

**Iowa Department of Inspections and Appeals
Health Facilities Division
Citation**

Citation Number: 6877		Date: November 9, 2018		
Facility Name: Country View		Survey Dates: October 22-25, 2018 & October 29, 2018		
Facility Address/City/State/Zip 1410 West Dunkerton Road Waterloo, Iowa 50703				
Rule or Code Section	Nature of Violation	Class	Fine Amount	Correction date

58.28(3)f	<p>58.28(3) Resident safety. <i>f</i> Residents shall be protected against physical or environmental hazards to themselves. (I, II, III)</p> <p>DESCRIPTION:</p> <p>Based on observation and staff interview the facility failed to assess bed side rails for the risk of entrapment to ensure gaps in side rails were not large enough for residents to be at risk of serious injury, impairment or death, placing the residents in immediate jeopardy for 26 of 83 resident beds observed. (Resident #84, #2, #82, #63, #20, #29, #11, #61, #7, #46, #13, #66, #80, #38, #37, #7, #24, #72, #47, #83, #28, #74, #58, #15, #36 & # 4)The facility census was 83.</p> <p>Findings include:</p> <p>Review of the Food and Drug Administration (FDA) Hospital Bed Safety Workgroup article, Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings dated April 2003, indicated, in pertinent part, "...Use of bed rails should be based on patients assessed medical needs and should be documented clearly and approved by the</p>	I	\$2500 (Held in Suspension)	UPON RECEIPT
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	<p>interdisciplinary team...Bed rail use for patients mobility and/or transferring, for example, turning and positioning within the bed and providing a hand-hold for getting into or out of bed, should be accompanied by a care plan...Inspect, evaluate, maintain, and upgrade equipment (beds/mattresses/bed rails) to identify and remove potential fall and entrapment hazards and appropriately match the equipment of patient needs, considering all relevant risk factors...If it is determined that bed rails are required...The mattress to bed rail interface should prevent an individual from falling between the mattress and bed. Maintenance and monitoring of the bed, mattress, and accessories such as patient/caregiver assist items...should be ongoing.."</p> <p>According to the FDA's Guidance for Industry and FDA Staff article, "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment", issued 3/10/06, "For 20 years, FDA has received reports in which vulnerable patients have become entrapped in hospital beds while undergoing care and treatment in health care facilities. The term "entrapment" describes an event in which a patient/resident is caught, trapped, or entangled in the space in or about the bed rail, mattress, or hospital bed frame. Patient entrapments may</p>			
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	<p>result in deaths and serious injuries. FDA received approximately 691 entrapment reports over a period of 21 years from January 1, 1985 to January 1, 2006. In these reports, 413 people died, 120 were injured, and 158 were near-miss events with no serious injury as a result of intervention. These entrapment events have occurred in openings within the bed rails, between the bed rails and mattresses, under bed rails, between split rails, and between the bed rails and head or footboards. The population 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 a variety of patient care settings..."</p> <p>A facility Bed Rail Policy revised 3/6/17, included the following section titled Overview of the U.S. Food and Drug Administration's (FDA) Potential Zones of Bed Entrapment:</p> <p style="margin-left: 20px;">-Zone 1: Within the Rail-any open space between the perimeters of the rail can present a risk of head entrapment. FDA recommended space: less than 4 3/4 inches.</p> <p style="margin-left: 20px;">-Zone 2: Under the rail, between the rail supports or next to a single rail support-the gap</p>			
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	<p>under the rail between the mattress, may allow for dangerous head entrapment. FDA recommended space: less than 4 3/4 inches.</p> <p>-Zone 3: Between the rail and the mattress-this area is the space between the inside surface of the bed rail and the mattress, and if too big can cause risk of head entrapment. FDA recommended space: less than 4 3/4 inches.</p> <p>- Zone 4: Under the rail at the ends of the rail-a gap between the mattress and the lower most portion of the rail poses a risk of neck entrapment. FDA recommended space: less than 2 3/8 inches.</p> <p>On 10/24/18 at 9:35 a.m., observation revealed the side rails on the bed in Room 231-1 appeared to be larger than 4 and 3/4 inches. At that time the surveyor asked the facility Director of Nursing (DON) if the facility assessed side rails for the risk of injury or entrapment. The facility Director of Nursing stated the facility maintenance department measured all side rails. At that time Staff I, Maintenance Director accompanied the surveyor to room 231-1. Staff I then held out two small wood blocks (2" and 4") and stated the facility had used them to measure the distance from the mattress to the side rail, and the distance from the top of the mattress to the top of</p>			
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	<p>the side rail. Staff I stated the facility did not complete any other measurements to assess for side rail safety because they had not been aware they needed to measure anything else. Staff I then used a four inch wood block and measured the distance of the gap within the upper side (head) rail and found it to be eight inches by eight inches. Staff I stated there had been no resident assigned to the bed but verified a resident could be admitted and assigned to it. Upon completion of the observation the surveyor notified the facility DON of the findings.</p> <p>At 9:55 a.m., the facility Maintenance Director measured the following gaps within side rails on surveyor request:</p> <ul style="list-style-type: none"> -Room 339, Resident # 84-7 inches x 7 1/2 inches, plastic side rail -Room 345, Resident #2- 9 inches x 7 1/2 inches, center metal rail -Room 327, Resident #82-7 inches x 7 1/2 inches, plastic rail -Room 224-1, Resident #63, 7 inches x 7 1/2 inches -Room 224-2, Resident #20, 7 inches x 7 1/2 inches -Room 223-1, Resident #29, 7 inches x 7 1/2 inches, plastic rail -Room 216-1, Resident #11, 7 inches x 7 1/2 inches, plastic rail 			
