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Hospital Bed Entrapment: New Guidance From FDA.

On August 30, 2004 the FDA issued a guidance document in draft form entitled "Hospital Bed System Dimensional Guidance to Reduce Entrapment."

See *Entrapment: New Draft Guidance From FDA Re Hospital Bed Systems,* Legal Eagle Eye Newsletter for the Nursing Profession (12)10 p.8 (Oct., 2004).

On March 10, 2006 the FDA replaced the draft document with a finalized version entitled "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment."

The guidance document conveys the FDA's recommendations to manufacturers and to healthcare facilities which use hospital beds how to reduce life-threatening entrapments associated with hospital bed systems.

The guidance document characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, recommends dimensional criteria for bed systems, provides information about so-called "legacy" beds (beds already manufactured and currently in use) and specifies information to include when reporting entrapment adverse events to the FDA.

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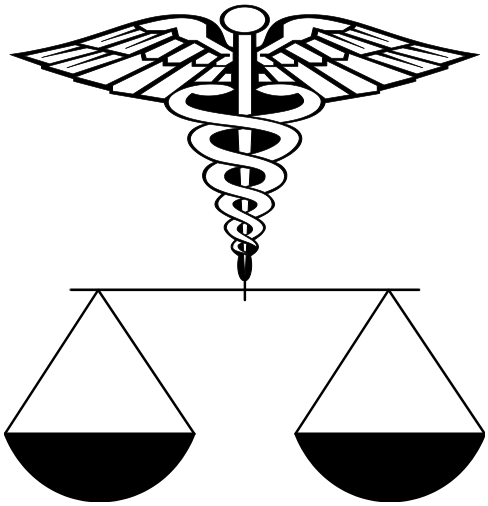

FDA guidance documents do not establish legally enforceable responsibilities.

Instead, guidance documents merely describe the FDA's current thinking on a certain topic and should be viewed only as recommendations unless the document makes reference to specific regulatory or statutory requirements.

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Hospital Bed Entrapment: FDA's Draft Recommendations Have Now Been Finalized.

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Visual Depiction of Entrapment

The older and newer guidances both contain a disturbing one-page graphic which dramatically conveys the patient entrapment risk associated with seven identified entrapment zones commonly associated with hospital beds:

1. Within the rail;
2. Under the rail, between the rail supports or next to a single rail support;
3. Between the rail and the mattress;
4 Under the rail, at the ends of the rail;
5. Between split bed rails;
6. Between the end of the rail and the side edge of the head or foot board;
7. Between the head or foot board and the mattress end.

Vulnerable Population Defined

According to the FDA, not all patients are at risk for entrapment and not all hospital beds pose a risk of entrapment.

The population most vulnerable to entrapment, according to the FDA, are elderly hospital patients and nursing home residents, especially those who are frail, confused, restless or have uncontrolled body movements.

Long-term care facilities have reported the majority of entrapment incidents reported to the FDA.

From 1985 through 2005, 691 such reports included 413 deaths, 120 injuries and 158 incidents described as "near-miss events" with no serious injuries.

The FDA suggests that facilities as well as manufacturers determine the level of risk for entrapment and take steps to mitigate the risk.

Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall assessment and mitigation strategy to reduce entrapment.

Healthcare facilities may use the FDA's latest guidance document as part of a bed-safety program to identify entrapment risks that may exist with current hospital bed systems.

We have the FDA's newest guidance document on hospital bed entrapment on our newsletter website at http://www.nursinglaw.com/entrapment.pdf.

The FDA's March 10, 2006 announcement in the Federal Register is available on our website at http://www.nursinglaw.com/fda031006.pdf. This 2-page notice contains information how to obtain copies of the guidance document directly from the FDA as a hard copy or on computer diskette.

According to the FDA, unlike FDA regulations, FDA guidance documents do not establish legally enforceable responsibilities.

Instead, guidance documents merely describe the FDA's current thinking on a certain topic and should be viewed only as recommendations unless the document makes reference to specific regulatory or statutory requirements.

That is, the FDA stresses that the word "should" in its guidance documents means that something is suggested or recommended, but not required by the FDA.

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The FDA has an extensive bibliography of references at the end of the latest guidance document to assist healthcare facilities in making decisions toward the goal of achieving a safe and comfortable sleeping environment for patients.

Exclusions

The FDA asks healthcare facilities to look carefully at the list of bed products which are excluded from the latest recommendations. For example, when mattresses are deflated on specialized therapy beds there is an entrapment risk, but for patients with skin-integrity issues the therapeutic benefit from addressing skin-integrity issues probably outweighs other risk considerations, the FDA says.

Pediatric beds and infant cribs are also excluded.

HBSW Test Methods for Assessing Entrapment Risk

According to the FDA, the newer guidance document differs from the older draft in that the newer document includes the Hospital Bed Safety Workgroup's (HBSW) July 2005 Dimensional Test Methods for Bed Systems.

The HBSW test methods include instructions for using a cone-and-cylinder tool to measure and assay the multiple potential entrapment zones which have been identified for existing bed systems, test procedures and sample data sheets.

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