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
	050100	A. BUILDING _____ B. WING _____	09/08/2008

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SHARP MEMORIAL HOSPITAL	7901 FROST STREET, SAN DIEGO, CA 92123 SAN DIEGO COUNTY

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	The following represent the findings of the Department of Public Health during an Entity Reported Incident Investigation on June 9, 10, 11 and 12, 2008 Complaint No. 153342 Category: Nursing Staff Development Representing the California Department of Public Health was [redacted] HFEN. 1280.1(a) HSC Section 1280 If a licensee of a health facility licensed under subdivision (a), (b), of (f) of Sections 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 ($25,000) per violation 1280.1(c) HSC Section 1280 For purposes of the 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 T22 DIV5 CH1 ART3-70214 Nursing Staff Development (a) There shall be a written organized in-service education program for all patient care personnel		**RECEIVED** **CA DEPT OF PUBLIC HEALTH** OCT 31 2008 **LICENSING & CERTIFICATION** **SAN DIEGO NORTH DISTRICT OFFICE** **The Plan of Correction is intended to serve as this Organization's compliance with Title XXII regulation and should be deemed to be credible documentation evidencing correction of the deficiencies cited on form #2567.** **T22 DIV5 CH1 ART3-70214 Nursing Staff Development**	

Event ID: PE4311 10/17/2008 12:54:52PM

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Joan M. Eng	Director, Regulatory	10/31/08

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	Continued From page 1 including temporary staff as described in subsection 70217(m). The program shall include, but shall not be limited to, orientation and the process of competency validation as described in subsection 70213(c). (2) All patient care personnel, including temporary staff as indicated in subsection 70217(m), shall be subject to the process of competency validation for their assigned patient care unit or units. Prior to the completion of validation of the competency standards for a patient care unit, patient care assignments shall be subject to the following restrictions. (A) Assignments shall include only those duties and responsibilities for which competency has been validated (C) Registered nurses shall not be assigned total responsibility for patient care, including the duties and responsibilities described in subsections 70215(a) and 70217(b)(3) until all the standards of competency for that unit have been validated On 6/10/08 at 11:45 A.M., hospital administrative representatives were informed that Immediate Jeopardy existed as the result of a patient receiving an over dose of a bolus [loading dose] of intravenous medication that resulted in the patient's death. The staff member who administered the medication had responsibility for the patient but had not demonstrated all the standards of competency for the Intensive Care Unit		1. An Alaris Practice Alert was created and posted above all Medication Pyxis stations in the ICUs and telemetry units where bolus/infusion is used. 2. The RN Alaris Pump competency was revised to include the following: • How to `bolus from an infusion' bag • What to do if the Alaris Guardrails® did not allow programming of any infusion (i.e., `hardstop') • A required online tutorial • A required post-test and return demonstration 6/16/08	6/6/08 6/16/08

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	Continued From page 2 Based on observation, interview and record review, RN 1 failed to demonstrate competency relative to the use of the Alaris Medley Infusion Pump. RN 1 failed to program the intravenous infusion pump with the name and dose of the drug which is required to activate the Guardrail safety feature of the infusion pump. The Guardrail safety feature is to ensure accurate dosing of a medication. The nurse activated the pump incorrectly without consulting his Preceptor/resource for assistance. As a result, Patient S received a medication (Milrinone) 3.6 times the prescribed dose by the physician in less than 10 minutes. Patient S expired on 6/4/08 at 11.58 a.m Findings. Patient S was admitted to the hospital's medical intensive care unit (MICU) on May 30, 2008 with a severe heart attack (myocardial infarction/cardiogenic shock). On 6/4/08, the treating physician ordered that Patient S be treated with a drug, Milrinone, for the treatment of congestive heart failure. The physician electronically ordered a bolus (a loading dose) of Milrinone as 50 mcg (micrograms per kilogram) based on Patient S' weight of 110 kilograms (Milrinone is a medication used in the management of heart failure only when conventional treatment vasodilators and diuretics have proven insufficient. This is due to the potentially fatal adverse effects of Milrinone including ventricular arrhythmias)		3. 100% of ICU and telemetry RN staff received infusion pump programming education re: how to correctly administer a 'bolus dose from an infusion' bag using the Alaris Guardrails® pump, with verbal or return-demonstration required. 4. Bi-weekly Competency assessment review of MICU/CCU preceptees are held between the preceptor, preceptee, and manager or lead. These meetings assess and review the preceptees' demonstrated ability to: • Dialogue regarding Medication Safety a. Use of Six Rights b. Review, use of medication resources and discussion with preceptor prior to any unfamiliar medications and all IV drip medications • Ask questions (the ability to self-identify when s/he has a knowledge deficit) • Delegate tasks, and	6/16/08 7/28/08