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	<p>-Room 216-2, Resident #61, 7 inches x 7 1/2 inches, plastic rail</p> <p>At that time the facility Maintenance Director stated they had not been aware of the requirements for the measurement within the side rail. The surveyor informed the Maintenance Director the gaps had been an entrapment risk and they stated they had been in the process of correcting the issue and measuring all side rails. The facility Maintenance Director then measured the side rail in Room 213, Resident #7 with gap in plastic rail of 7 inches x 7 1/2 inches. (total of 9 beds/rails this observation)</p> <p>At 10:26 a.m., surveyors measured a gap between bars of the upper (head) side rail in Room 327, Resident #82 and found it to be seven inches (top to bottom, inside of rail gap) by seven and one half inches (across, inside of rail gap). The surveyors head easily fit through the rail.</p> <p>At 10:39 a.m., observation revealed Resident # 2 in Room 345-2 to be lying in bed with an upper (head) side rail in the up position. One side of the bed had been against the wall and one side of the bed had the upper (head) rail up. (earlier measured at 9:55 a.m. observation with gap 9 inches x 7 1/2 inches)</p>			
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	<p>At 11:02 a.m., surveyor observations revealed the following beds assigned to residents with side rails having greater than a 4 and 3/4 gap within the rail bars:</p> <ul style="list-style-type: none"> -Resident #46, Room 205-1 -Resident #13, Room 206-1 -Resident #66, Room 207-1 -Resident # 80, Room 209-1 -Resident # 38, Room 334-1 -Resident #37, Room 335-3 -Resident #7, Room 213 -Resident #24, Room 217 -Resident # 72, Room 222-2 -Resident # 47, Room 223-2 -Resident #83, Room 222-1 -Resident # 28, Room 220-2 -Resident #74, Room 219-2 -Resident # 58, Room 219-1 -Resident #15, Room 331-2 -Resident # 36, Room 340 -Resident # 21, Room 348 <p>(total of 26 rails)</p> <p>Staff E, Registered Nurse stated on 10/24/18 at 3:30 p.m., no side rail safety assessments had ever been completed by the nursing department in the facility for any resident with a side rail.</p>			
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	<p>The facility abated the Immediate Jeopardy on 10/24/18 at 3:30 p.m. by implementation of the following actions:</p> <p>-11:00 a.m., facility maintenance staff were re-trained and immediately began process of assessment of facility side rails to identify beds that did not meet regulatory standards.</p> <p>-Registered Nurse Unit Managers reviewed the resident's plan of care and the actual bed device usage and made lists of all residents who use devices attached to the beds on the 3 units.</p> <p>-Assistant Administrator, Provisional Director of Health Services and Provisional Administrator reviewed the lists and identified beds which were available to be utilized with the positioning devices.</p> <p>-12:30 p.m., side rails on beds that did not meet guidelines were disabled with a tie down device that is not able to be cut off for release per usual measures to ensure no risk for entrapment starting on the Oaks unit, completed as soon as the list complied to remove the opportunity of any resident entrapment risk.</p> <p>-Beds found to be within compliance standards were relocated to accommodate residents who</p>			
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	<p>were in need of an assistive device for spatial identity or a grip device for positioning aide. Side rails that were not used for this purpose were also disabled from use, using the tie down mechanism. Residents were not allowed to return to their bed until a safety check had been completed and relocation of a new bed if necessary.</p> <p>-12:50 p.m., Assistant Administrator and Provisional Director of Health Services went to Oaks unit to supervise bed relocation process.</p> <p>-1:55 p.m., Oaks unit bed relocation process complete.</p> <p>-Maintenance moved to Willow-Wood unit to complete bed relocation process.</p> <p>-2:05 p.m., Assistant Administrator to Oaks unit to complete final review of bed relocation.</p> <p>-2:30 p.m., informed surveyor team of plan of corrective action taken to address practice.</p> <p>-2:45 p.m., one-half of Willow-Wood unit completed.</p> <p>-3:30 p.m., Willow-Wood unit completed with final bed audit completed by Assistant Administrator.</p>			
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	<p>A review of positioning bed device will be completed on all residents that currently use a bed positioning device and will be completed quarterly or more frequently if condition warrants.</p> <p>Alternate devices for consideration may include wing mattresses for persons who benefit from a spatial identity device, and grip device to be used for positioning. Only devices that pass the measurement test will remain in service.</p> <p>On 10/25/18 at 8:07 a.m., Staff I verified the facility had also found a total of 26 occupied beds that were found to have greater than 4 3/4 inch gaps within side rails. Staff I verified remedies were made to all beds during the abatement process on the previous day.</p> <p>FACILITY RESPONSE:</p>			
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