



Lakeside Consulting
Division of Rabe Enterprises Inc.
6527 Smith Ave
Rome, NY 13440
(315) 337-5372

November 19, 2004

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

Dear FDA:

In reference to the **Hospital Bed System Dimensional Guidance to Reduce Entrapment** issued on August 30, 2004, I have prepared comments, suggestions, attachments and power point presentation disk as requested. The following document consists of Lakeside Consulting, Inc. guidelines for proper bed set up to eliminated entrapment areas. Also attached is a copy of New York State Bed Safety Checklist and User's Guide. Finally I am inclosing a CD and paper copies of a power point presentation comparing FDA Standards, New York Standards and a Durable Bed Solutions Standards.

If you need any additional information or I can assist you in anyway please contact Scott Rabe at 315 -796-0440

Sincerely,

Scott D. Rabe
Owner

2004D - 0343

C 8



Lakeside Consulting
Division of Rabe Enterprises Inc.
6527 Smith Ave
Rome, NY 13440
(315) 337-5372

November 19, 2004

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

Suggestions and Comments in reference to the Food and Drug Administration's issuing of Hospital Bed Systems Dimensional Guidance to Reduce Entrapment.

Background:

I, Scott Rabe, am the president of Lakeside Consulting, Inc. as well as Durable Bed Solutions. In November of 1999, New York State Developing Disabled Service's Office contacted our company to develop a product to prevent bed rail entrapment problems. We developed a prototype entrapment shield and had it test in a 32 person ICF. The design of the shield is to prevent inner and under bar entrapment especially when the head of the bed is elevated. Originally this design worked on a Lumex 5086 bed rail. In developing this prototype it was determined that no existing bed manufacture had bed rails that would prevent inner and under bar entrapment as well the lateral gap between the mattress and bed rail bars was to large. In April 2000 we retrofitted 120 new Hill Rom beds with Lumex side rails and entrapment shields.

In spring of 2001 we designed a new entrapment shield which is currently called the See-thru shield to work with different manufactures of bed rails and requires less mounting hardware and time. The new design incorporates a 180-degree "J" hook that hooks over the top rail and mounts with 2 clips to the bottom rail. This new design has complete coverage of inner and under bar entrapment as well as under bar entrapment coverage with the bed elevated to 45-degrees. With the use of the See-thru shield, aftermarket bed rails and crossbars we have been able to meet or exceed all of New York Standards for bed rails. To dated there are currently over 700 shields in service in New York and Tennessee. The See-thru shield was patented in Oct 2003.

Twin beds were another one of our issues and in 2003 we developed a new twin bed that incorporates a new style head and footboard as well as a rugged steel frame. The twin bed also has lateral mattress stops as well as crossbar brackets to hold our bed rails and shields. This twin bed meets or exceeds all of New York State Standards. Currently there are 21 twin beds in service with no callbacks.

Comments and Suggestions:

The seven zones of entrapment listed by the HBSW are all of great importance by of our company, but the HBSW dimensional limits seem to be large for some zones. We have worked very closely with the OMRDD of New York to meet or exceed New York Bed Standards. We have been able to meet these guidelines with designing a few new products that adapt to existing beds.

HBSW Zone 1 comments: Inner bar spacing:

The dimension of 4 ¾ inches for inner bar spacing is very large. New York Bed Safety Standards are 2 1/3 inches and Lakeside Consulting, Inc. Standards are 2 ¼". Our Company has been able to use an aftermarket rail made by Lumex to achieve these standards. Also the use of the See-thru shields eliminates most inner bar spacing.

HBSW Zone 2 comments: Top of compressed mattress and bottom rail:

The 4 ¾ inch HBSW dimension for top of compressed mattress to the bottom rail is large and has many factors to take into effect. First the mattress compression will vary during the life of the mattress. The bed rails also have the possibility of loosening up. These two factors alone can constantly change and might not be checked by the staff for some time. Other factors to consider are as the consumer gets his head or other body parts between the mattress and the bed rail the mattress can move or they can compress the mattress more than normal as they struggle. New York State recommends that the bar overlap the mattress. Our standards are the same as New York State standards but we also use the see-thru shields to have coverage down to the mattress support. One topic that is mentioned but no dimensions are given is when the head or feet of the bed are elevated. Our company has a standard that a see-thru shield for hospital beds be used which will give complete coverage thru 30 degrees and cover all gaps greater than ¼" between the mattress and shield.

