

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050168	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/23/2009	
NAME OF PROVIDER OR SUPPLIER ST. JUDE MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 101 E. VALENCIA MESA DRIVE, FULLERTON, CA 92835 ORANGE COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during the investigation of COMPLAINT NO: CA00177085</p> <p>Inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility.</p> <p>Representing the Department of Public Health: [REDACTED]</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</p> <p>T22 DIV5 ART3-70215(a)(1) Planning and Implementing Patient Care (a) A registered nurse shall directly provide: (1) Ongoing patient assessments as defined in the Business and Professional Code, Section 2725(d). Such assessments shall be performed, and the findings documented in the patient's medical record, for each shift, and upon the receipt of the patient when he/she is transferred to another patient care area.</p> <p>T22 DIV5 ART6-70417 Basic Emergency Medical Service, Physician on Duty, Equipment and Supplies</p> <p>All equipment and supplies necessary for life support shall be available, including but not limited to, airway control and ventilation equipment, suction devices, cardiac monitor defibrillator, pacemaker capabilities, apparatus to establish central venous pressure</p>		<p>T22 Planning and Implementing Patient Care</p> <p>a. Initial and ongoing assessments by nursing were reviewed and re-educated post this incident. Specific education to the Emergency Department nursing staff was conducted. This education was specific to the immediate needs of critical patients, and the need for ongoing assessments of these types of patients who will exhibit less than routine signs and symptoms of their disease. Ongoing assessment is conducted by the unit manager to assess that care planning is occurring concurrently.</p>	

Accepted
[Signature]
5/20/09

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9:15:47AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
Paula K. Allman TITLE
Manager Regulatory Compliance (X6) DATE
5/20/2009

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	<p>Continued From page 1</p> <p>monitoring, intravenous fluids and administrative devices.</p> <p>These regulations were NOT MET as evidenced by:</p> <p>Based on interview and record review, the nurse failed to assess Patient G after a cardiac monitor change. Additionally, the clinical alarm system for the cardiac monitor was not set to ensure patient safety. Patient G died in the emergency room.</p> <p>Findings:</p> <p>Review of Patient G's medical record on 2/6/09, showed the patient was admitted to the ED (Emergency Department) with increasing chest pressure on 2/3/09 at 0523 hours. The ED physician's initial diagnosis was chest pain with an abnormal heart rhythm. During the patient's stay in the ED, the patient was taken for a cardiac stress test/treadmill with results that showed the patient had an MI (myocardial infarction- heart attack).</p> <p>Further review of the medical record, showed a cardiac monitor strip for Patient G. The strip showed, on 2/3/09 at 1830 hours, the patient had slightly over four seconds of ventricular fibrillation (a lethal heart rhythm) and then there was no further rhythm recorded. Further record review showed a Code Blue (cardiac resuscitation) was initiated at 1914 hours. The ED physician's progress note of the Code Blue</p>		<p>b. Emergency Department Director has responsibility.</p> <p>c. Concurrent audits of the care planning process from the Emergency department were conducted during Jan 2009 at 100%. Continued audits are weekly and focused on the care plans in place and specific to the patients needs.</p> <p>T22 Emergency Medical Services, Physicians on duty, Equipment and Supplies</p> <p>a. Immediately upon discovery of the alarm setting being inaudible all of the alarm settings in the Emergency department were checked and reset to a decibel that could be heard from the farthest corner of the unit. This was accomplished with the Biomedical Department and Quality Management department personnel. A process was established that restrict reduction of the sound without the authorization of both of these areas. The alarm settings for all alarms within the hospital were</p>	<p>04/02/2009 and 2/28/2009</p> <p><i>04/02/09 in 0182009 Pallette Sketch 8/27/09 1630</i></p>

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Caulette Fletcher *Manager Regulatory Compliance* *5/20/2009*

