



**American Association  
of Homes and Services  
for the Aging**

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

**[Docket No. 2004D-0343]**

Dear Sir or Madam:

The American Association of Homes and Services for the Aging (AAHSA) appreciates the opportunity to comment on the Food and Drug Administration (FDA) Notice; Draft Guidance for Industry and Food and Drug Administration Staff; Hospital Bed System Dimensional Guidance to Reduce Entrapment. AAHSA is a national nonprofit organization representing almost 6,000 mission-driven not-for-profit members, providing nursing home care, affordable senior housing, assisted living, continuing care retirement communities, and community services to more than 2,000,000 individuals daily.

As a member of the Hospital Bed Safety Workgroup (HBSW) since its inception, AAHSA strongly supports the FDA's efforts to reduce life-threatening entrapments associated with hospital bed systems.

Following are AAHSA's responses to the FDA's Requests for Comments.

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**1. Exclusions (Framed flotation therapy products and bed systems using powered air mattress replacements). Should FDA reconsider these exclusions and recommend the application of dimensional limits for all entrapment areas to these products?**

*Advancing the Vision of Healthy, Affordable, Ethical Aging Services for America*

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2004D-0343

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The pressure reduction products identified for total or partial exclusion from the proposed dimensional guidance criteria offer significant therapeutic benefits to patients in various health care settings, including long term care. The FDA's decision to continue the exclusions or make the guidance applicable to the items in question, i.e., framed flotation therapy products, powered air mattress replacements, and mattress overlays, must be weighed against the relative risks of each product as indicated by the published information as referenced in the guidance and reports of entrapment related to their use. Use of these products should then be driven by determinations of benefits vs. risks to the individual patient or resident.

**RECOMMENDATION:** If the exclusions are to be retained, the FDA should include a caution in the final guidance and any related documents that exclusion from application of these criteria does not render these products free of risk. Users should be clearly advised that potential entrapment areas must be identified and addressed for each patient.

**Pages 15-16**

**2 and 3. More stringent dimensional limits at Zones 2 and 3. Should FDA modify its recommendation to recommend a dimensional limit of less than 2 1/3 inches (60 mm)?**

It is our understanding is that Zones 2 and 3 were among those identified as posing the greatest potential risk. The care provided to patients/residents in these beds would not be impeded by the proposed modifications and the additional degree of protection needed would be afforded.

**RECOMMENDATION:** AAHSA supports the proposed reductions in dimensional limits for Zones 2 and 3 based on the FDA's cited retrospective data and complementing factors.

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**4, 5, and 6. Recommendations for a dimensional limit for Zones 5, 6 and 7. Should FDA recommend dimensional limits for these additional zones as specified at each respective section in the guidance?**

AAHSA supports FDA recommendations for dimensional limits for these additional zones based on the Agency's continued receipt of entrapment reports for Zones 5 and 6, and the potential for entrapment identified at Zone 7. However, the HBSW recommended dimensional limits for only Zones 1 - 4 based on frequency of occurrence in entrapment reports and the identification of these zones as the areas of greatest jeopardy for patients/residents. We are concerned that directing manufacturers to focus design changes on all seven zones concurrently (and to include dimensional limits for articulated positions as per our response to Request 7) may hinder the overall timeliness and effectiveness of the design changes. This would delay modification and implementation for Zones 1 - 4, the areas of highest risk.

**RECOMMENDATION:** AAHSA recommends that FDA adopt a phase-in approach, concentrating first on Zones 1 – 4, and applying the additional dimensional limit recommendations for Zones 5-7 as a second stage of guidance.

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**Additional Request for Comments: 7. Articulated bed positions. Should FDA apply these dimensional limits to articulated positions?**

FDA notes in the section Potential Zones for Entrapment, “Entrapment may occur in flat or articulated bed positions...” Additionally, the descriptions for Zones 2-6, state specifically that “...the size of the zone may change” and the potential for entrapment may still exist when the bed is articulated.

Hospital beds in nursing homes and acute care settings are used more frequently in articulated positions, usually in the semi-fowlers position, than in the flat deck position. Beds may be articulated for patient comfort or for clinical reasons. For example, patients/residents with swallowing difficulties are placed in a semi-sitting position during and immediately after eating to prevent aspiration. Similarly, residents/patients with certain venous disorders have their legs elevated while in bed. Failure to include guidance that addresses potential entrapment risks for beds in articulated positions can place caregivers in the untenable position of having to choose between the risks of entrapment and those related to the patient’s/resident’s clinical needs or preferences.

**RECOMMENDATION:** AAHSA supports application of the dimensional limits to articulated positions.

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**8. Application of this guidance to all health care settings. Is there a reason why this guidance document should not apply to hospital beds used in all care settings?**

Entrapment potential is determined not by location, but by the characteristics of the individual patient/resident and the hospital bed system being used.

The FDA states in the Background section on pages 2 and 3, “For more than 19 years, there have been events reported in which vulnerable patients have become entrapped in hospital beds while undergoing care and treatment in health care facilities.” “The populations most vulnerable to entrapment are elderly patients and residents, especially those who are frail, confused, restless, or who have uncontrolled body movement. Entrapments have occurred in all patient care settings, including hospitals, nursing

homes, and private homes.” The position for application across settings is further supported in APPENDIX F (page 32), “Because hospital bed systems primarily intended for one type of care setting can be moved into other care settings during the life of a bed system, beds used in all healthcare settings are included within the scope of this guidance.”

**RECOMMENDATION:** There is no reason why this guidance should not apply across care settings.

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**APPENDIX F – Healthcare Facilities**

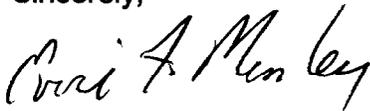
APPENDIX F states that, when finalized, the dimensional guidance may be used by healthcare facilities and related entities to evaluate legacy equipment as well as current and newly manufactured beds systems. The FDA also encourages healthcare facilities to contact their equipment suppliers for entrapment mitigating solutions that may already be available.

The FDA states in this section that the HBSW is developing procedures for the measurement and assessment of hospital bed systems, and that the 3<sup>rd</sup> of the HBSW publications, “A Guide for Modifying Bed Systems and the Use of Accessories to Reduce the Risk of Entrapment” is to be finalized upon publication of the final dimensional guidance. We recognize that the final dimensional criteria will constitute guidance rather than a mandate. However, these prospective HBSW publications will provide critical assistance to many providers and caregivers in accurately assessing and addressing entrapment risks and in making informed decisions on whether existing and future mitigating strategies and solutions provide effective recourse for a particular patient/resident.

**RECOMMENDATION:** AAHSA strongly urges the FDA to assure that the Guide for Modifying Bed Systems and procedures for measurement and assessment are in place and available before proceeding with and recommending that providers and caregivers act on the final dimensional guidance.

Again, we appreciate the opportunity to comment on this Notice. If you have questions or would like to discuss our comments further, please do not hesitate to contact us.

Sincerely,



Evvie F. Munley  
Sr. Health Policy Analyst