CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050168	A. BUILDING _____ B. WING _____	02/23/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. JUDE MEDICAL CENTER	101 E. VALENCIA MESA DRIVE, FULLERTON, CA 92835 ORANGE COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00212243 - Substantiated Representing the Department of Public Health: [redacted], Pharmaceutical Consultant II The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): 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. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY 1279.1(a) HSC Section 1279 (a) A health facility licensed pursuant to subdivision (a), (b) or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health or safety of patients, personnel or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.		1279.1 (a) A: How the correction will be accomplished, both temporarily and permanently. The St. Jude Medical Center (SJMC) Sentinel Event/Adverse Event Reporting and Analysis policy is in compliance with the reporting timeframe of "immediate and within five days" as it relates to the SB1301 regulation. In the investigation of this event and the reporting date of Dec. 9, 2009 it is noted that the original coroner's report was not available until Oct. 14, 2009 at which time a request for a subsequent review of the case was made with further evidence provided to the coroner. This process took over three weeks and the final report completed on Nov. 18, 2009. Based on the substantiated toxicology report of Morphine toxicity there was a complete review of the smart pump and programming by the nurse in question. Upon completion of this review the case was self-reported on Dec. 9, 2009.	

Event ID:MRC011 12/29/2010 8:40:20AM

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1/12/11 - approved, Jay Rubin, Pharm.D.

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	Continued From page 1 1279.1(b)(4)(A) Medication Error (b) For purposes of this section "adverse event" includes any of the following: (4) Care management events, including the following: (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose. 70213(a) Nursing Service Policies and Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. 70263(c)(1)(g) Pharmaceutical Service General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and		B: Director of Clinical Excellence Department C: All Adverse Events that are reported in adherence to the SB1301 regulation will have the timeline monitored and reported to the Patient Safety Performance Improvement Committee. 1279.1 (b) 4 A: How the correction will be accomplished, both temporarily and permanently. A comprehensive investigation and review of policies and practices was completed. The following areas were part of that review: 1. The smart pump drug library for the Morphine administration parameters were programmed to a "hard stop". All physician order sets with Morphine orders were updated to reflect these changes. This change will result in a redundancy to the PCA pump programming by nursing that will prevent a programming contradiction of a physician order.	March 8, 2010

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	Continued From page 2 chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. The above regulations were NOT MET as evidenced by: Based on interview and record review the hospital failed to ensure that Staff 2 (a newly hired RN in orientation) received a physician		2. St. Jude Medical Center PCA infusion policy was reviewed with respect to the double check process and nurse's responsibility to the process. While the nurse in question did not follow established hospital policy by double checking the PCA pump programming against the physician order and with another nurse to double check the entry, this was not found to be a practice among other nursing staff and changes to the policy were not warranted. Despite this finding all nursing staff received a review of the policy and "Lessons Learned" regarding the double check process and the safety measures it provides patients was completed. 3. Nursing Orientation and annual skills review were updated to include the PCA pump changes. The nursing orientation preceptor program was updated to include an improved verification of the skills program; including critical skills and thinking review. Preceptors were provided criteria to ensure competencies and critical	

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	Continued From page 3 order prior to increasing the dose of morphine (a potent narcotic medication to treat pain) for Patient 1. The unordered increase in dosage resulted in Patient 1 receiving 10 times the dose of morphine ordered by her physician. According to the coroner's report, Patient 1 died of "Acute Morphine Intoxication." The hospital also failed to ensure Staff 2 complied with their policy and procedure (P&P) entitled, "Patient Controlled Analgesia Infusion" which required confirming a dosage change on the Patient Controlled Analgesia (PCA) pump with a second nurse. Staff 2 did not obtain a second nurse's confirmation. This safeguard in the P & P is set to prevent the administration of excessive amounts of pain medication. Findings: On 2/23/10 at 1301 hours, during an interview with Staff 1 (the Registered Nurse risk manager) stated Patient 1 was brought to the Emergency Department on [redacted]/09 after an accidental overdose of diltiazem (medication indicated for high blood pressure and to stabilize abnormal heart beats). Patient 1 was admitted to the ICU (Intensive Care Unit) where she was treated for low heart rate and low blood pressure. According to Staff 1, on [redacted]/09, Staff 3, (a physician) explained to Staff 2 (the Registered Nurse who cared for Patient 1 and resigned from her job 12/16/09) that during palliative care some patients require morphine doses up to 20 mg (milligrams) per hour intravenously. Staff 1		4. thinking processes are evaluated as well as basic skill levels. B: Chief Nursing Officer and the Director of Pharmacy C: Monitoring process 1. Weekly monitoring of the PCA smart pump data is performed for any deviation from the parameters. This information is reported to the Medication Error Committee and the Pharmacy and Therapeutics Committee for recommendations and changes to the drug library. March 8, 2010 2. Proactive audits of the PCA process were conducted and continue to be completed to account for both the programming of the pump, use of correct drug profile and adherence to the double check process. 3. The education department oversees the orientation program and the annual skills review process that includes the preceptor program.	