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	Continued From page 3 RN 1 was granted California licensure on May 4, 2005 and was new to the hospital with the hire date of 5/1/08. According to the documentation on RN 1's employment application, RN 1 had extensive background in an emergency department setting prior to coming to the MICU. RN 1 was currently undergoing clinical training with a preceptor in the MICU. RN 1 administered the Milrinone to Patient S using the Alaris Medley infusion pump. The Alaris Medley infusion pump is equipped with a drug error reduction system called the Guardrail (safe guard setting). The Guardrail is software inside the Alaris pump designed to manage how medications can be programmed with the infusion system by setting limits on the rates, volumes and doses that are appropriate for the delivery of intravenous medication. This allows nursing staff to safely select, calculate and program infusion of medications to a patient. On 6/4/08, RN 1 received from the hospital pharmacy a 100 cc IV bag that contained a concentration of 20 mg of Milrinone /100 ml or 200 mcg (0.2 mg)/ml. This is equivalent to 20,000 mcg in 100 milliliters (ml) of fluid. The physician order was for Patient S to receive a bolus (a loading dose) of 50 mcg/kg (micrograms per kilogram) of Milrinone. Patient S weighed 110 kilograms. Based on Patient S' weight of 110 kilograms, she was to receive 5,500 mcg bolus of Milrinone. Upon programming the IV Bolus dose of Milrinone on the Alaris Medley pump, the Infusion Pump		• Identify and seek out available resources • The Competency Assessment Reviews are documented in the unit preceptor book. When performance trends are identified, an individualized learning contract is developed with clear expectations and timelines. 5. A discussion occurred at the SMH Pharmacy and Therapeutics (P&T) committee and recommendations were made regarding safest method to practice infusion of Milrinone bolus and infusion doses at SMH. 6. Upon extensive review at Pharmacy and Therapeutics (P&T) Committee, the recommendation to discontinue Milrinone 'bolus dose from an infusion' bag was made. Rather, bolus, or "LOAD" doses were recommended to be administered as a separate IVPB from the continuous, or DRIP, infusion. 7. Milrinone usage data was reviewed for a period of seven months (4/08-10/08). Based upon usage data, Milrinone bolus	9/2/08 10/7/08 10/24/08

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	Continued From page 4 Guardrail (safeguard setting) would prompt a HARD STOP (maximum limit) when the drug calculation exceeded the Guardrail limit. However, RN 1 was not able to program the Alaris pump for the bolus infusion. Having been previously instructed to consult his Preceptor, RN 1 proceeded to use the basic infusion mode as a way to deliver the IV Bolus outside the Guardrail without consulting his Preceptor who was his resource person. RN 1 overrode the Guardrail limit and programmed the Alaris pump for a basic infusion at a rate of 999 ml/hr in order to administer what he perceived was the bolus dose. The Alaris pump has a tracker that provides a report of the actual total time of when the medication was infused and or administered. The tracker recorded that the entire 100cc of Milrinone was administered within approximately 7 minutes. RN 1 began infusion on 6/4/08 at 10:18 a.m. and completed the infusion at approximately 10:35 a.m. This indicated that Patient S received 20,000 mcg in 100 milliliters (ml) of fluid which was 3.6 times the physician's prescribed dose of Milrinone. Pharmacist 1 was interviewed on 6/9/08 at 11:00 a.m., and stated that Patient S should have received 27 ml of medication but received 100 ml of the medication instead which was 3.6 times the prescribed dose of Milrinone. On 6/4/08 at 10:45 a.m. per the nursing note documentation, Patient S' blood pressures dropped and the patient developed insufficient respiratory patterns. Physicians were notified and orders were		(LOAD) and infusions (DRIPS) will be limited to the Specialty areas and Telemetry units with ECG-monitored beds (except 6S and 7S) at SMH. 8. A Milrinone Practice Alert was posted on the ICUs and specified Telemetry units, reflecting the following: • Revision of the SMH Alaris Guardrails Dataset to differentiate Milrinone LOAD vs. Milrinone DRIP items, with hard stop field limits respecting FDA approved dosage, and default LOAD duration of ten minutes, per FDA. The continuous infusion Bolus mode (i.e., "bolus from a bag") was disabled. • Pharmacy will label LOAD doses with a neon sticker entitled "Milrinone LOAD". • Pharmacy will deliver the LOAD and continuous infusion DRIP to the nurse. The LOAD IVPB will be specified to the RN. • The Medication Administration Record (MAR) has had a	10/24/08

