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
	053303	A. BUILDING _____ B. WING _____	05/14/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RADY CHILDREN'S HOSPITAL - SAN DIEGO	3020 CHILDREN'S WAY, SAN DIEGO, CA 92123 SAN DIEGO COUNTY

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	The following reflects the findings of the California Department of Public Health during an Entity Reported Incident. Complaint No: CA 000183430 Category: State Monitoring Inspection does not represent the findings of a full inspection of the facility. Representing the State of California Department of Public Health Services: [redacted], Pharmaceutical Consultant II, Specialist. 1279.1 (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. 1280 1 (c) HSC Section 1280 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.		ACTION ITEM #1 A second corrosive cabinet was purchased to improve storage of phenol products in the pharmacy department. One cabinet was labeled "external" and the other was labeled "internal (injectable)". RECEIVED CA DEPT OF PUBLIC HEALTH JAN 21 2010 LICENSING & CERTIFICATION SAN DIEGO NORTH DISTRICT OFFICE ACTION ITEM #2 A communication system was implemented to effectively communicate essential quality, safety, and operational information to the pharmacy staff. The staff acknowledges they have read the material by initialing a sign-off sheet within two weeks of the information being posted. Non-compliant staff are reported to their supervisor and if they fail to immediately acknowledge the information, appropriate disciplinary action is taken. ACTION ITEM #3 Reviewed current Meditech pharmacy computer module entries and updated them to reflect concentration of the phenol external product (89%) and injectable product (5%) and route of administration.	04/02/09 04/14/09 04/01/09

Event ID: H6O611 12.18/2009 12 34 04PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE Director of Pharmacy DATE 1/7/2010

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State-2567

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	Continued From page 1 The facility's failure to dispense a medication solution (phenol 5 %), as ordered by the physician, resulted in the administration of an 89.5 % phenol solution to Patient K. The administration of the 89.5 % phenol solution is a deficient practice that has caused or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. Based on observation, interview, record review, and policy and procedure review, the facility failed to ensure that a physician's order for a 5 % phenol solution was dispensed as ordered. As a result, a phenol solution of 89.5 % was dispensed and administered to Patient K resulting in inflammation and fluid build-up in the muscles of both thighs which had the potential for muscle death. Findings: On 03/27/09 at 9:19 A.M., Patient K, a 3 year old child, was admitted for outpatient treatment of spasms affecting both legs secondary to mild cerebral palsy. Physician M ordered, 2.5 ml of 5% phenol solution (a toxic carbolic acid that in diluted medicinal strengths relieves severe muscle spasms) to be administered intramuscularly into each of Patient K's thighs (for a total amount of 5 ml). On 3/27/09 at 10:30 A.M., Pharmacist S		ACTION ITEM #4 Placed an example of the canned text and appropriate auxiliary labels on the topical phenol bottle. Canned text states, "Liquified Phenol 89% solution (undiluted) 2 mL volume." In addition, the text includes the manufacturer, lot number, expiration date, who prepared the bottle, the date it was transferred, and which pharmacist checked the product. It also states: *** TOXIC CHEMICAL *** and has a "FOR EXTERNAL USE ONLY" auxiliary label. The "2 mL volume" represents the small aliquot that we are now dispensing rather than a large bulk bottle. ACTION ITEM #5 Developed and educated the pharmacy staff on a pharmacy operational guideline for dispensing phenol 89% that describes the repackaging, ordering, processing, dispensing and wasting of unused product. Pharmacists and technicians were re-educated on process for logging out both the topical phenol 89% and injectable phenol 5% with appropriate canned text (we only used "canned text" for	04/01/09 04/24/09

