

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052048 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 05/14/2007 |
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| NAME OF PROVIDER OR SUPPLIER KINDRED HOSPITAL MODESTO | | STREET ADDRESS, CITY, STATE, ZIP CODE 730 17TH STREET, MODESTO, CA 95354 STANISLAUS COUNTY | | |
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| | <p>Health and Safety Code 1280(a) For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>Health and Safety Code 1280(c) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation.</p> <p>70207. Medical Service Equipment and Supplies There shall be adequate equipment and supplies maintained related to the nature of the needs and the services offered.</p> <p>70701. Governing Body (a) The governing body shall: (4) Provide appropriate physical resources and personnel required to meet the needs of the patients and shall participate in planning to meet the health needs of the community.</p> <p>70701. Governing Body (a) The governing body shall: (5) Take all reasonable steps to conform to all applicable federal, state and local laws and regulations, including those relating to licensure, fire inspection and other safety measures.</p> | | | |

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3/18/2008

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| | <p>Continued From page 1</p> <p>70701. Governing Body (a) The governing body shall: (7) Require that the medical staff establish controls that are designed to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter.</p> <p>70703. Organized Medical Staff (a) Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital.</p> <p>Based on observations, interviews, document review and record review, the hospital failed to develop, implement and maintain an effective, ongoing, hospital-wide, data-driven Quality Assessment and Performance Improvement (QA/PI) program. The hospital's governing body failed to ensure that the program involved all hospital departments and services, including those services furnished under contract. The hospital's governing body failed to ensure that the focus of the QA/PI program was based on indicators related to the prevention and reduction of medical errors, including but not limited to, medical equipment failures and medication use monitoring. The hospital failed to maintain and demonstrate</p> | | | |
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| | <p>Continued From page 2</p> <p>evidence of its QA/PI program for review.</p> <p>Findings:</p> <p>On 05/07/07, the Chief Executive Officer (CEO), the Chief Clinical Officer (CCO), the Director of Quality Management (DQM) and two of the Medical Directors were asked to supply information about the QA/PI program and specifically, about the development of a plan of action designed to prevent accidental entrapment and death of patients similar to an event that occurred on 01/14/07, when a patient (Patient #16) was found dead after being entrapped between the bed rails and the therapeutic mattress.</p> <p>The hospital provided for review, the QA/PI plan, a document entitled, "A Strategic Plan for Quality 2007." This document is a general plan for QA/PI for the corporation that owns the hospital (Owner Corp). It does not have any specific information for how QA/PI would be done at the local hospital; nor does it address the type of patient accidental death that occurred on 01/14/07.</p> <p>In two interviews conducted on 05/07/07, the hospital administrative staff, CEO and DQM, reviewed their evaluation of the circumstances surrounding the 01/14/07 accidental death. The DQM and CEO also provided copies of two documents, "Guidance for Industry and FDA (Food and Drug Administration) Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment, March 10, 2006" (FDA Document) and "A Guide for Modifying Bed</p> | | | |

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| | <p>Continued From page 3</p> <p>Systems and Using Accessories to Reduce the Risk of Entrapment, June 21, 2006, Developed by the Hospital Bed Safety Workgroup" (HBSG Document).</p> <p>They explained that in the spring of 2006, the Owner Corp had conducted a survey of all their facilities and found that at this hospital, 95 of the 99 beds (96%) were in need of bed rail modifications to make the risk of entrapment less likely. At that time, (spring of 2006) the Owner Corp made a determination that in August, 2007 they would have 74 of the 95 beds modified by adding new bed rail kits that would reduce the risk of entrapment. However, neither before the 01/14/07 death, nor after that death, had the hospital developed a plan of action to mitigate entrapment in these beds.</p> <p>In these interviews, when the hospital administrative staff began to explain the actions taken and contemplated by the Owner Corp related to modifying bed rails for the 74 beds, it became evident that neither of the two Medical Directors had been involved and neither had seen the FDA Document or the HBSG Document. In later interviews (05/08/07 and 05/09/07) with the Medical Director for the LTAC (Long Term Acute Care), and the Medical Director for the Skilled Nursing Distinct Part (SN/DP), both acknowledged that they had not been involved in any development of a plan for modifying the side rails or for any other specific plan to develop mitigation for patient entrapment.</p> <p>The hospital's investigation of the situation showed that (among other factors):</p> | | | |