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	Continued From page 5 obtained to mitigate the situation. By 11:11 a.m. Patient S's condition deteriorated and Code Blue (emergency resuscitation) was called. A second Code Blue was called when the patient's cardiac status deteriorated again at 11:44 a.m. Patient S was eventually made a DNR (Do Not resuscitate) by the family and resuscitative efforts were terminated. Patient S expired on 6/4/08 at 11:58 a.m. On 6/10/08 at 10:00 a.m. RN 1 and Nursing Administrative Representative (NAR) were interviewed related to the medication error. RN 1 stated that during the administration of the Milrinone on 6/4/08 the Alaris intravenous (IV) pump system was utilized. RN 1 described the process of programming the pump and described the problems that he encountered during the programming. The NAR clarified that RN 1 failed to set up continuous infusion prior to the IV Bolus (loading dose of medication) which is a mandatory step in the safeguard (Guardrail) process. RN 1's competency related to the Alaris Medley Infusion Pump dated 5/13/08 was reviewed. The performance criteria section evaluation method was left blank. The evaluation key codes were observation, demonstration, quality monitoring, test, document review and trended data. Since the performance criteria section evaluation section of the competency was left blank there was no indication how or if RN 1 was evaluated regarding the pump use.		comment added "***Loading Dose***" to highlight the LOAD dose as separate from the infusion drip. • The term "Use Alaris Guardrails®" has been added to the Milrinone labels (LOAD and DRIP) and MAR. • The 1st page of the Milrinone Practice Alert will accompany Milrinone Loads and Drips distributed by Pharmacy to the respective nursing unit X 3 months 9. The Sharpnet Alaris website was updated, reflecting the following: • The updated Dataset Versions summary • The posting of the complete SMH NON-NICU 2.1 NC dataset • The updated Summary Quick Drug Lists for drips and intermittent infusions. 10. All ICU and specified Telemetry RN staff will receive education on the revised LOAD and infusion DRIP process. All individuals unable to attend the formal inservice sessions will receive 1:1 instruction.	10/24/08 11/7/08

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	Continued From page 6 The Immediate Jeopardy was abated on 6/12/08 at 11:50 a.m., with an acceptable plan of correction. The elements of the plan of correction are as follows: Re-education through Alaris Practice Alert, Bolus from bag for ICU and telemetry nurses. Re-education on use of clinical resources any time a hard stop occurs in Alaris. Competency changes to include clarify guardrail rates, including methods.		11. SHC P&P 43030 "Guidelines for Ordering Medications" was revised to reflect Pharmacy calculated weight-based dosing: "For physician orders stating dosage per patient weight (i.e., 10 mg. kg), pharmacy will check patient's weight and calculate the total dose. Pharmacy will apply clinical judgment when estimating patient's weight for dose calculation." The revised policy will be presented to P&T for approval. **Responsible Party:** Chief Nursing Officer (CNO) Nursing Director, Critical Care Managers, ICUs and telemetry units Director, Pharmacy **Monitoring Process:** An audit will be performed weekly X 3 months for all Milrinone LOAD doses dispensed by pharmacy to ensure Milrinone (LOAD and DRIP) is administered via the Alaris Guardrails® system. Staff not infusing Milrinone via the Guardrail system will receive re-education and counseling.	11/4/08 1/31/09

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