

Bed Safety Consulting, Inc.

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Dear Sir:

Subject: Docket No. 2004D-0343

I am writing to express my concern as to the scope of the **Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment** issued March 10, 2006. As it now stands, the Dimensional Guidance is organized around and pictorially displayed only for hospital beds with split side rails. The detailed attention given to split side rail bed systems leaves the impression that the dimensions presented for split side rail bed systems are freely transferable to any other type of hospital bed /side rail system. Unfortunately, for hospital beds with full length side rails attached to the bed deck with cross bars, see Figure 2, this impression is not correct.

The basis for the size of the maximum allowable gap for Zone 3 presented in the current Guidance centers on the assumption that the breath of a patient's head would block the entry into this critical entrapment area. However, as I stated in my previous comments to the docket, dated November 10, 2004,

"Regrettably, only split side rails have been used to exemplify entrapment possibilities. Split side rails fail to demonstrate the full entrapment potential within Zone 3 that is present when full-length side rails are used, see Figure 1. Accordingly, the belief that the head blocks the entry of the neck into this gap is not true. With full length side rails, the legs slide between the side rail and the mattress and the weight of the legs pulls the trunk through the Zone 3 gap until either the chest or the head becomes entrapped."

The fact entrapments can and do take place in different ways depending on the type of side rails being used changes the basis for determining the size of a maximum allowable gap. The legs first entrapment potential is the first fundamental difference between hospital beds with split side rails and those with full length side rails attached to the bed deck with cross bars.

The second difference between split side rail bed systems and full length bed rail systems is that the cross bars can be expanded, thereby increasing the size of the gap in Zone 3, **without tools**. Figure 3 shows the placement of the rail guides relative to the bed deck is established by fitting a push button in one half of the cross bar into one of many adjustment holes on the other half of the cross bar. The ease and opportunity presented with push button adjustable cross bars to create the space needed for an entrapment has proven to be fatal.

Finally, it is noted that on page 53 in Appendix F, Dimensional Test Methods for Bed Systems, two of the pictures, used to illustrate the position that a bed should be in for testing Zone 2, show a full length side rail. However, this full length rail is attached to the

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bed frame not the bed deck. When cross bars are used to attach the side rails to the bed deck, these telescoping side rails articulate with the head of the bed and the effect of this articulation on the under bar space in Zone 2, see Figure #2, is significantly more than that created by the bend in the mattress alone. Legs first entrapments have taken place in twin beds with full length side rails much less in an articulated hospital beds with a full length side rails in which the space in Zone 2 merges with the space in Zone 3 once the head of the bed is raised.

A full length bed rail that is attached to the bed deck with cross bars is a part of the bundled semi electric hospital bed package that is provided by Medicaid and Medicare under billing code E0263. These price point bed systems are found in a wide variety of settings, many of which have persons at high risk of entrapment. It is my assertion that the application of the current split side rail dimensions to a hospital bed with full length side rails attached to the bed deck with cross bars will have tragic consequences

It is my recommendation that a warning be immediately issued not to apply these split side rail dimensions to full length side rails with cross bars and that the appropriate standards, i.e. Checkpoints 2, 10, and 20, listed in the Bed Safety Checklist, see Attachment 1, be adopted for Zones 2 and 3 in beds with full length side rails attached to the bed deck with cross bars.

If I can be of any further assistance, please contact me directly at 315-339-4798.

Yours truly,



William Schatz
President

cc: Joan Ferlo Todd

Bed Safety Checklist (Updated 10/2002)

Individual: _____

Address: _____

For both standard twin and hospital beds:

1. Yes ___ No ___

A risk assessment has been completed for the person, and a determination made that bed rails are required for safety.

2. Yes ___ No ___

With the mattress pushed against one side rail, the space between the mattress and the other side rail is minimal, if any. ["Minimal space" is when you feel resistance on both sides of your OPEN hand when you place it between the mattress and the side rail.]

3. Yes ___ No ___

The mattress is in good, firm condition, and can support a person's weight without excessive compression on the sides. [This should be determined with individual or person of equivalent size in the bed.]

4. Yes ___ No ___

Bed sheets are a proper fit. ["Proper fit" means that the mattress is not compressed when the sheets are used on the mattress.]

5. Yes ___ No ___ NA ___

If needed, cross bars and side rails are appropriate for use with the person's bed. ["Appropriate for use" means the cross bars and side rails are compatible with the bed as defined by manufacturer's instructions.]

6. Yes ___ No ___

The bed rails, including cross bars, locking mechanism and side rails, are not damaged or broken.

7. Yes ___ No ___ NA ___

All four pull pins or other securing mechanism actually lock and hold the side rails in the up position.

8. Yes ___ No ___ NA ___

The side rails are located appropriately to prevent entrapment points at the headboard/footboard ends of the bed. ["Appropriately" means that with the bed flat, the side rails should be less than or equal to 2 1/3 inches, or greater than or equal to 10 inches from the headboard/footboard.

