



**American Hospital
Association**

ASHE

American Society for Healthcare Engineering

ASHRMSM

**American Society for
Healthcare Risk Management**
of the American Hospital Association

January 14, 2005

Daniel G. Schultz, M.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

**Re: Draft Guidance for Industry and FDA Staff:
Hospital Bed System Dimensional Guidance to Reduce Entrapment
Division of Dockets Management (HFA-305)
Docket No. 2004D-0343**

Dear Dr. Schultz:

On behalf of the American Hospital Association (AHA), the American Society for Healthcare Engineering (ASHE), and the American Society for Healthcare Risk Management (ASHRM), we are writing to express our concern regarding the Food and Drug Administration's (FDA) *Draft Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment (Dimensional Guidance)*, and its retroactive applicability to existing hospital beds. A safe environment for patient care is a fundamental principle in health care delivery and preventing harm from reaching any patient is a critical goal of the AHA, ASHRM and ASHE. We take a collaborative approach to managing all types of risk in health care, including proactive assessment and evaluation of solutions to eliminate or reduce the risk to patients, and we commend your efforts to raise awareness about the risk of entrapment in hospital beds.

The draft *Dimensional Guidance* provides recommendations intended to reduce entrapments associated with hospital bed systems by characterizing the body parts at risk for entrapment, identifying the locations of hospital bed openings that are potential entrapment areas, and recommending dimensional criteria for these devices.

We have actively worked to educate hospitals and create a greater awareness of bed rail safety risk. ASHE and ASHRM have been active participants on the FDA's Hospital Bed Safety Work Group (HBSW) since its inception. ASHE and ASHRM were participating organizations in the

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development of the brochure *A Guide to Bed Safety* and have been supportive of the development of the *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospital, Long Term Care, and Home Care Setting (Clinical Guidance)*. ASHE participated in the HBSW subgroup on dimensional guidance and, within that subgroup, debated the scope and effectiveness of its report, *Dimensional Guidance*. Through these discussions within the HBSW workgroup, ASHE has consistently argued for limiting the scope of *Dimensional Guidance* to new bed systems only.

However, in the report's introduction and Appendix F, it is clear that FDA intends these limitations to be applied retroactively to existing, or legacy, hospital beds. AHA, ASHE and ASHRM disagree.

For all hospital beds, health care organizations should use the *Clinical Guidance* to first consider the patient population that is served and their risk for bed rail entrapment, and then, if appropriate, focus on the bed rail dimensions. Bypassing the patient assessment and simply focusing on the measurement of bed rail gaps will lead organizations directly into an incomplete solution that misses the critical first step of clinical assessment. Assessing the individual needs of the patient and, if indicated, re-evaluating the bed for entrapment potential, is a more appropriate way to manage this risk. But *Dimensional Guidance* does not adequately establish the role that clinical assessment and clinical intervention play in reducing the risk of entrapment. The *Clinical Guidance* is not referenced in the body of the *Dimensional Guidance*.

In fact, the FDA Web site on bed rail entrapment claims the *Clinical Guidance* document was neither written nor endorsed by FDA. This is odd considering page three of the *Clinical Guidance* identifies FDA's role in the creation of the document: "In April 1999, the Food and Drug Administration (FDA) in partnership with representatives from the hospital bed industry, national healthcare organizations, patient advocacy groups and other federal agencies formed the Hospital Bed Safety Workgroup. The workgroup's goal is to improve the safety of hospital beds for patients in all health care settings who are most vulnerable to the risk of entrapment." Given FDA's role in the creation of this document, we recommend that clinical assessment be identified as a key safety strategy and that the *Dimensional Guidance* document the *Clinical Guidance* as a reference.

Without a clear discussion of the critical role of clinical assessment, the specific dimensional limitations may be viewed as a model code, and be adopted by state or other agencies with the requirement for proactive measurement of existing beds for compliance with these new dimensional limitations. Establishing dimensional limitations and a measurement methodology to assure that new hospital beds meet these limitations is a forward thinking strategy. But implying that legacy beds that were not designed under these dimensional limitations should now be held to meet these limitations is unreasonable. In addition, by not limiting the scope of the dimensional limitations to new equipment only, this document creates the impression that reduction of the risk of entrapment is achieved solely through the identified dimensional limitations. **AHA, ASHE and ASHRM**

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recommend that the introduction and Appendix F be revised to indicate that this document applies only to new hospital bed or rail design configurations.

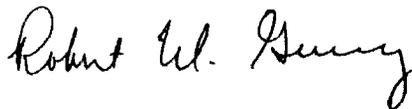
We are concerned about the enormous cost implications associated with bypassing the patient assessment and focusing exclusively on the measurement of bed rail gaps in existing hospital beds. Extrapolating from a Veterans Administration (VA) pilot study of the dimensional measurement process, it would take nearly 87,000 workdays to complete this activity for all the nations existing hospital beds, and the national cost in labor just to measure the beds will be over \$17 million. In addition, this estimate does not consider the fact that 75 percent of the workers in the VA pilot sustained workers' compensation injuries in the process. Further, since all hospital beds measured in the VA pilot failed the test, there would be enormous costs associated with potential solutions including retrofitting all hospital beds, replacing mattresses and/or total bed replacement.

Thank you for the opportunity to comment on this important matter. If you have concerns or questions about these comments, please contact ASHE's Dale Woodin at dwoodin@aha.org or (312) 422-3812; AHA's Roslyne Schulman at rschulman@aha.org or (202) 626-2273; or ASHRM's Elizabeth Summy at esummy@aha.org or (312) 422-3989.

Sincerely,



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Robert Guerry, PE, CHFM
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