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	<p>Continued From page 2</p> <p>showed the patient was found to be in asystole (no heart activity), no respirations, and with no signs of life. Resuscitation was attempted for 21 minutes, was unsuccessful, and the patient was pronounced dead at 1935 hours on 2/3/09.</p> <p>On 2/11/09 at 0905 hours, Nurse A (the nurse caring for the patient during the events described above) was interviewed. The nurse stated she took over the care of the patient at 1630 hours. According to the nurse, several times during the patient's stay in the ED he was off the monitor. The leads were removed when he wanted to go to the bathroom. The nurse stated she observed the wife leave the patient at about 1830 hours. At 1905 hours, the night shift nurse came in. According to Nurse A, while reporting off to the night shift nurse, Nurse A, at the nurses' station, observed a "0" (no heart rhythm) on Patient G's cardiac monitor screen. The nurse stated she thought the patient's monitor leads must have come off. She stated she could see the patient sitting upright on the gurney and thought the patient was alright. She did not go over and check the patient. Nurse A stated she continued to give report, the CCT (Clinical Clerical Technician) walked by the patient, noticed something was wrong with the patient, called the physician over and a Code Blue (cardiac resuscitation) was started.</p> <p>On 2/23/09 at 0830 hours, the CCT was interviewed. The CCT stated that on 2/3/09 at</p>		<p>also checked and reset. The same process was used. The Biomedical Department conducts audits of the alarm settings on a weekly basis when this occurred and is now monthly. Staff was educated regarding the importance of the alarm settings, keeping paper stocked and in place on the monitors. Unit audits are being conducted.</p> <p>b. Chief Nursing Officer, VP of Operations and Chief Medical Officer are responsible for these corrections.</p> <p>c. Biomedical department staff made daily rounds during the first 2 weeks post incident. The audit consistent of alarm settings at the level there were originally set. The audits are now at monthly, Nursing/tech audits consist of paper in monitors each shift.</p>	<p>2/28/09 2/04/2009 AS per Discussed with Paula the Fletcher 1630 5/20/09</p>

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	<p>Continued From page 3</p> <p>around 1900 hours she was passing a meal tray to a patient and walked by Patient G's gurney. The patient's overhead light was off and the patient was lying with his face pressed against the gurney's rail with one leg hanging off the gurney. The patient's bedside monitor showed no heart rhythm. She tried to rouse the patient but was unable to and called the physician, who was present in the area, over. The CCT said the physician stated the leads were off and the physician began reattaching them while attempting to rouse the patient. The monitor continued to show a flat line and a Code Blue was called.</p> <p>The Joint Commission on Accreditation of Healthcare Organizations defines a clinical alarm as any alarm that is intended to protect the individual receiving care or alert the staff that the individual is at increased risk and needs immediate assistance.</p> <p>Observation of the patient monitoring system in the ED at 1500 hours on 2/6/09 showed the system had several features to alert staff to changes in a patient's heart rate. Two such features were an audible alarm and a visual alarm. According to the ED manager, interviewed concurrently, the auditory alarm sounded when changes occurred in a patient's heart rate and when that occurred a paper printout with the patient's cardiac rhythm would run continuously until the alarm was stopped, serving as the visual alert.</p>			

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Christine Fitehiko Manager Regulatory Compliance 5/20/2009

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	<p>Continued From page 4</p> <p>The monitor with the paper printout roll was located above and at the rear of the nurses' station.</p> <p>According to the Quality Manager, interviewed on 2/6/09, review of the events surrounding Patient G's death showed when the monitoring system was checked, the monitor alarm volume was found to be set at 2 (range of 0 to 10). Also, the paper printout roll was pulled out of the monitor disabling the printing function.</p> <p>On 2/11/09 at 1050 hours, the manager of the engineering department was interviewed. When asked if the cardiac monitor's volume setting of two was sufficiently audible, the engineering manager stated the ability to hear this volume would depend on the time of day and volume in the area. The manager of the engineering department stated the paper printout did not work because the paper roll was pulled out. The monitor functions were tested and there were no malfunctions. During the interviews with both the CCT and Nurse A, neither one knew who had turned the monitor volume to two or who disabled the monitor paper roll.</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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Paulette A. Hildebrand Manager, Regulatory Compliance

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