9. Yes ___ No ___ NA ___

Both cross bars are adjusted for a tight fit and all push buttons are locked into the adjustment holes.

10. Yes ___ No ___ NA ___

The bottom bar of the side rail overlaps the side of the mattress.

11. Yes ___ No ___

There are no gaps covered or filled by any devices, such as pads, pillows or bolsters.

12. Yes ___ No ___ NA ___

If bed-rail covers/side-rail pads are used to protect a person from impact injuries, there are NO tears, rips, loose straps, etc. They are also securely attached to the side rail.

13. Yes ___ No ___

Spacing between the bars (inter-bar) is appropriate to the size of the person to prevent injury or entrapment. ["Appropriate spacing" for a child or small adult will be less than for an adult of "normal size." If a person is 35 inches or less in height, the space between the side rails must be 2 1/3 inches or less.]

14. Yes ___ No ___

The side rails are high enough to prevent the person from rolling out of bed, particularly when the specialty mattress and/or alternate positioning wedges are used.

For standard twin beds:

15. Yes ___ No ___ The bed frame, mattress and box spring are the same width.
16. Yes ___ No ___ NA ___ When a headboard is used, it overlaps the mattress by at least 2 ½ inches.
17. Yes ___ No ___ NA ___ When a footboard is used, the space between the mattress and footboard is minimal. ["Minimal space" is when you feel resistance on both sides of your open hand when you place it between the mattress and foot board with the mattress pushed against the headboard.]

For hospital beds:

18. Yes ___ No ___ The mattress is at least the same length and width as the bed deck.
19. Yes ___ No ___ With the bed flat and the mattress pushed against the headboard, there is a maximum of a 3" gap between the mattress and the footboard. [This space is to allow for adjustment of mattress position.]
20. Yes ___ No ___ With the head of the bed raised, the triangular space between the bottom side rail and the mattress is not large enough to entrap a person.
21. Yes ___ No ___ NA ___ If split side rails are used, with the bed flat, the rails are either less than 2 1/3 inches apart or more than 10 inches apart.

(Note: There is a wide variation in the operation of hospital beds. The following checkpoints may not be appropriate for the specific type of hospital bed being reviewed. In these instances, refer to manufacturer instructions.)

22. Yes ___ No ___ NA ___ Each cross bar is attached to either both sides of the frame or to both sides of the bed deck.
23. Yes ___ No ___ NA ___ Both side rails telescope smoothly when the head or foot of the bed is raised and lowered.

