Points from Propel
Entrapment Risk and Side Rails

Entrapment risk is present in every level of care, even in the home setting. Basically, any time a rail or bar is attached to the bed frame, placed under the mattress, or near the bed frame or mattress, the risk of entrapment is present. The level of risk varies based on the device, the entrapment zones created, and the resident's age, size, physical strength and cognitive status.

There are many misconceptions regarding side rails as assistive devices or protection and unfortunately side rail usage can result in serious injury and even death. Looking at some misconceptions, statistics, resulting litigation, and regulatory risk related to entrapment will offer insight and identify opportunities to improve bed safety, reduce entrapment, and mitigate the risk.

Misconceptions

- Side rails keep residents safe
- Side rails prevent falls
- Side rails should be placed automatically at the resident's or family's request
- Only full side rails present an entrapment risk
- Only full side rails meet the definition of a restraint
- Assist bars do not create a risk of entrapment

Statistics

- Approximately 550 nursing home resident deaths secondary to bed rail entrapment have been reported since 1995.
- 284 entrapment deaths related to adult portable bed rails were reported to CPSC (Consumer Product Safety Commission) between January 2003 and December 2021.
- Approximately 4,000 elderly residents are treated in emergency departments for bed rail related injuries every year.

Litigation Risk

When entrapment occurs, this validates the side rail(s) created a hazard. Side rail hazards are considered "well known" as the hazards have been recognized by the FDA, CPSC, CMS and state surveyors at all levels of care. During litigation a death or significant injury related to a "known" hazard is amplified and presented as negligence; this strategy can successfully increase the value of the claim.

"You knew about the risk – you should have prevented the incident."

If regulatory citations related to entrapment and/or side rail usage have been cited, especially if citations were issued in response to the actual event, this also has the potential to significantly increase the value of the claim and makes defending the case more challenging.

Claim value also has the potential to increase with deaths that occur during the use of a well-known "bad" bed design, a "bad" rail/bed/mattress combination (bed system), or an older bed or side rail that should have been replaced.

Graphic illustrations and photographs depicting entrapment scenarios are readily available on web searches and photographs are usually taken by authoritative investigators at the time of event, both have the potential to add shock value for allegation resulting in a claim.

Potential allegations related to side rail usage include:

- Failure to justify the use of a bed rail (negligence)
- Failure to correctly install creating a safety hazard
- Failure to adequately supervise the use of the bed rail
- Failure to discover resident in time to prevent injury/death related to entrapment
- Lack of observation related to side rail usage

Regulatory Risk

Side rail and entrapment incidents resulting in injury and/or death are associated with high level regulatory citations. Citations are often cited at a "J" or "K" level and result in monetary fines.

Associated statement of deficiencies contain the following verbiage:

- Failed to assess for entrapment risks including impaired muscle strength, increased agitation, loss of dignity, falls, and entrapment resulting in pain, bruising, fractures, strangulation, hanging or death.
- Observations (by surveyors) of residents with extremities trapped within side rail openings.
- Falls with significant injury contributed to residents climbing over or attempting to go around raised side rails.

Regulatory guidance for skilled nursing facilities is outlined at F 700. There are no federal standards for the assisted living level of care but there is still the potential for regulatory citations at the state level related to resident safety.

Risk Mitigation

Entrapment risk and side rail safety should be assessed prior to placing side rails or any added device even at the resident or family request. It is imperative to acknowledge there is risk associated with rail usage regardless of the size, type or number of rail(s) including assist bars and even "stick" or "lollipop" style handrails or grab bars.

The risk and benefits of side rails for the individual resident should be identified and discussed within the interdisciplinary team (IDT) as well as with the resident and resident representative. Prior to placing side rails, it should be evident that the benefits of the rail(s) outweigh the risks. Written consent should be obtained from the resident and/or resident representative. Development of a negotiated/shared risk agreement should also be considered; the negotiated/shared risk agreement should include the risk of serious injury including the possibility of death from entrapment.

Additional recommendations regarding side rail usage are available in this FDA document.

Careful consideration should be given to the type of device that will be utilized prior to purchasing or allowing the device to be installed. This process should include checking the CPSC website to determine if the device has been associated with any recall or hazardous warning. Side rails including assist rails should be compatible with the bed system in place; only rails compatible with the bed system should be placed.

Best practice is to not permit adult portable side rails.

Systems should be in place to verify all entrapment zones created by the bed system (bed, mattress, rails) are within FDA guidelines. It is vital to note different bed systems, different combinations of beds, mattresses and side or assist rail(s) create different entrapment zones; all entrapment zones recognized by the FDA may not be present based on the combination.

Best practice is to follow the manufacturer's recommendations regarding what combinations are permitted for the specific bed system. Side rails are not manufactured to be interchangeable among different bed systems and should not be altered to fit.

Entrapment zones should be verified prior to putting the bed or bed system into use and verified each time a different resident utilizes the bed system. There should also be a system to re-verify entrapment zones as mattress compressibility will change over time and there is the potential for the resident's status to change. This should also drive review and replacement of mattresses based on manufacturer's recommendations and mattress compromise based on wear and tear.

Entrapment zones and guidelines for zone opening are outlined in FDA's *"Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment"* that is included with this *Point from Propel*.

Written protocols should drive processes that restrict third party providers such as hospice, therapy groups, or home health from placing side rails without permission from the community. Prior to placing side rails the provider should meet with the IDT, resident and family to discuss the risks and benefits for the individual resident and obtain written informed consent from the resident and/or family prior to placement.

Resident handbooks should clearly outline side rail protocols, list the risk and benefits of side rail usage, and restrict families from bringing adult portable side rails into the community. Families have sought litigation for incidents related to side rails the family brought into the community. If bed systems utilized have pre-attached side rails, consider placing a statement in the resident handbook such as "Please do not raise the side rail on your loved one's bed without checking with the nurse or caregiver."

Regulatory Compliance

Regulatory guidance for the skilled level of care requires that alternatives to side rails be attempted prior to placing side rails; this is a best practice for the assisted living level of care as well.

The FDA lists the following alternatives to side rails:

- Roll guards
- Foam bumpers
- Lowering the bed
- Concave mattress

Skilled nursing facilities should review regulatory guidelines at *F 700 – Bed Rails* and *F 909 – Resident Beds* to confirm policies and protocols align with the regulatory guidelines. *F 604 – Respect and Dignity* should also be reviewed as abuse is frequently cross tagged in response to side rail citations and placement of side rails could inadvertently create a physical restraint for certain residents.

Side rail usage should also be considered when identifying fall risk. Prior to placing side rails for a resident at risk for falls careful consideration should be given as to whether or not the rails may inadvertently increase the risk of serious injury related to a fall should the resident attempt to go over or around the side rails to exit the bed.

Consider the device, consider the reason, and consider the risk.