HBSW Zone 3 comments: Between Mattress and Rail laterally:

The horizontal distance between the mattress and bed rail is similar to Zone 2. The HBSW and IEC recommend a distance of no more than 4 ¾ inches while New York Standards use a distance of ¾ of an inch and our standards are ¼ of an inch. Our concern is that if a gap can be large enough to get a arm in, as the person wiggles and the mattress compresses or moves horizontally the gap can open up to get a head between the mattress and bed rail. As in Zone 2 comments, the mattress will breakdown and compress more as it gets older and more use. Also as the bed rail hardware gets more pressure applied to it, the rail guides will possibly loosen up and lean outward. We have been very successful in obtain our suggested gap of ¼ of an inch through the use of after market side rails and see-thru shields. We have also made a testing device to check this dimension, which is very convenient for the staff to use.

HBSW Zone 4 comments: Between Top of Compressed Mattress and Bottom Rail at the End of Rail:

The HBSW and IEC dimensions for the end of the bed rail between the top of compressed mattress and bottom rail are again very large. Again New York Standards recommend $\frac{3}{4}$ of an inch, while our standards are $\frac{1}{4}$ of an inch. We recommend that the rail end be below the top of the mattress. We do agree that the angle of the end rail be at least 60 degrees so that the consumer's head will not get wedged under it. Our recommendation is to use a rail where there are no angles along the outside and the rail supports and vertical rail slides are at the outmost end of the bed rail. The style of rail depicted in the illustration is similar to a half rail and our recommendation is not to use half rails but to use full-length rails where possible.

HBSW Zone 5 comments: Between Split Rails:

We agree that the recommendations by the HBSW for distance between split rails of less than 2 $\frac{1}{3}$ inches or greater than 12 $\frac{1}{2}$ inches. New York Standards and our standards dictate distances of less than 2 $\frac{1}{3}$ inches or greater than 10 inches. Our recommendation is not to use split rails but the use of full-length bed rails whenever possible.

HBSW Zone 6 comments: Between End of Rail and Edge of Head and Foot Board:

The New York Standards and our standards use less than 2 $\frac{1}{3}$ inches or greater than 10 inches at both the head and footboard. Our experience with these dimensions is they work well with full-length bed rails. We have been able to achieve these dimensions with the full-length telescoping rails and maintain all the other standards. These dimensions allow the use of our see-thru shields.

HBSW Zone 7 comments: Between Head or Foot Board and End of Mattress:

The dimensions proposed by the HBSW for the distance between the end of the head or footboard and edge of mattress of less than 2 $\frac{1}{3}$ inches is agreeable with our studies. The head and footboard must overlap the mattress so the consumer can't get their head under the head or footboard of a compressed mattress. For the purpose of measuring this dimension the mattress needs to be moved to either the head or footboard and measured at the other end. New York State Standards state that the dimension for a twin bed is less than $\frac{3}{4}$ of an inch and the dimension for a hospital bed is less than 3 inches. Our standards that we use state the dimension be the same for both twin and hospital bed. This dimension we use is less than $\frac{3}{4}$ of an inch. In our finds of this dimension, most beds that were outside of this dimension could be fixed with the use of the appropriate mattress. (Hospital beds of 84" long were using a mattress that was meant for an 80" long hospital bed.) Also with the use of custom foam mattress you can achieve this dimension.

Overall Comments and Suggestions:

1. We are pleased to see that the FDA is developing guidelines for hospital beds and twin beds. We feel that it might be difficult to come up with one set of guidelines to cover the all the different organizations that exist out there. (VA, Mentally Retarded, Nursing Homes, Hospitals, Etc.)

