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<p>ENTRAPMENT:</p> <p>IT'S NOT JUST FOR LAW AND ORDER ANYMORE</p>	
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<p>Restraints in the Past: Definitions</p>	
<ul style="list-style-type: none"> • Restraint regulations were previously under 483.13, Resident Behavior and Facility Practices. • <u>42 CFR 483.13(a): "The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms."</u> 	

Restraints in the Past: Definitions



- **Physical Restraint:** "any manual method or physical 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."
- **Medical Symptom:** "an indication or characteristic of a physical or psychological condition."
- **Freedom of Movement:** "any change in place or position of the body or any part of the body that the person is physically able to control."
- **Removes Easily:** "the manual method, device, material, or equipment, can be removed intentionally by the resident in the same manner as it was applied by the staff (e.g. side rails are put down, not climbed over) . . . considering the resident's physical condition and ability to accomplish objective (e.g. transfer to a chair).

See State Operations Manual, Appendix PP, Guidance to Surveyors.

Restraints in the Past: Examples



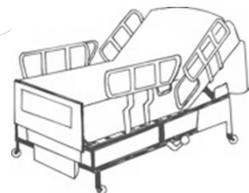
- Using side rails that keep a resident from voluntarily getting out of bed.
- Tucking in or using Velcro to hold a sheet, fabric, or clothing tightly so that resident's movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars, or belts that the resident can not remove easily, that prevent the resident from rising; and
- Placing a resident in a chair that prevents that resident from rising.



See State Operations Manual, Appendix PP, Guidance to Surveyors.

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Restraints in the Past: Side Rails



- "Side rails *sometimes* restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms or assist with physical functioning." See State Operations Manual, Appendix PP, Guidance to Surveyors.
 - Treating Medical Symptoms (must have a physician's order)
 - Note: Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of physical restraints.
 - Side Rails for Physical Functioning/Positioning

Why Fix What's Not Broken?



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**IF IT'S NOT
BROKEN
FIX IT
UNTIL IT IS**

- Codified guidance that was already in place related to using the least restrictive alternative before using restraints.
- Commentators pointing to the "unsafe" use of bed rails.
- The risk of entrapment.
- Documented cases of residents being injured or suffocating due to the use of bed rails.

Why Fix What's Not Broken?: Examples of Bed Rail Entrapment

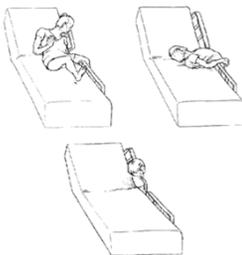


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Case 1:

In Case 1, an obtunded patient with a traumatic head injury died of asphyxiation. Videotape frames show two phases of movement: the patient leaving the bed and the patient becoming entrapped in the bedrail. *Figure 1a* shows the patient's left leg moving off the bed and into the space between the upper and lower bedrails. *Figure 1b* shows the patient's torso sliding into the slot between the upper and lower bedrails. The tape shows that once the patient's legs were in the slot, the raised head of the bed allowed the patient to slide into the slot. After the patient's pelvis moved off the bed, his weight pulled him into the space between the upper bedrail and the mattress frame.

Figure 1c shows the final position of the patient, in which the patient is suspended with his thorax lodged and compressed in a 6-inch gap between the upper bedrail and the mattress frame. Ten minutes elapsed between the time that the nurse last centered the patient on the bed and the time that the patient became positioned as shown in *Figure 1a*. Two more minutes passed from the time the patient was in the position in *Figure 1a* to the time that he was in the position shown in *Figure 1c*. The patient was found asphyxiated 14 minutes after reaching the position in *Figure 1c*, and resuscitation efforts failed.



Why Fix What's Not Broken?: Examples of Bed Rail Entrapment



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Case 2:

Case 2 involved a confused, agitated, small elderly person who died after sliding between the mattress and the bedrail. *Figure 2* shows the patient's torso compressed in the space between the bedrail and the mattress, with the buttocks hanging above the floor. With the mattress pressed against the opposite bedrail, the space was only 4 inches wide. *Figure 1c* shows the final position of the patient, in which the patient is suspended with his thorax lodged and compressed in a 6-inch gap between the upper bedrail and the mattress frame. Ten minutes elapsed between the time that the nurse last centered the patient on the bed and the time that the patient became positioned as shown in *Figure 1a*. Two more minutes passed from the time the patient was in the position in *Figure 1a* to the time that he was in the position shown in *Figure 1c*. The patient was found asphyxiated 14 minutes after reaching the position in *Figure 1c*, and resuscitation efforts failed.

The patient in Case 2 had fallen from her bed on several previous occasions. On two occasions shortly before her death, the patient was found trapped by the bedrail. The patient had been monitored with a string-type position alarm that sounds when a patient moves out of position and pulls a cord out of an alarm box. The alarm did not sound during her death because the string was not pulled out of the alarm box. The alarm failed during a previous bedrail entrapment when the alarm box was pulled from the headboard and dragged across the mattress. The patient did not use the nurse call signal (seen hanging over the bedrail) before this or previous falls.