24. Provide detailed comments for any NO response above:

Reviewer: _____

Date: _____

An Overhead View of Bed Rails on a Twin Bed

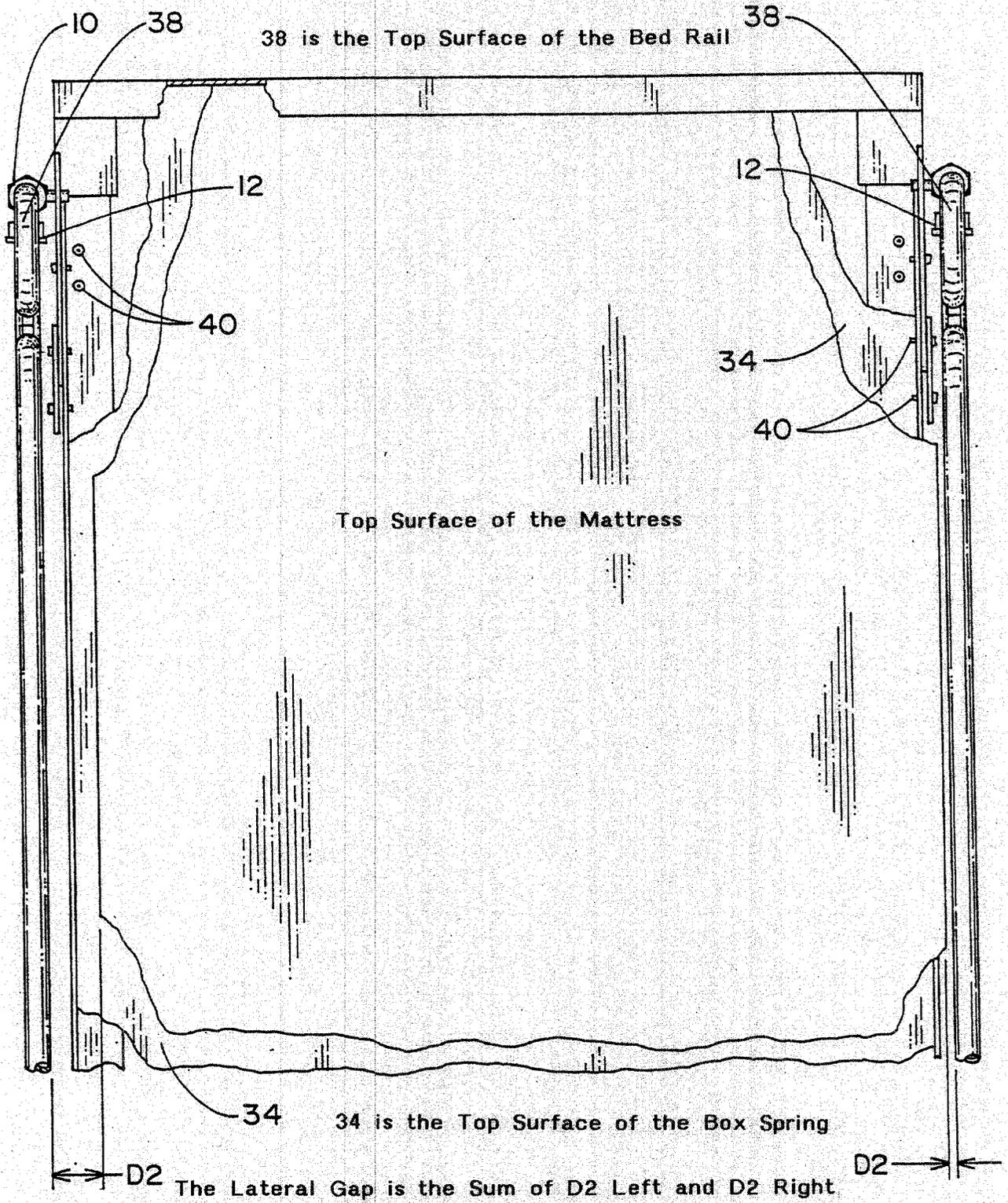


