

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050327</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>02/20/2008</b>
NAME OF PROVIDER OR SUPPLIER <b>LOMA LINDA UNIVERSITY MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>11234 ANDERSON STREET, LOMA LINDA, CA 92354 SAN BERNARDINO COUNTY</b>		
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	<p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident.</p> <p>Complaint (entity reported incident): CA00138220</p> <p>Representing the Department: [REDACTED], Pharm.D., Pharmaceutical Consultant</p> <p>The inspection was limited to the specific complaint (entity reported incident) investigated and does not represent the findings of a full inspection of the facility.</p> <p>Immediate Jeopardy was issued for Complaint number CA00138220.</p> <p>HSC 1280.1(a)(c)</p> <p>1280.1 (a) 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. 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.</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE</p>			

Event ID:CLVS11

8/14/2008

2:16:04PM

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	<p><b>Continued From page 1</b></p> <p><b>JEOPARDY</b></p> <p>70263 (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.</p> <p>(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 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.</p> <p>Based on document reviews, staff interviews, clinical record reviews, and policy and procedures reviews, the facility failed to protect patients from potential adverse medication consequences as evidenced by failure to compound, and administer Neutra-Phos -K (oral potassium phosphate mixture) to Patient 1 in a safe manner.</p> <p>Patient 1 was an eight week old neonate who was born prematurely at 26 week gestation on 11/18/07 and admitted to the Neonatal Intensive Care Unit (NICU) for continued medical care. A review of the clinical record showed that on 1/4/08, at 10 AM,</p>			

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	<p><b>Continued From page 2</b></p> <p>the physician prescribed, "Neutra-Phos-K (15mg Phos/kg/day) 5.5mg per NG (nasogastric tube)" four times daily to replenish phosphorus.</p> <p>The order was entered into the pharmacy computerized order entry system, PharmNet by a pharmacist which subsequently appeared on the eMar (an electronic Medication Administration Record) on the nursing unit (NICU).</p> <p>The eMAR dosing instructions as seen by the nurse read: "potassium phosphate, 0.02 packet GTube PE Powder QID, 01/04/08 1300:00 Hard Stop 02/02/08 23:59:00 mix 1 packet in 10 ml of sterile water = 25mg/ml of"</p> <p>The remaining instructions were not visible on the eMAR. The initial entry instructs the nurse to give 0.02 packet powder, and also, mix 1 packet in 10 ml of sterile water producing a concentration of 25 mg/ml. The instructions were unclear and ultimately created confusion, therefore, the pharmacy failed to communicate clear instructions via the eMAR documentation to Nurse A. In addition, the initial eMAR medication order entry visible to the nurse does not show that 5.5 mg Phosphorus was ordered by the physician.</p> <p>Also visible on the eMAR is a yellow highlighted 'sticky note' icon, which according to the training instructors for the new eMAR system implemented 11/6/07, should be clicked or hovered over to expand out and show further mixing and dosing</p>				

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	<p><b>Continued From page 3</b></p> <p>instructions. Nurse A did not click or positioned the cursor over the icon to expand out and obtain further instructions.</p> <p>When expanded out, the instructions were as follows: "Order Comment 1/4/2008 15:14 (pharmacist name) mix 1 packet in 10ml of sterile water=25mg/ml of phosphate component &amp; give 0.22 ml=5.5 mg 1/4/2008 11:05 (pharmacist name) mix 1 packet in 10ml of sterile water=25mg/ml &amp;give 0.22ml=5.5 mg" MAR Note "1/4/2008 11:05 (pharmacist name) NOTE POTASS CONTENT = 14.2MEQ+PHOS 250MG PER PKT NOT SAME AS PLAIN NEUTRAPHOS OR K-PHOS NEUTRAL"</p> <p>The pharmacy delivered the Neutra-Phos-K packets to the NICU to be mixed by nursing staff for Patient 1. Each packet was supposed to be mixed in 10 milliliters of sterile water and 0.22 milliliters (5.5 mg) was to be administered to Patient 1. Nurse A and Nurse B, double- checked the order and eMAR, but misread the dose and volume to be administered.</p> <p>During the interview with pharmacy management and clinical pharmacy staff on 2/6/08, at 2:35 PM - 2:50 PM, RPH 3 assigned to NICU, and pharmacy management (RPHs A, 1, 2) reported that they had attempted to research the stability of Neutra-Phos-K. Having not received a definitive answer from the manufacturer or sufficient information from the internet regarding the stability</p>				