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| | <p>Continued From page 4</p> <ul style="list-style-type: none"> * Entrapment on 01/14/07 had occurred in "Zone-5" (behind and between the upper and lower bed rails and in front of the mattress) as defined in the FDA Document. * All four side rails had been up. * There was no order to have the patient restrained by having all four side rails up. * The therapeutic mattress used in treating Patient #16 in January, 2007 was a Synergy Pulse 2 mattress. <p>On 05/07/07 and the morning of 05/08/07, the hospital staff were not able to provide evidence that a specific and complete action plan had been developed to prevent similar entrapments from occurring. Hospital staff had developed a plan to educate their nursing and other direct care staff. However, this did not involve any specific steps to prevent a recurrence of the entrapment that occurred on 01/14/07 to Patient #16, or as outlined on page 11 of the HBSG Document. The administrative staff was awaiting the arrival of their Regional Director of Clinical Operations (RDCO) to assist them in presenting evidence of their actions taken to prevent similar patient entrapments. When the RDCO arrived on the afternoon of 05/08/07, she gave a general overview of the same material presented previously by the administrative staff. When asked if the hospital had taken any specific mitigating action as outlined on page 11 of the HBSG Document, she acknowledged that they had not.</p> <p>On 05/08/07, the hospital had 18 beds equipped with Synergy Pulse 2 mattresses. On the evening</p> | | | |

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| | <p>Continued From page 5</p> <p>of 05/08/07, the hospital staff had placed rolled blankets (fashioned as bolsters) as gap-fillers between the sides of these mattresses and the bed rails for each of those 18 beds. This was the first specific remediation action taken to prevent a repeat of the patient entrapment event.</p> <p>The morning of 05/09/07, in an interview, the RDCO stated that in February, 2007, she sat on a similar bed with a Synergy Pulse 2 mattress to see if the entrapment occurrence could be repeated. She placed both her feet between the raised upper and lower side rails and discovered that when the mattress "pulsed" (a shift of air pressure designed to cause the shift of weight for the patient) it pushed her away from the center of the bed and into the space between the mattress and the side rails. She stated that this event startled and frightened her, even though she was fully capable and strong enough to prevent actual entrapment.</p> <p>At 12:55 p.m. on 05/09/07, the CEO was informed that an Immediate Jeopardy situation had been identified and declared. This was because there were at least 77 beds in the hospital that could still entrap patients in "Zone-5" when all four bed-rails were up.</p> <p>At 6:00 p.m. on 05/09/07, the hospital administrative staff demonstrated that on each of the beds in the hospital, the lower side-rails had been securely fastened down using a plastic zip tie. The staff explained that only the upper bed rails would ever be used unless there was a specific, physician written order for all four bed rails. Only a</p> | | | |

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| | <p>Continued From page 6</p> <p>nursing supervisor would ever be permitted to cut the zip ties for lower bed rails use, and that would only happen when the bed was equipped with additional entrapment prevention remediation, such as a set of bed rail bolsters.</p> <p>The staff presented a plan of corrective action that detailed extensive documentation that policies and procedure were in place, and all staff that were currently caring for patients had received in-service training. Also, all staff would be trained on patient entrapment prevention before they were permitted to resume caring for patients.</p> <p>The CEO and CCO were notified that the condition of Immediate Jeopardy related to the safety of hospital beds was removed on 05/09/07 at 6:00 p.m., based on observations, interviews with hospital staff, and review of facility documents.</p> <p>The violation(s) has caused or is likely to cause serious injury or death to the patient(s).</p> | | | |

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