**Why Fix What's Not Broken?:
Examples of Bed Rail Entrapment**

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Conclusions:

- Confused, agitated people who behave impulsively are at an especially high risk of entrapment.
- The patient in Case 1 was semiconscious; the patient in Case 2 was confused. Both were impulsive and actively mobile.
- Both had experienced "rehearsal incidents" with nonlethal bedrail entrapments shortly before their deaths.

APPENDIX
Drawings of Potential Entrapment in Hospital Beds

**Why Fix What's Not Broken?:
Examples of Bed Rail Entrapment**

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- **Bryant v. Oakpointe Villa Nursing Ctr., Inc. 684 N.W. 2d 864 (Mich. 2004):**
 - **Facts:** Resident with no control over locomotive skills had an order from the attending physician and medical director authorizing the use of various physical restraints, including bed rails to keep the resident from sliding out of the bed. On March 1st, CNAs noticed that the resident was tangled up in her sheets and there was a gap between the mattress and bed rails. The CNAs informed their supervisor that the wedges used to fill the gap were slipping out.
 - On March 2, the resident "slipped between the rails of her bed and was in large part out of the bed with the lower half of her body on the floor but her head and neck under the bed side rail and her neck wedged in the gap between the rail and the mattress, thus preventing her from breathing." The Resident died as a result of asphyxiation.
 - **Allegations:** Plaintiff alleged that the nursing facility was negligent in four distinct ways: (1) by failing to provide "an accident-free environment" for her aunt; (2) by failing to train its Certified Evaluated Nursing Assistants (CENAs) to recognize and counter the risk of positional asphyxiation posed by bed rails; (3) by failing to take adequate corrective measures after finding Ms. Hunt entangled in her bedding on the day before her asphyxiation; and (4) by failing to inspect plaintiff's bed arrangements to ensure "that the risk of positional asphyxia did not exist for plaintiff's decedent."

**Changes with the New
Requirements of Participation**

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- Restraint regulations moved to 42 CFR 483.12, Freedom From Abuse, Neglect, and Misappropriation.
- New requirements specifically related to Bed Rails in 483.25, Quality of Care.
- New requirement for maintenance checks of all bed frames, mattresses, and bed rails to identify areas of possible entrapment in 483.90(c)(3), Physical Environment.

**The New Requirements of Participation:
The Same Old Stuff (Or is it?)**

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- **Resident Rights:** "The Resident has the right to be treated with respect and dignity, including: (1) the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with § 483.12(a). 42 CFR 483.10(e)(1).
- **Freedom from Abuse, Neglect, Exploitation:** "The resident has the right to be free from abuse, neglect . . . and any physical or chemical restraints not required to treat the resident's medical symptoms. (a) The Facility must – (2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints. 42 CFR 483.12(a)(2).

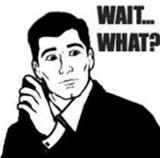
**The New Requirements of Participation:
Requirements for Bed Rails**

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Quality of Care – 42 C.F.R. § 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:

- (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.



**The New Requirements of Participation:
Requirements for Bed Rails**

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- Bed Rail requirements apply to all bed/side rails – even those that are not considered a restraint.
- Reports that bed rails are now *presumed* to be restraints.
- To rebut this presumption, must have detailed documentation that the bed rail is not a restraint.
- Bed rails that could be considered a restraint must *also* meet the old requirements of 42 CFR 483.12(a)(2), including medical necessity and least restrictive alternative.
- Informed consent means written consent
- Document the least restrictive or appropriate alternatives in the resident's medical chart.



**The New Requirements of Participation:
Assessing for Entrapment**

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- The clinical team must assess the resident for a risk of entrapment prior to installing side rails.
- Create a resident assessment tool for entrapment
- Use the resident assessment tool during admission
- Conduct entrapment assessments on residents with bed rails at regular intervals.



**The New Requirements of Participation:
Assessing for Entrapment**

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Objective Assessment:

- Use the manufacturer's guidelines
- Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm>
- Assess the Resident's behaviors and diagnoses



**The New Requirements of Participation:
Assessing for Entrapment**

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What are we going to do tonight Brain?

Same thing we do every night Pinky...



...TRY TO TAKE OVER THE WORLD!

Subjective Assessment:

- Sometimes you have to eyeball it.
- Will the resident's head fit through the bed rail?
- Does the resident slide in the bed?
- Does the resident have a tendency to move around a lot?
- Is there a large gap between the headboard and the mattress and/or the mattress and the bed rail?
- Document, Document, Document!

The New Requirements of Participation: Requirements for Bed Rails

- It is best practice to assume that the bed rails are restraints.
- Document the medical necessity.
- Get the physician's order.
- Document the other least restrictive alternatives that were used.
- Document the discussion with the resident or resident representative with a thorough informed consent acknowledgement.





The New Requirements of Participation: Physical Environment





42 CFR 483.90: Physical Environment:

- **Space and Equipment (c)(3):** Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, facility must ensure that the bed rails, mattress, and bed frame are compatible.

The New Requirements of Participation: Physical Environment

- Create a maintenance assessment tool which includes specific measurements for each area of the bed.
- Manufacturer specifications provide the necessary measurements.
- Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm>
- Get inventive to ensure there are no gaps between the bed frames and mattresses or between the mattresses and bed rails.





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