



Carolinus HealthCare System

Re: Docket No. 2004D-0343

December 22, 2004

Thank you for the opportunity to comment on the ***FDA draft guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment.***

We understand and appreciate the intention of this document, to minimize the potential of patient entrapment in a hospital bed. The introduction statement and Appendix F, however, focuses attention on proactive testing of existing beds with little or no actual risk reduction. In fact, this focus will stretch currently scarce resources that would be better spent on patient assessment and modification of the bed environment if warranted based on patient size and/or condition.

As written, the FDA draft guidance creates an expectation that hospitals and long term care facilities will inspect all of their existing (legacy) hospital beds for compliance with the dimensional limitations set forth in the FDA draft guidance. Within Carolinus HealthCare System in Mecklenburg County, N.C., the FDA draft guidance would affect 1,307 hospital beds and 349 long term care beds. Our understanding is that pilot testing of existing beds has revealed that most if not all existing beds will not meet these dimensional limitations. The extensive time and effort that will be required to determine that our existing hospital beds will not pass will be wasted effort, with no significant risk reduction. The dimensional guidance only has value to existing beds if the primary focus is on a clinical assessment of the patient's physical condition to establish that such patient is vulnerable to the risk of bed entrapment. At that point, the focus of the clinical and support staff should be the assessment of the hospital bed system with a clear plan for addition or modification of that system to meet that specific patient's needs.

FDA must revise its draft guidance to clearly exempt existing beds from the dimensional limits and identify existing (legacy) beds as not inherently "unsafe" even though they do not meet the new dimensional limits established in the FDA draft guidance. The dimensional limits must be applied on a prospective basis only that is on new beds manufactured after the implementation of this document. The focus on legacy equipment is patient assessment first, with risk mitigation efforts based on meeting that patient's need.

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