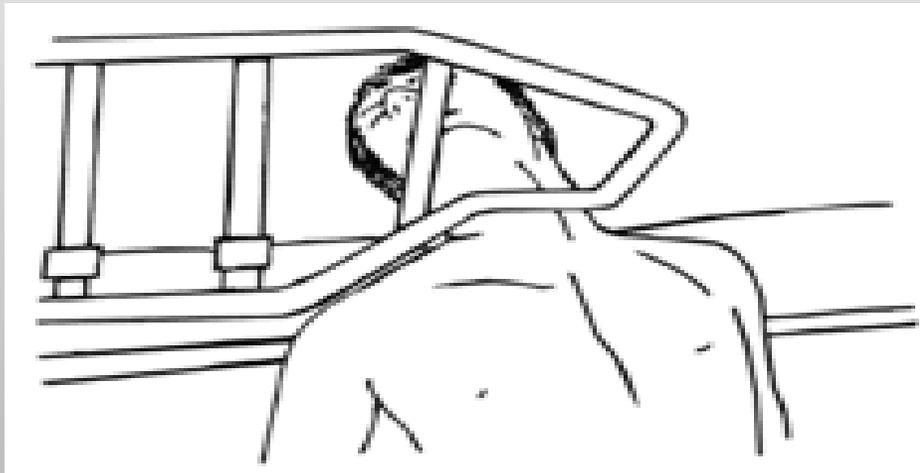
The dimensional limit of less than 4 3/4 inches is recommended.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 4 – Under the Rail at the Ends of the Rail

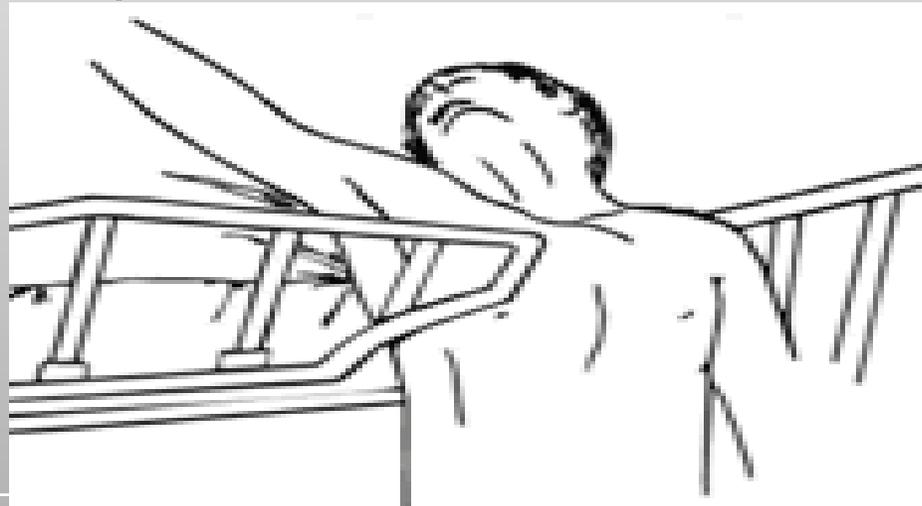
A dimensional limit of less than 2 3/8 inches measured between the mattress support platform and the lowest portion of the rail at the rail end.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 5 – Between Split Bed Rails

- It occurs when partial length head and foot side rails (split rails) are used on the same side of the bed. Rationale must be documented in care plan when split rails are used instead of full rails.
- In addition, any V-shaped opening between the rails may present a risk of entrapment due to wedging.
- Nursing Homes are to report entrapment events at this zone to the FDA.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 6 – Between the End of the Rail and the Side Edge of the Head or Foot Board

- It is the space between the end of the rail and the side edge of the headboard or footboard.
- In addition, any V-shaped opening between the end of the rail and the head or footboard may present a risk of entrapment due to wedging.
- Nursing Homes are to report entrapment events at this zone to the FDA.



