LEGAL EAGLE EYE NEWSLETTER
For the Nursing Profession

Entrapment: New Draft Guidance From FDA Re Hospital Bed Systems.

The US Food and Drug Administration (FDA) has jurisdiction over manufacture and sale of medical devices.

The FDA has begun the process of formulating Federal regulations to define engineering specifications for hospital beds to reduce the risk of life-threatening patient entrapment. On August 30, 2004 the FDA published "Hospital Bed System Dimensional Guidance to Reduce Entrapment." At this time this draft guidance document is not mandatory for manufacturers, sellers or users of hospital bed systems. It is intended only to express the FDA's current thinking on the scope and severity of the problem and what may need to be done about it.

Entrapment – Awareness

We believe the FDA's draft guidance document is an excellent formulation of the risks of entrapment and may be useful to nurses and risk managers. We have placed the 35 page document on our website at http://www.nursinglaw.com/entrapment.pdf. It is also available directly from the FDA at http://www.fda.gov/cdrh/ocer/guidance/1537.html.

The FDA has identified seven potential zones for entrapment:

1. Within the rail.
2. Between the top of the mattress and the bottom of the rail, between the rail supports.
3. Between the rail and the mattress.
4. Between the top of the mattress and the bottom of the rail, at the end of the rail.
5. Between the 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.

Appendix D has a convenient one-page illustration showing what is meant by each of these hazard zones.

There is also an extensive list of library references.

The FDA's 8/30/04 announcement from the Federal Register invites public comments on this issue at http://www.fda.gov/dockets/ecomments.

FEDERAL REGISTER, Page 52907
August 30, 2004

Chlamydia Pneumonia: Nurse Was Infected In The Community, Workers Comp Claim Is Denied.

A hospital neonatal intensive care nurse came down with pneumonia that was linked to Chlamydia by her treating physician, an infectious disease specialist from a university teaching hospital.

The nurse became disabled. She filed for workers compensation, claiming her condition was an occupational disease.

The Supreme Court of Kentucky, in an unpublished opinion, agreed that infectious agents are far more prevalent in hospitals than in the community at large and that hospital nurses are routinely exposed to infectious agents to a much greater extent that persons at large in the community.

However, there is more to the picture than that.

To be compensable under workers compensation an occupational disease must be a condition that the worker has contracted in the workplace rather than in the community at large.

True, infectious diseases are more prevalent in the hospital than in the community, but this specific infectious agent has not been identified in the nurse's workplace.

SUPREME COURT OF KENTUCKY
UNPUBLISHED OPINION
August 26, 2004

The hospital's head of infection control testified that Chlamydia had never been specifically identified in the neonatal intensive care unit at any time in the years the nurse worked there.

Further, the patient's own physician conceded that the patient more likely than not contracted the illness in the community, as Chlamydia pneumonia is uncommon in newborns and children younger than five years.

In a workers compensation case for occupational disease it is up to the worker to prove that the specific infectious agent was more likely than not contracted in the workplace. Even for hospital nurses the legal presumption is that an infectious agent was acquired in the community. **Roberson v. Norton Hosp., 2004 WL 1908247 (Ky., August 26, 2004).**

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