

# MINNESOTA HEALTH & HOUSING ALLIANCE

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## FDA Guidance on Bed and Side Rail Safety

The Food and Drug Administration recently released its guidance on institutional bed and side rail safety, “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment,” March 10, 2006. The FDA’s guidance contains nonbonding recommendations. The guidance is based in part on recommendations from the Hospital Bed Safety Workgroup, which was formed in 1999 in response to widespread concerns about resident entrapments and deaths attributed to side rails. The principal intended use for the guidance is by manufacturers, but it can also be helpful to providers who have existing institutional beds with side rails. Members should note that the FDA is not concerned with whether the side rails are physical restraints. The concern is with the safety of the resident, regardless of whether the side rail is a restraint under the federal certification regulations.

The degree of risk posed by a bed with side rails depends on many factors—the size, shape, and location of the side rail; the “fit” of the mattress to the side rail; the compressibility of the mattress; the physical, mental, and cognitive status of the individual resident. Not all beds and side rails pose dangers, and not all residents are at risk. Although the FDA’s guidance recommends dimensional limits for particular situations, these limits are based upon studies that contain typical measurements of the body parts most at risk—the head, neck, and chest. Obviously, any facility can have residents for whom these dimensions are not appropriate for evaluating their risk of entrapment.

The FDA points out that there are several factors that often need to be taken into account when measuring these distances. These include:

1. Compression of the mattress by the resident’s weight, especially nearest the side rail.
2. The physical size of the part of the resident’s body at potential risk.
3. Compressibility of the body part, especially the neck.
4. Any “give” or looseness in the side rail or other equipment.
5. The “fit” of the mattress in relation to the width of the bed frame or deck.

6. The articulation of the bed and side rail—i.e., elevation of part of the mattress can change the dimensions.

Many nursing homes have institutional beds that may contain equipment or mattresses that are not identical to the originals.

The table below provides the dimensional limits that the FDA recommends for four different “zones” or potential entrapment situations. These zones will be familiar to members who have the Minnesota Department of Health’s brochure on physical restraints, first published in 1999. The smaller the actual dimension, the less likely an entrapment.

<b>Maximum Size</b>	<b>Zone</b>	<b>Location</b>	<b>Body Part at Risk</b>
4 ¾” diameter	1	Inside rail perimeter, usually with vertical bars	Head
4 ¾” diameter	2	Underneath rail, between rail supports, but not at the end of the rail	Head
4 ¾” diameter	3	Between rail and mattress that is not wide enough	Head
2 3/8” diameter angle > 60°	4	Wedged under end of rail between vertical rail and mattress, angle > 60° reduces risk	Neck

The FDA’s recommendations assume that the resident’s head weighs 12 pounds, so the measurements in zones 2, 3, and 4 reflect a mattress that is pressed down by a weight of 12 pounds, compared to its position with no one on it. The head diameters represent the 5<sup>th</sup> percentile female head in all data sources used by the FDA. The neck diameter represents the 1<sup>st</sup> percentile female neck, reduced by 25 percent to account for tissue compression related to loss of muscle mass due to aging, neck compressibility of a soft muscle, and the asymmetrical shape of the neck. The FDA used female measurements because the male measurements are typically larger.

As is obvious from the percentiles given by the FDA, slightly larger dimensions would not pose risks for most female residents, let alone male residents. The FDA guidance, however, does not present any dimensional limits for higher percentile measurements, so it is not an individualized assessment of any particular resident’s safety or exposure to risk with respect to their bed and side rails.

The FDA guidance also discusses three other zones, but it does not recommend any dimensional limits for them. Zone 5 is between split side rails, and the principal dangers are entrapment and compression of the chest or the neck or wedging. Zone 6 is between the end of a side rail and the side edge of the head or foot board, and the principal danger is entrapment of the neck or chest. Zone 7 is the space between the inside surface of the head or foot board and the mattress, and the principal danger is entrapment of the head.

The FDA does not recommend that its dimensional criteria be used on certain types of beds. Types of beds and equipment excluded totally or in part from this guidance are the following:

- Air fluidized therapy beds
- Bariatric beds, pediatric beds, and infant cribs
- Stretchers, examination tables, operating tables, and similar tables and devices not typically used as beds
- Kinetic treatment tables and rotation beds (except for spaces within rail perimeters, or Zone 1 spaces)
- Beds with specialty designs for obstetric care
- Pressure reduction therapeutic beds (except for spaces within rail perimeters, or Zone 1 spaces)

The FDA guidance also references a Bed Safety Entrapment Kit developed by the Hospital Bed Safety Workgroup and others. The kit contains a number of documents and a test tool kit. The tool itself is complicated, both in its design and use. It has a cone, a cylinder, a spring scale, and a safety belt. It also is somewhat risky to use—the description of each test for the four zones contains warnings on the dangers involved in using the tool, so there may be some OSHA concerns.

MHHA has received questions from members about whether they are required to conduct tests on the dimensions in the four zones, and whether they should purchase (\$1,260) or rent the tool kit. At this point, MHHA does not recommend using the tool kit, partly because of the risks and partly because, as the FDA appendix mentions, different testers can get different results for the same bed system. There is also no requirement to conduct tests on the FDA's recommended dimensions in the four zones.

MHHA does recommend, however, that you use side rails only when they are safe for the particular resident. For residents with smaller than average heads or necks who use side rails, you may want to evaluate the four zones to see if the side rails pose a risk to the resident. Use the FDA distances as a guideline. If it is a close call, it would be safer to remove the side rail, replace it with a different design, or make some other adjustment to mitigate the risk.

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