Assessment/evaluation for conformance to FDA's bed system entrapment zones

Zone 7 – Between the Head or Foot Board and the End of the Mattress

- It is the space between the inside surface of the head board or foot board and the end of the mattress.
- This space may present a risk of head entrapment when taking into account the mattress compressibility, any shift of the mattress, and degree of play from loosened head or foot boards.
- Nursing Homes are to report entrapment events at this zone to the FDA.



Reporting an Entrapment Adverse Event

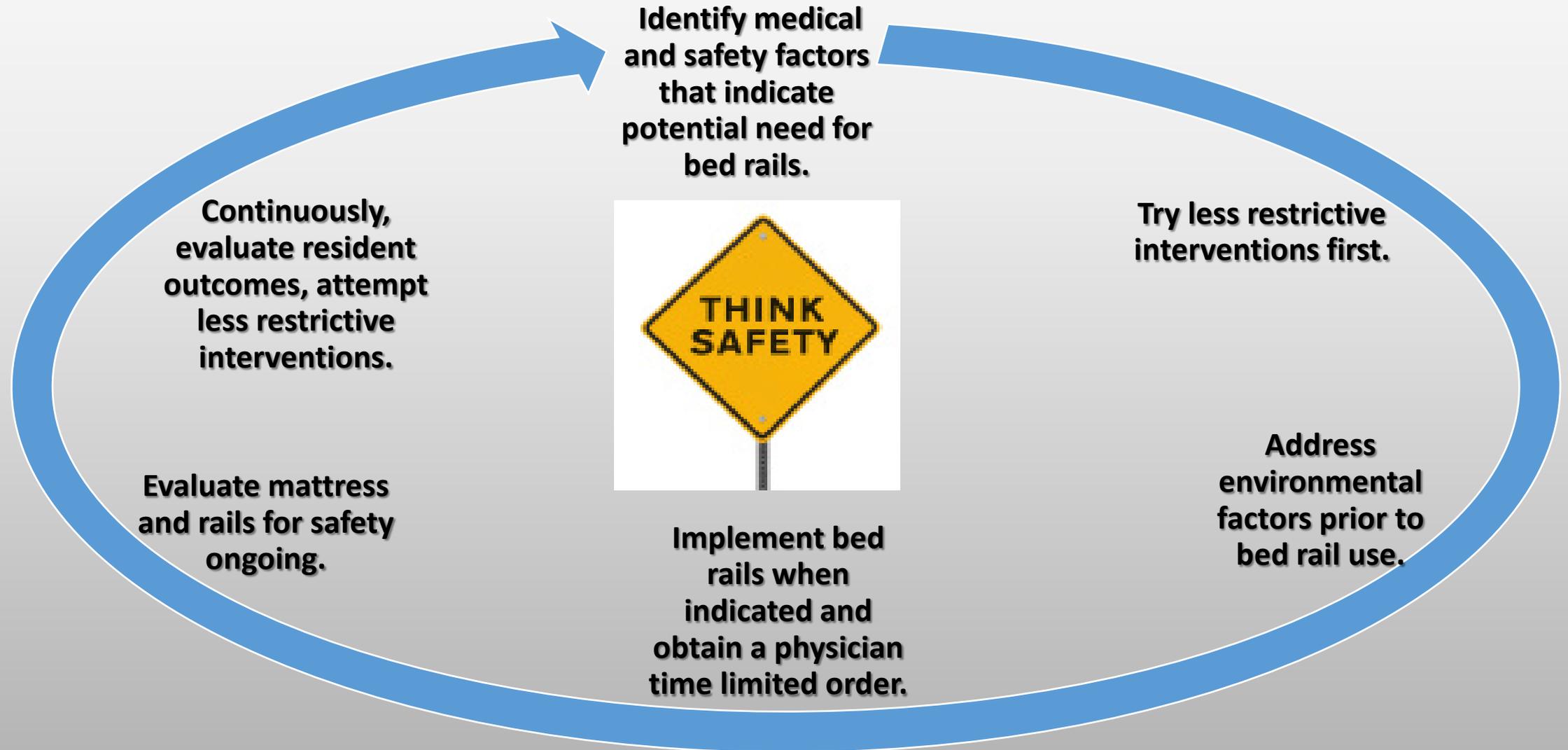
To improve the quality of entrapment adverse event reports, the following information is important and helpful to include:

