

December 28, 2004

Thank you for the opportunity to comment on the FDA draft guidance: *Hospital Bed System Dimensional Guidance to Reduce Entrapment (204D 0343)*.

Providence St. Peter Hospital (PSPH) is a 390-bed, not-for-profit regional teaching hospital founded by the Sisters of Providence in 1887. Located in Olympia, the state capital of Washington, Providence St. Peter Hospital offers comprehensive medical, surgical and behavioral health services.

PSPH has been named one of the 100 Top Hospitals in the nation for cardiology, orthopedics and stroke care. Our outpatient surgery center has received national benchmark awards for its work in cataract surgery, knee arthroscopy and many other procedures.

We understand and appreciate the intention of this document, to minimize the potential of patient entrapment in a hospital bed. But we feel that the introduction statement and Appendix F will focus 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, this guidance will create an expectation of hospitals and long term care facilities inspecting all of their existing (legacy) hospital beds for compliance with these dimensional limitations. Our understanding is that pilot testing of existing beds has revealed that most if not all existing beds will not meet these dimensional limitations. So the extensive time and effort that will be required to determine that our forty-five (45) existing hospital beds will not pass is wasted with no risk reduction. The dimensional guidance has value to existing beds if it is clearly stated that the primary focus must first be clinical assessment of the patient physical condition to establish that they are 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.

Of the many tools that Providence St. Peter employs to insure patient safety two are significant in assessing this issue. These tools are the Biomedical Equipment Risk Assessment and the Hospital's Unusual Occurrence Report.

Each piece of equipment entering Providence St. Peter Hospital is risk assessed to determine whether scheduled maintenance is required and additionally, what the frequency for planned maintenance is. This is a dynamic system, taking into consideration several factors, which is largely driven by data and industry knowledge. The continuous practice, refinement, and data collection from this process and the supporting computerized maintenance system has provided a very robust database on a myriad of hospital based medical equipment over the last decade.

The second tool referenced above is that of the hospital required Unusual Occurrence Report. This may be an over-simplification but Unusual Occurrence Reports are required whenever there is occurrence that could benefit from a cause and effect review. This process is particularly relevant to clinical review and patient safety.

Our records, derived from both of the tools mentioned above, mirror that of the national findings noted in the proposed guidelines, statistically insignificant. This finding does not in any way posit the significance of the saving of one life but instead suggests that clinical awareness of this potential for harm be raised versus the assessment and modification of diminishing legacy bed inventories.

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The FDA must revise this draft document to clearly identify that 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 is patient assessment first, with risk mitigation efforts based on meeting that patient's need.

Sincerely,

A handwritten signature in black ink, appearing to read "K. A. Deline". The signature is fluid and cursive, with a large initial "K" and "A" followed by "Deline".

Keith A. Deline MPA  
Manager Facility and Technology Services  
Providence St. Peter Hospital