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	<p><b>Continued From page 4</b></p> <p>of the product, the physician and a pharmacist calculated the desired phosphorus dose of 5.5mg. Then the decision was made by pharmacy to send the Neutra-Phos-K packets to the NICU with written mixing/dosing instructions.</p> <p>During a joint interview with nurse managers, quality coordinator, pharmacy management/staff, and physicians on 2/6/08 at 3:29 PM, the nurse managers reported that during their investigation of the incident, it was determined that Nurse A, the AM nurse received report about the mixing and dosing instructions from a new nurse, however, at the dose intervals (12 PM and 6 PM), Nurse A only recalled '10 ml' which was seen on the initial eMAR's screen. The practice of double checking medication doses on a critical care unit did not prevent the medication error from occurring at 12 PM and 6 PM. The nurse managers stated that the NICU nursing staff were not familiar with Neutra-Phos-K 's use in neonates as it's normally prescribed as an adult dose, and that Nurse A did not recall the eMAR training that included how to expand out and access additional cell 'sticky note' information. Before administering a drug, the nurse should know if the ordered dosage is safe. This is important for adults and critical for infants and children.</p> <p>Review of nursing notes, laboratory data, EKG documents, and physicians' progress notes confirmed that on 1/12/08, Nurse A administered one packet of Neutra-Phos-K diluted in 10 ml of sterile water at 12 PM, and again at 6 PM to Patient 1. Each packet contained 556 mg of</p>			

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	<p><b>Continued From page 5</b></p> <p>potassium (K) and 250 mg of phosphorus, therefore Patient 1 received 45 times the phosphorus dose at each dosing interval. Since 39.1 mg of potassium is equivalent to 1 mEq (milliequivalent) of potassium, Patient 1 received 14.2 mEq/dose of potassium instead of 0.31 mEq/dose that resulted in an extraordinary elevated potassium level of 12.9, and subsequent bradycardic (slow heart rate) event. Pre potassium and phosphorus levels at 3:30 AM on 1/12/08 were within the normal range at 5 mEq/L and 2.2 mMol respectively.</p> <p>In an interview with MD 1 on 2/6/08 at 3:35 PM, he stated that on 1/12/08 1950 he was on the Unit when Patient 1 became bradycardic (slow heart rate). A 12-lead EKG tracing was indicative of electrolyte abnormality. Labs were drawn at 8:15 PM and a potassium level of 12.9 reported.</p> <p>Therapeutic measures were taken to reverse the effects of potassium (K). Kayexalate and insulin drip ordered to normalize the potassium level to 4.7 which occurred on 1/13/08 at 1:05 AM. Arterial blood gases showed severe acidosis. IV (intravenous) hydration, calcium gluconate and sodium bicarbonate were given. During MD 1's investigation to determine the cause of the bradycardic event he reviewed the clinical record. He contacted and interviewed Nurse A. The record review confirmed that on 1/12/08 at 12 PM and 6 PM, Nurse A administered 10 ml of Neutra-Phos-K solution to Patient 1.</p> <p>MD 1 stated that Nurse A reported that she had administered ten (10) ml doses of Neutra-Phos-K to</p>				

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	<p><b>Continued From page 6</b></p> <p>Patient 1 on 1/12/08 at 12 PM and 6 PM during the interview. A review of MD1's progress notes read, "bedside charting documented 10 ml of prep ...given to the infant".</p> <p>As a result of (a) unclear e-MAR documentation by pharmacy, (b) Nurse A's failure to read beyond the initial screen, (c) pharmacy 's failure to compound (mix) for this patient population, (d) Nurse A and Nurse B failure to use the double-check system effectively, and lack of awareness of an irregular dose, and (e) administration of wrong medication doses at 12 PM, and repeat of the medication error at 6 PM, Patient 1 was harmed.</p> <p>On 2/6/08 at 3:59 PM, the hospital administration staff, Medical Director for NICU, and the quality coordinator were informed that Immediate Jeopardy (IJ) had been identified based on the hospital's failure to protect Patient 1 from undue adverse medication consequences from Neutra-Phos-K. The hospital was asked to provide a plan of correction to address the issues surrounding the Immediate Jeopardy. On 2/6/08 at 4:49 PM, a plan of correction was submitted and accepted.</p> <p>These violations caused, or were likely to cause, serious injury or death to a patient.</p>				

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