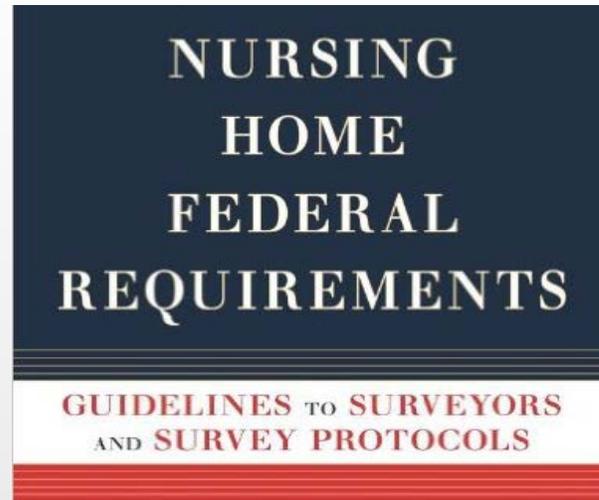
- the exact location or zone of entrapment
- the body part that was entrapped, and, if possible, the size of the entrapped body part (i.e., head breadth, neck diameter, chest depth)
- the position of the rails (fully raised, intermediate, or lowered)

Reporting an Entrapment Adverse Event

- type of rails in use (full length, 3/4 length, 1/2 length, split rails or 1/4 length), and the number of side rails raised at the time of the event
- the articulation of the bed deck (which sections of the deck were raised, and the approximate degree of elevation for each deck section)
- mattress type, mattress height, and height of the rail from the top of the mattress, and
- information on the size of the gap that contributed to the **entrapment**

Re-evaluation





F221 – The resident has the right to be free from any physical restraints

- “Physical restraints” are defined as any manual method or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body..”

Could the use of a bed rail be cited?

It could be if:



- ✓ The facility did not follow a **systematic process** of evaluation and care planning prior to using bed rails and alternatives to the bed rail have not been tried.
- ✓ There is no documentation of **Medical Symptoms** that led to the consideration of the use of bed rails? (“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.)
- ✓ The facility did not determine how the use of bed rails would treat the medical symptom.
- ✓ The facility is unable to show the bed rail is being used to protect the resident’s safety, and/or assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being.
- ✓ The facility has not used the **least restrictive** device for the **least amount of time**.

Care Area Assessments – Restraint Use

Did the facility use the Care Area Assessments (CAAs) to **evaluate the appropriateness** of the bed-rail being used as restraint?

Care Area Assessment

1. Delirium
2. Cognitive Loss/Dementia
3. Visual Function
4. Communication
5. Activity of Daily Living (ADL) Functional/Rehabilitation Potential
6. Urinary Incontinence and Indwelling Catheter
7. Psychosocial Well-Being
8. Mood State
9. Behavioral Symptoms
10. Activities
11. Falls
12. Nutritional Status
13. Feeding Tubes
14. Dehydration/Fluid Maintenance
15. Dental Care
16. Pressure Ulcer
17. Psychotropic Medication Use
18. Physical Restraints
19. Pain
20. Return to Community Referral



Case Review

“....the facility failed to obtain a physician’s order with medical indication for use, a resident’s written consent with explanation of risks and benefits, side rail measurements, and monitor side rail use for one... of two residents...”

Facts:

1. Observation of resident bed with bilateral one-half side rails on bed
2. Interview with resident revealed, “I don’t like it. It’s hard to get into bed”. Interview with DON revealed, “I don’t know where that bed came from. It’s not like any of our other beds”.
3. Record review revealed there were no physician’s orders, no resident consent, and no assessment or measurements for the use of bed rails. Quarterly MDS revealed resident was cognitively intact and required extensive assistance with bed mobility, transfer and toilet.

F 323 - ACCIDENTS AND SUPERVISION - FALLS

“According to medical professional studies, the potential for serious injury is more likely from a fall from a bed with side rails than from a bed where the side rails are not used. (Miles, Irvine, P. Deaths caused by physical restraints.”

