



November 29, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket ID: 2004D-0343

To Whom It May Concern:

Our Director of Risk Management, Patient Safety Officer, Director of Materials Management and I have all reviewed the *Hospital Bed System Dimensional Guidance to Reduce Entrapment* and would like to take the opportunity to submit our comments and concerns regarding the guidance as currently written.

The proposed guidance document focuses on the physical dimensions of hospital beds and bed rail designs and suggests that bed rail-related entrapment deaths can be prevented by testing and measurement of beds currently in use in our facilities during preventive maintenance (PM). While we support the more stringent recommendations in the guidance document defining safe dimensions and designs for bed manufacturers for future production to reduce the risk of patient entrapment, we feel that other risk reduction strategies would be more beneficial in preventing patient entrapment for beds currently in use.

The Hospital Bed Safety Workgroup of the FDA released the document *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings* in May 2003. This guidance document along with the September 2002 Joint Commission on Accreditation for Healthcare Organizations (JCAHO) Sentinel Event Alert #27 titled *Bed rail-related entrapment deaths* directs healthcare organizations to emphasize the importance of adequate patient assessment for risk of falls and potential need for restraint. These documents also stress the importance of matching patient assessment with proper equipment to ensure patient safety. To this end, we recommend that the guidance for new bed manufacturers include a requirement that beds be made to go as low to the floor as possible and that the lower side rails be made easily removable to assist organizations in enforcing a policy of not using lower bed rails, except in some very defined situations where the risk of not using them would pose greater risk to the patient than the risk of using them.

Considering the many types of beds, mattresses, and combination of the two in use in healthcare facilities today, it is our opinion that measuring all the beds in our facility at a point in time will not ensure patient safety and prevent patient entrapment. Also, the document doesn't clearly state what corrective action hospitals would be expected to take when beds are found to be out of compliance with the guidelines. Replacing all such beds would not be feasible for most organizations. What would make more sense at the PM check would be to remove and replace worn or sagging mattresses that no longer fill the rail-to-rail space.

We feel that further emphasis on staff education to promote skills toward identifying patients and beds at risk and communicating this through the appropriate organizational channels is the best enterprise risk management approach. In addition, we plan to incorporate a discussion with manufacturers about their compliance with dimensional guidance when we purchase new bed systems in the future and to have our Plant Engineering department perform measurements and/or testing of new mattress/bed combinations prior to purchase to document that they meet a minimum standard set by our hospital.

Thank you for this opportunity to respond to the draft guidance. We hope you will consider our comments.

Sincerely,

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Senior Vice President, Patient Care Services and Chief Nursing Officer

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