Iowa Department of Inspections and Appeals
Health Facilities Division
Citation

Citation Number: 7000			**Date:** July 22, 2019
Facility Name: QHC Winterset		**Survey Dates:** June 17-20, 2019	
Facility Address/City/State/Zip 411 East Lane St Winterset, IA 50273			
	JKM		

Rule or Code Section	Nature of Violation	Class	Fine Amount	Correction date
56.6(1)	**481—56.6(135C) Treble and double fines.** **56.6(1) Treble fines for repeated violations. The director of the department of inspections and appeals shall treble the penalties specified in rule 481—56.3(135C) for any second or subsequent class I or class II violation occurring within any 12-month period, if a citation was issued for the same class I or class II violation occurring within that period and a penalty was assessed therefor.**	I	**$23250 ($7750 x 3) treble fine** **(held in suspension)**	**Upon Receipt**
58.28(3)e	**481—58.28(135C) Safety. The licensee of a nursing facility shall be responsible for the provision and maintenance of a safe environment for residents and personnel. (III)** **58.28(3) Resident safety** **e. Each resident shall receive adequate supervision to protect against hazards from self, others, or elements in the environment. (I, II, III)** **DESCRIPTION:** Based on the United States Food & Drug Administration's Guide, observations, clinical record review, and staff interviews, the facility failed provide adequate nursing supervision to protect against hazards when they failed to assess bed rails for the risk of entrapment and obtain consent for the use of side rails for 5 out of 50 beds reviewed for side rail safety (Resident #21, #20, #51, #103, #1). This failure			

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	constituted immediate jeopardy to resident health and safety. The facility reported a census of 50 residents. Findings include: The website article updated 8/30/18 titled Hospital Beds (https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/hospital-beds), published by the United States Food & Drug Administration (FDA), included the following factual information: Between January 1, 1985 and January 1, 2013, FDA received 901 incidents of patients caught, trapped, entangled, or strangled in hospital beds. The reports included 531 deaths, 151 nonfatal injuries, and 220 cases where staff needed to intervene to prevent injuries. Most patients were frail, elderly or confused. The efforts of the FDA and the Hospital Bed Safety Workgroup (HBSW) have culminated in FDA's release of Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment. This guidance provides recommendations for manufacturers of new hospital beds and for facilities with existing beds (including hospitals, nursing homes, and private residences). Healthcare facilities developing comprehensive bed safety programs should consider - a. following the Clinical Guidance for the Assessment and Implementation of Bed Rails to assess an individual patient's needs when using a side rail; and			

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	b. consulting with the hospital bed manufacturer and their facilities' risk managers. The Guidance for Industry and FDA Staff Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment issued on 3/10/06 included the following documentation: <u>Introduction</u> This guidance provides recommendations relating to hospital beds (the terms "medical bed" and "hospital bed" are used interchangeably throughout this document and include adult medical beds with siderails) and hospital bed accessories. The guidance provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems (as used in this guidance, "hospital bed system" encompasses the bed frame and its components, including the mattress, bed side rails, head and foot board, and any accessories added to the bed). It characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, and recommends dimensional criteria for these devices. <u>Background</u> 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			

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	may result in deaths and serious injuries. <u>Key Body Parts at Risk</u> Three key body parts at risk for life-threatening entrapment in the seven zones of a hospital bed system discussed in this guidance are the head, neck, and chest. International anthropometric data references have been used to determine the relative sizes of these body parts for the population at greatest risk for entrapment and to provide a guide for the dimensional limits that would reduce their risk of entrapment. a. Head - To reduce the risk of head entrapment, openings in the bed system should not allow the widest part of a small head (head breadth measured across the face from ear to ear) to be trapped. Country-specific anthropometric data show that a 1st percentile female head breadth may be as small as 95 mm (3 ¾ inches). A dimension of 120 mm (4 ¾ inches) encompasses the 5th percentile female head breadth in all data sources used to develop these recommendations, and includes 1st percentile female head breadth as reported in some data sources. FDA is therefore using a head breadth dimension of 120 mm (4 ¾ inches) as the basis for its dimensional limit recommendations. This dimension is consistent with the dimensions recommended by the HBSW and the IEC (International Electrotechnical Commission). <u>Potential Zones of Entrapment</u> This guidance describes seven zones in the hospital bed system where there is a potential for patient			

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	entrapment. Entrapment may occur in flat or articulated bed positions, with the rails fully raised or in intermediate positions. a. Zone 1 - Within the Rail - Zone 1 is any open space within the perimeter of the rail. Openings in the rail should be small enough to prevent the head from entering. A loosened bar or rail can change the size of the space. The HBSW and IEC recommend that the space be less than 120 mm (4 ¾ inches), representing head breadth. 2. An observation completed on 6/20/19 at 9:12 a.m. of all the bed side rails in the facility revealed the following rooms contained quarter side rails on both sides of the bed with measurements greater than 4 and 3/4 inches (") within the perimeter of the side rails: a. Room 106B - Resident #51 sat in a wheelchair beside the bed during measurement, both bed rails in the up position. b. Room 204A - Resident #21 not present in room at time of measurement, right side rail against wall in up position left one down. c. Room 310A - Resident #20 not present in room at time of measurement, both side rails in down position, only 1 bed in room. d. Room 311B - Resident #103 lay in the first bed by the door during measurement, right side rail against the wall in the up position left one down. e. Room 507A - Resident #1 lay in bed during the measurement, both bed rails in the up position, and stated she used the rail for positioning.			