Gerontologist 1992;32(6):762-6 and Parker K, Miles SH. Deaths caused by bed rails. J Am Geriatr Soc 1997;45(7):797-802)

F 323 - ACCIDENTS AND SUPERVISION - ENTRAPMENT

“The facility failed to ensure that Resident 1's immediate environment remained free from accident hazards by not putting down the resident's side rails when the resident was not being turned...Resident 1 was found with her head stuck between the bed rail and the bed, her chin was resting on the lower portion of the bed rail and her feet were on the floor. Resident 1, who was totally dependent for all activities of daily living, choked to death on the side rail while she was unable to free herself from the side rail...”

Other Possible Regulations Which May Apply

- Residents Rights
- Resident Behavior and Facility Practice
- Quality of Life
- Quality of Care
- Administration

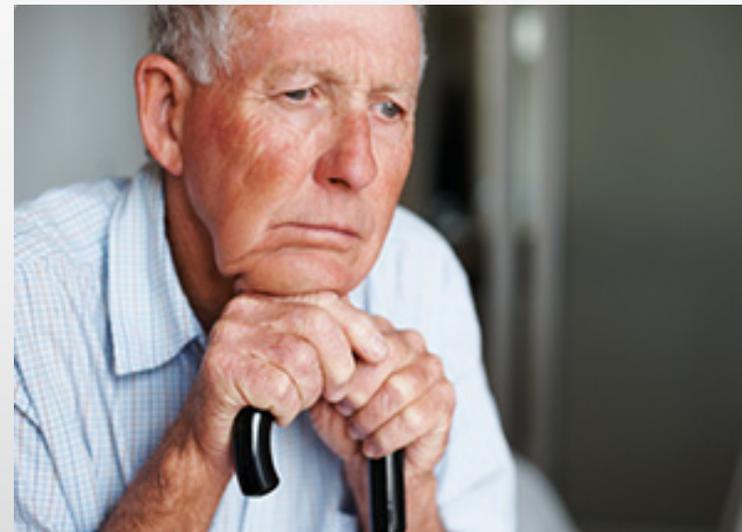


Observation examples:

- Is the spacing correct? Is the bed rail defective? Installed correctly? Removed? Not provided? Does it meet the resident's needs (poor fit or not adapted)?
- Is bed rail up or down when not in use?
- Is the bed rail fixed/not moveable (grab bar)? Does it restrict the resident's movement?
- Is the bed rail moveable, does it function properly?

Observation examples:

- Is the resident capable of moving the bed rail up and down when they want to?
- Does the resident look trapped or distressed, or secluded by the bed rail?
- Can the resident see over/through the bed rail?
- Is the bed rail used with/without adequate supervision, in relation to the facility's assessment of the resident?
- Does staff implement the care plan consistently over time and across various shifts?



Interview questions with Resident/Responsible Party examples:

- Did the resident or legal surrogate make an informed choice about the use of the use of the bed rail, the potential risks and benefits of all options under consideration?
- Do you know why you have bed rails? How do you use them?
- Can you put them up and down when you want?
- How does having bed rails make you feel?

Interview questions with Staff examples:

- Why is the use of a bed rail a hazard? What are the 7 Entrapment zones?
- Why does your resident have this device, and how is it's use care planned?
- Is your resident using the bed rail as care planned?

Record Review examples:

- Physician order with specific medical indication for use and time frames?
- Signed resident/responsible party consent with proof of education?
- Bed entrapment assessments as required?
- Risk/benefit analysis?

Record Review examples:

- Is there an accurate, comprehensive resident assessment reflecting the bed rail as a restraint, if it is acting as a restraint (MDS section P)?
- Comprehensive care plan with appropriate Nursing Diagnosis, goals, interventions, and ongoing reevaluation?
- Comprehensive Policy and Procedure on the use of bed rails?
- Evidence of staff education (sign in logs and syllabus)?

Best Practices

- Identification, assessment and planning for persons at high risk for entrapment.
- A defined and routine inspection process to eliminate the hazards of poorly fitting or mismatched equipment.
- Avoidance of bed rail use as a protective restraint.
- Ongoing monitoring and staff training.



Questions?

