

Thank you for the opportunity to comment on the FDA draft guidance: *Hospital Bed System Dimensional Guidance to Reduce Entrapment*, Docket 2004D-0343.

We understand that the intention of this document is to reduce the potential of patient entrapment in a hospital bed. We support efforts to help insure that new hospital beds are designed to be as safe as possible. However, we feel that the statement “...the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and **the assessment and modification of existing (legacy) hospital bed systems**” in the introduction statement and the language in Appendix F will ultimately result in the testing of existing beds without providing an actual reduction in risk. We believe that patient assessment and modification of the bed environment based on the patient assessment will be more effective in preventing entrapment than will testing of existing (legacy) beds.

We believe that this guidance will produce an expectation of hospitals inspecting all of their existing (legacy) hospital beds for compliance with these dimensional limitations. It is our understanding that pilot testing has been performed, and it has been found that most existing (legacy) beds do not meet the dimensional guidelines. We have approximately 250 hospital beds in use in an acute care setting, approximately 20 beds in use in Critical Access setting and approximately 600 beds in long term care settings . If it is already known that most existing beds do not meet the guidelines, we believe that the time we would spend in testing would be better spent in support of the clinical staff in providing patient assessment and developing a plan for modification of the bed environment when the patient assessment reveals a need. The dimensional guidance is of value to existing beds if the language states clearly that the primary focus must first be clinical assessment of the patient physical condition in determining if they might be susceptible to the risk of bed entrapment.

The FDA must revise this draft document to clearly identify that existing (legacy) beds are not inherently “unsafe” even though they do not meet the new dimensional limits established in this document. The focus on dimensional limits must be on new beds manufactured after the implementation of this document. The focus on legacy equipment should be patient assessment first, with risk mitigation efforts based on meeting that patient’s need.

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