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	Each side rail contained the same style of side rails with 3 rungs within the side rail. The spaces within the rails measured: a. space towards head of bed - 5 and 3/4" width, 7 and 3/4" length, 9" diagonal b. center space - 7 and 1/4" width, 7 and 3/4" length, 10" diagonal c. space towards end of bed - 7" width, 7 and 3/4" length, 9 and 3/4" diagonal The Zone recommendations for 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 and 3/4" 1. Observation on 6/20/19 at 9:34 a.m. revealed a surveyor with her head thru the middle section of the side rail. This finding reported to the Administrator at 9:40 a.m. The Administrator stated the facility would remove and replace the side rails immediately. On 6/20/19 at 12:38 p.m. the Administrator and the Nurse Consultant reported 5 beds with that type of side rail removed from the building and placed outside by the dumpster after they became aware of the concern for potential for entrapment with the side rail measurements. The Administrator stated discussed a plan moving forward to ensure proper side rail/equipment use. The Nurse Consultant reported facility to complete side rail assessments for residents to determine if need or type of side rail.			

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	2. According to the Minimum Date Set Assessment too dated 6/6/19, Resident #21 had diagnoses of Alzheimer's disease and glaucoma and experienced severe memory impairment and displayed fluctuating inattention and disorganized thinking. The MDS revealed the resident required limited physical assistance of 1 staff for bed mobility and transfers and did not identify that the resident used bed rails. a. On 4/1/19, the care plan focus area documented the resident displayed altered thought processes. b. On 4/2/19, the care plan identified a risk for falls related to antidepressant medication use, glaucoma, and c. Alzheimer's disease. d. On 4/26/19, the facility revised the care plan to identify a moderate risk for falls and directed staff to round hourly and anticipate the resident's needs (offer drinks, water, offer to take to restroom). e. On 5/8/19, the care plan identified the resident had impaired visual function. Observation on 6/17/19 at 11:33 a.m., revealed: Resident # 21 sat next to the nurses station in a regular chair and made multiple attempts to stand by herself with a wheeled walker. At 2:19 p.m., Resident #21 lay in bed with a quarter side rail in the up position. Resident # 21 yelled for help, sat up in bed, and tried to scoot to the end of the bed. After a couple of unsuccessful attempts, Resident # 21 lay back down. On 6/20/19 at 10:00 a.m., clinical record review			

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	revealed Resident #21's hard chart contained a form titled Use of Side Rails Education Sheet/Consent Form. The form documented the resident requested side rails be used per preference for mobility and/or safety but the form failed to contain a date or signature of the resident or resident representative. The record also contained a Side rails Risk Assessment for the use of Side Rails that contained the resident's name and room number on it but was otherwise left blank. 3. According to the MDS assessment dated 4/4/19, Resident # 20 had a diagnoses of non-Alzheimer's dementia and a Brief Interview for Mental Status (BIMS) score of 03 (severe cognitive impairment). The MDS documented the resident displayed with fluctuating behaviors of inattention and disorganized thinking and was fully dependent of staff . A score of 03 indicated . The MDS revealed the resident totally dependent upon 1 person for bed mobility and 2 persons for transfers. The MDS recorded bed rails not used. The care plan focus area revised 1/24/19 identified a risk for injury related to non-compliance with transfers. On 2/8/19 the care plan identified a high risk for falls related to gait, balance problems, generalized weakness, incontinence, and psychoactive drug use. On 2/11/19 the care plan documented the resident attempted self-transfers, required assistance of 2 persons, and to help minimize potential for falling from bed, staff directed to use a bolstered mattress. On 6/20/19 at 10:00 a.m. record review revealed			

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	Resident #20's clinical record lacked a bed side rail assessment or consent for the use of side rails. 5. The MDS assessment dated 5/30/19 for Resident #51 identified a BIMS score of 14 indicating intact cognition. The MDS revealed the resident independent with bed mobility and transfers. The MDS documented diagnoses that included recurrent major depressive disorder and chronic pain syndrome. The care plan focus area revised 12/15/17 identified mobility deficits and at times needed assist with ADLs related to chronic arthritis, ankylosing spondylosis (causes inflammation of the spinal joints), RA (rheumatoid arthritis) in hands, and flexion contractures in knees. The care plan informed staff the resident no longer able to ambulate and wheelchair dependent. On 6/5/19 the care plan revised for a risk for falls related to mobility deficits, arthritis, contractures, chronic pain, and use of antidepressant, hypnotic, opioid, antianxiety, and anticonvulsant medications. On 6/20/19 at 10:00 a.m. record review revealed Resident #51's clinical record lacked a bed side rail assessment or consent for the use of side rails. 6. The electronic record for Resident # 103 revealed the resident newly admitted to the facility on 6/14/19. The care plan focus area dated 6/15/19 identified a			

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	risk for falls related to history of falls, use of walker, decreased strength, natural aging process, and diagnoses of muscle weakness, TIA (Transient Ischemic Attack), COPD (Chronic Obstructive Pulmonary Disease), Alzheimer's disease, and dementia with behaviors. The care plan direct staff to provide frequent checks of the resident. On 6/20/19 at 10:00 a.m. record review revealed Resident #103's clinical record lacked a bed side rail assessment or consent for the use of side rails. 7. The MDS assessment dated 6/5/19 for Resident #1 documented a new admit to the facility. The care plan focus area dated 6/7/19 identified a risk for falls related to a history of falling, hip displacement, and Afib (atrial fibrillation). On 6/20/19 at 10:00 a.m. record review revealed Resident #1's clinical record lacked a side rail assessment or consent for the use of side rails. **FACILITY RESPONSE:**			

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