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	Continued From page 4 stated that Staff 2 misinterpreted Staff 3 and considered this a verbal order. On 2/23/10 at 1322 hours, Staff 1 stated on [redacted]/09 at 1730 hours, the PCA (Patient Controlled Analgesia pump that delivered the morphine) dose setting was changed from morphine 2 mg per hour to morphine 20 mg per hour by Staff 2. This was determined by reviewing the PCA pumps' memory of events. Staff 1 stated there was no order by a physician to increase Patient 1's dose of morphine to 20 mg per hour. Patient 1's respiration rate (number a breaths a person takes per minute) was running low at between 9-12 breaths per minute (normal 15-20 breaths per minute) and the patient died within an hour of the morphine dose increase, at 1808 hours. Staff 1 stated the hospital requested an autopsy to determine the cause of death. The coroner's autopsy report revealed a blood level of morphine of 4.1 milligrams/Liter and the coroner determined the cause of death was due to "Acute Morphine Intoxication." On 2/23/10 at 1420 hours, Staff 1 stated that Staff 2 was completing the last week of her 3 month orientation when Staff 2 administered the overdose of morphine to Patient 1. According to the hospital's administrative document, Staff 2 admitted she did not know how to program a PCA pump but did so anyway and thought Staff 3 increased the dose of Morphine to 20 mg.		4. Our audit reviews the preceptor's ability to provide constructive feedback to new employee and validate the preceptor's evaluation of the staff. 70213 (a) Nursing Service Policies and Procedures A: How the correction will be accomplished, both temporarily and permanently. 1. The Telephone Order/Verbal Order policy was reviewed for content. Despite the nurse in question not following the hospital's existing policy and procedure with respect to having physician orders for all services, no changes were made to these policies. Both physicians and nursing were provided education on the use of verbal orders in emergent situations only. Nursing was specifically provided information regarding the PCA order process and how it relates to the programming of the smart pump.	

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	Continued From page 5 The hospital's P&P (Policy & Procedures) entitled, "Patient Controlled Analgesia Infusion" states before changing a prescription, "A second registered nurse must verify that the parameters are correct and co-sign the E-MAR (electronic medication administration record) or PCA flow sheet." Staff 2 changed the dose of morphine without following the hospital's P&P which required verification and documentation of dosage changes by a second nurse. The hospital failed to prevent this overdose of morphine by failing to ensure that Patient 1 received the dose of morphine ordered by her physician. The hospital also failed to ensure that Staff 2 followed the hospital's P&P entitled, "Patient Controlled Analgesia Infusion' which required a second nurse to double check and verify the programming of the PCA pump. The hospital failed to follow the policies and procedures for programming a pump for Patient Controlled Analgesia resulting in the death of Patient 1 by morphine overdose. The hospital's Pharmacy and Therapeutics Committee failed to ensure that the pharmacy and nursing representatives on the committee provided adequate training and oversight for their staff so patients were administered morphine accurately, safely, and according to hospital policies and procedures.		2. The existing policies for PCA pump infusion and medication administration that emphasize the double check process were reviewed.Despite the nurse in question not following the existing policy after the review was completed no changes were made. The development of "Lessons Learned" regarding the patient safety mechanism of the double check process was completed and distributed to all nursing staff. B: Chief Nursing Officer C: Monitoring 1. Verbal order process is monitored on a monthly basis with any occurrences reviewed for reason and education. March 8, 2010 2. Proactive audits of the PCA process were conducted to account for both the programming of the pump, use of correct drug profile and adherence to the double check process.	

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