FIGURE 1

The triangular gap created when the head of the hospital bed is raised

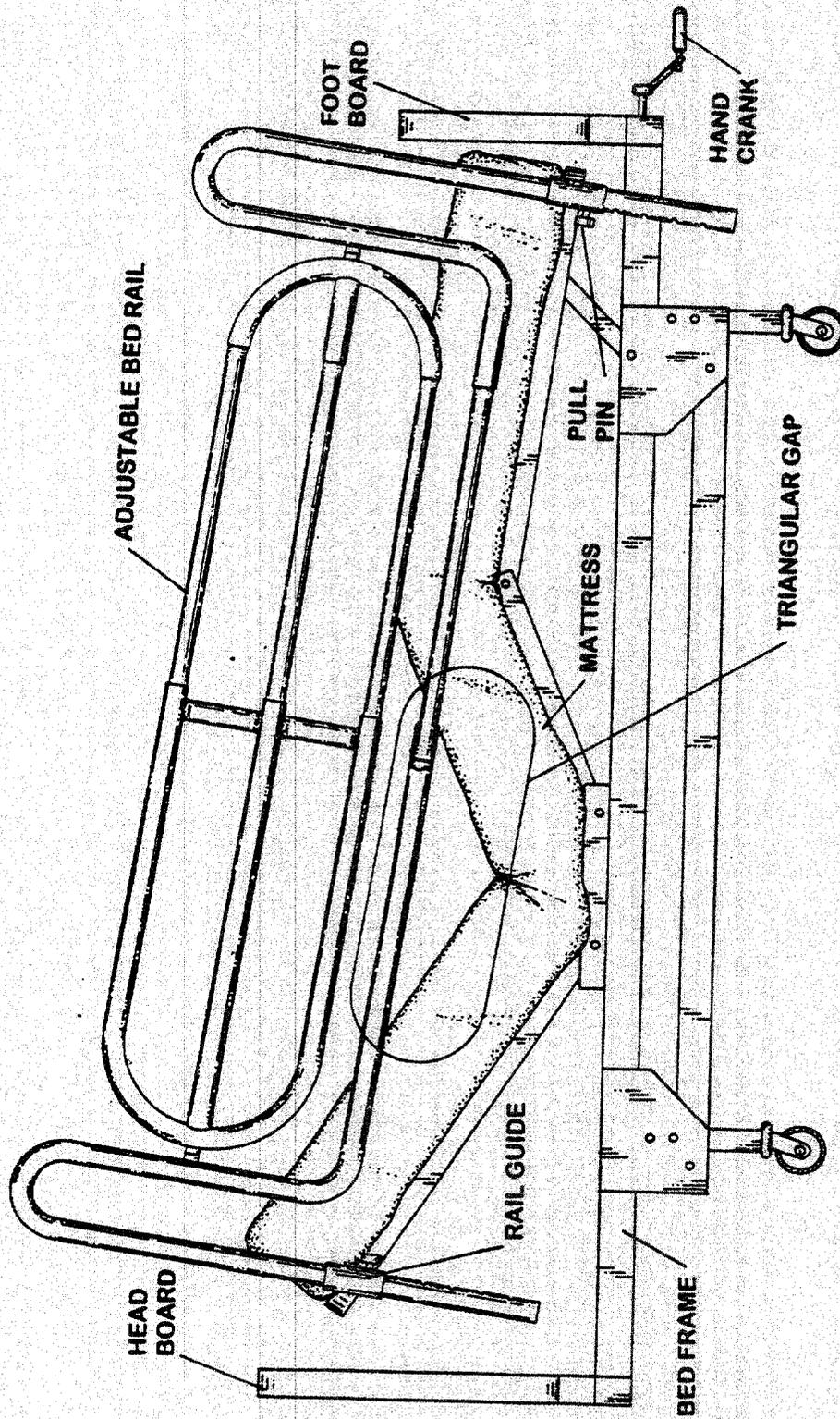


FIGURE 2

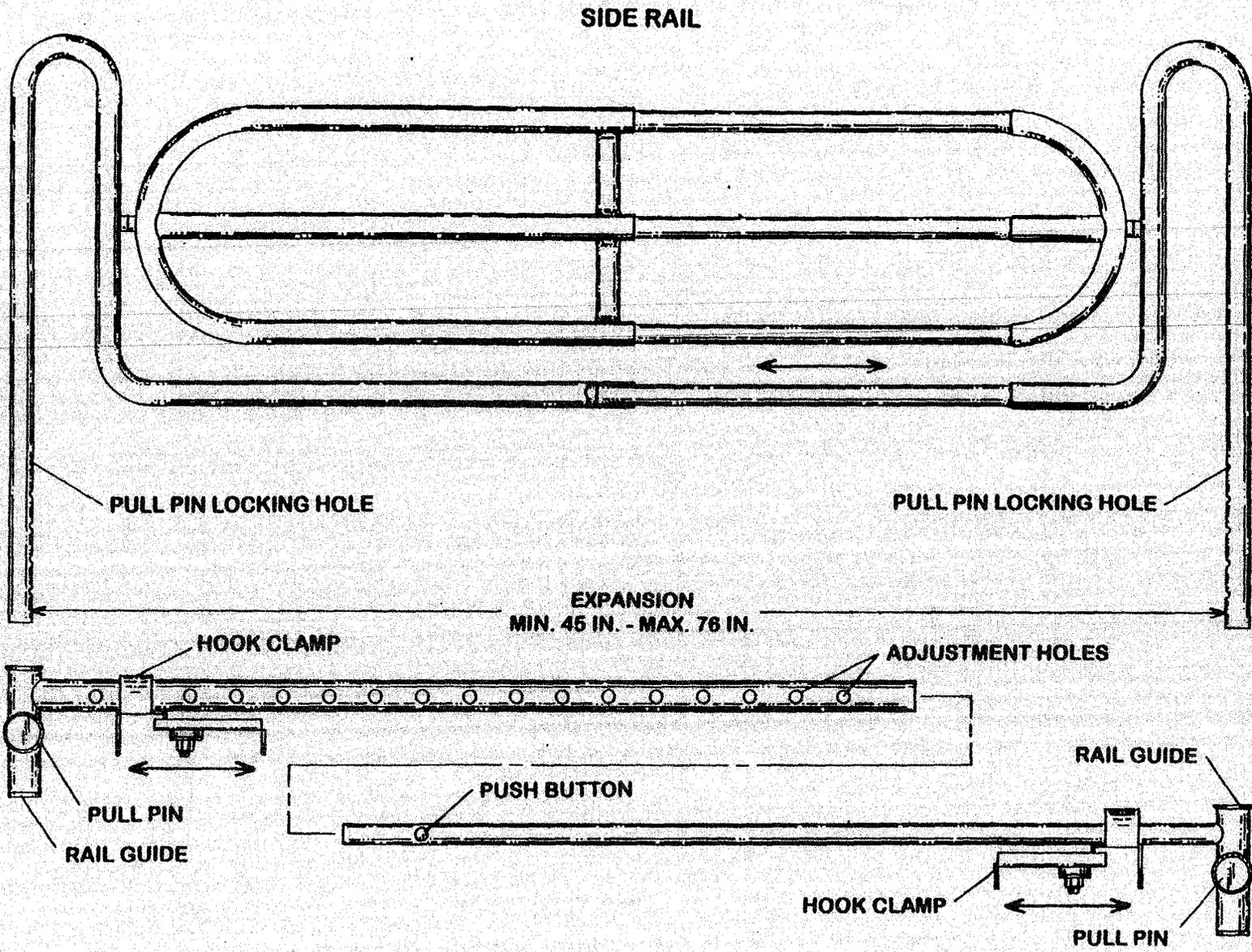


FIGURE 3