2. A major concern we have identified is when the head of the bed is elevated the need exists to have this area between the mattress and bottom bed rail covered. The gap between the bottom rail and mattress will expand as the head is elevated to a higher position. Through the use of aftermarket products we have been able to provide coverage up to 45 degree's of head elevation. We believe that the HBSW needs to give dimensions for this area since this has been the major area for entrapment.
3. We find it interesting the New York Bed Safety Checklist and User Guide was not used as a reference for any of the dimensional information. We have worked very hard to achieve New York Standards in our business and found that with a few aftermarket items and designing of products from our company we can supply a safe and reliable bed.
4. Finally we have found that only a few manufactures can supply a bed that meets all of New York State Bed Safety Guidelines. There is not one manufacture of hospital beds that can supply a bed that has the dimensions need for all 7 zones of entrapment that is reasonably priced. We have been able to take a regular hospital bed and modify it with reasonably priced items to conform to all 7 zones of entrapment mentioned.

Summary:

For the past 5 years of working in New York State we do not know of any bed deaths in the 7 zones of entrapment as well as the triangle area under a bed rail of an elevated head for organizations that must comply with the New York State Bed Safety Guidelines. Below is a summary of all 7 zones of entrapment and comparisons with New York State Bed Safety Guidelines and Our Standards. As stated earlier we are creating the company called Durable Bed Solutions to provide all necessary products to provide a safe and reliable bed.

Zones	HBSW Recommended Limits	HBSW Alternative Limits	Bed Safety Checklist Guidelines	Durable Bed Solutions Limits
1	Less Than 4 3/4"	None	Less Than 2 1/3"	Less Than 2 1/3"
2	Less Than 4 3/4"	Less Than 2 1/3"	0"	0" (Use See-Thru Shield)
3	Less Than 4 3/4"	Less Than 2 1/3"	Less Than 3/4"	Less Than 1/4" None (Don't Recommend rail style)
4	Less Than 2 1/3"	None	None	Less Than 2 1/3" or Greater Than 10"
5	Not Specified	Less Than 2 1/3" or Greater Than 12 1/2"	Less Than 2 1/3" or Greater Than 10"	Less Than 2 1/3" or Greater Than 10"
6	Not Specified	Less Than 2 1/3" or Greater Than 12 1/2"	Less Than 2 1/3" or Greater Than 10"	Less Than 2 1/3" or Greater Than 10"
7	Not Specified	Less Than 2 1/3"	Twin bed 3/4" Hospital Bed 3"	Twin bed 3/4" Hospital Bed 3/4"



STATE OF NEW YORK
OFFICE OF MENTAL RETARDATION AND DEVELOPMENTAL DISABILITIES
44 HOLLAND AVENUE
ALBANY, NEW YORK 12229-0001
(518) 473-1997 • TDD (518) 474-3694

MEMORANDUM

To: Executive Directors, Voluntary Agencies
From: Jan Abelseth 
Deputy Commissioner OMRDD Quality Assurance
Date: October 1, 2002
Subject: Release of 2002 Bed Safety Checklist and User's Guide

The OMRDD Bed Safety Checklist and User's Guide were first released in 1999 to state and voluntary agencies that provide residential services to persons with mental retardation and developmental disabilities. During these past three years all providers have learned the importance of individual planning and risk assessment to insure that the people we serve have safe sleeping arrangements. Using the 1999 documents as foundations, the 2002 Checklist and User's Guide was developed to further clarify safety points, present new strategies, and reinforce the consideration of bed safety options beyond bed rails.

The 2002 User's Guide includes:

- Updated recommendations for minimum review for each check point;
- Detailed problem lists along with cross references;
- Updated choices available for correcting various problems and enhancing bed and bed rail safety;
- Factors and format to consider when assessing risk of injury while in bed; and
- Line drawings of particular check points from the Checklist and User's Guide.

Please feel free to duplicate and share the 2002 Updated Bed Safety Checklist and User's Guide within your organization with persons directly involved with bed and bed rail equipment. This includes service coordinators, residential staff, clinicians, business personnel, including those involved with purchasing, managers responsible for homes serving consumers in need of bed rails for safety, and those involved with quality assurance at a local level. The document continues to be helpful as a reference document when working with vendors during and following purchases of bed rail equipment.

The following individuals are available if you or your staff require additional information or clarification on bed and bed rail safety issues: Robert Albani, Division of Quality Assurance – New York City (212) 229-3350; Elaine Czerw, Office of Internal Affairs (518) 474-4376; and Denise Pensky, Litigation Support Services (518) 473-6026.

Cc:
Commissioner Maul
OMRDD Leadership Team