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	Continued From page 2 checked a 2 ounce amber bottle that contained and was labeled as phenol 89.5% solution against the physician order for phenol 5% solution. Even though the 2 oz bottle of phenol solution was clearly labeled with a much higher concentration, Pharmacist S failed to identify that the prepared phenol solution was not what Physician M ordered. The incorrect strength of phenol was dispensed to Physician M. and between 11:28 A.M. to 11:50 A.M., Physician M administered 2.5 ml of 89.5 % phenol instead of 5% phenol into each of Patient K's thighs. This concentration of phenol was 17.9 times the concentration ordered by Physician M. The excessive dose of the medication administered resulted in inflammation and fluid build-up in Patient K's thigh muscles. Following the procedure, Patient K was admitted to a medical surgical unit at 6:00 P.M. for observation. On 3/29/09 a magnetic resonance imaging (MRI) of Patient K's thighs was performed. The MRI Report reflected that there was swelling and fluid build up in the middle and back thigh muscles of both legs, with "no definitive evidence of necrosis (changes that indicate cell destruction or death of the muscles or tissues), however, early necrosis cannot be completely excluded." According to the report entitled: "Outpatient Clinic Report" (dated 4/13/09), the MRI was repeated on 4/6/2009. The MRI noted a worsening of the swelling and fluid build-up in the thigh muscles with a concern for		ACTION ITEM #5 (continued) the topical phenol since we are transferring a 2 mL aliquot into a smaller container, the injectable phenol is dispensed in the same manner as other injectable medications requested by the OR for outpatient cases - which is the typical scenario for these patients) and auxiliary labels. Pharmacy reconciles both topical and injectable phenol vials dispensed every business day. Any discrepancies result in immediate follow-up with the department to whom the phenol was dispensed in order to retrieve and reconcile all dispensed phenol. ACTION ITEM #6 The pharmacy operational guideline for repackaging products into patient specific unit-dose packages was updated to provide specific labeling guidance on hazardous products. When repackaging from bulk supply the following information is a part of the label: product name, product concentration, manufacturer, manufacturer's lot number, beyond-use date, product specific information, prepared by, date transferred and checked	04/24/09

Event ID:H6O611 12/18/2009 12:34:04PM

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	Continued From page 3 breakdown of muscle tissue and bleeding. On 4/3/09 an interview was conducted with Pharmacy Technician B. On 4/8/09 an interview was conducted with Pharmacist S. These interviews revealed the following: On 3/27/09 at 10:20 A.M., Physician M was at the pharmacy and wrote an order for, "Phenol 5% 1 vial of 10ml". Pharmacy Technician B went to the external corrosive cabinet and removed a 500 ml bottle of phenol 89.5% solution for external use. The 500 ml bottle of phenol 89.5% solution (for external use) and the phenol 5% per 10 ml Injection vials were stored in the same external corrosive cabinet. Pharmacy Technician B poured 10 ml of the phenol 89.5% solution into a 2 ounce amber bottle. Pharmacist S checked the bottle of 89.5% phenol against the MD order for phenol 5% solution and handed the bottle to Physician M. On 4/3/09 at 3:25 P.M., Physician M stated that after the administration of the phenol solution, Physician M noticed skin discolorations on the injection sites of each of Patient K's thighs. Physician M immediately spoke to the mother to see if Patient K had any history of skin sensitivity. The mother denied any that Patient K had any sensitivities. According to the facility's material safety data sheet for liquid 89.5% phenol solution: "Corrosive! Skin: Causes severe irritation and can cause burns. The skin may turn white and		ACTION ITEM #6 (continued) by. Additional ancillary stickers (i.e. "For External Use Only" or "Poison") are applied when appropriate. PM 9-121 "Medication Labeling for Safe Administration" was reviewed and a new policy PM 9-139 was written regarding "Pharmacy Labeling of Medications Intended for Bulk Supply or Batch Production Use." ACTION ITEM #7 Implemented pharmacy operational guideline and practice that restricts phenol from being kept as a floor stock item. Both topical and injectable phenol will be dispensed from Pharmacy for a specific patient's use. ACTION ITEM #8 Provided education to Toe Nail Clinic and Operating Room regarding dispensing topical and injectable phenol with patient specific labeling. ACTION ITEM #9 Re-educated the pharmacy staff on Policy PM 9-69 "Pharmacist's Clarification of Medication Orders with Escalation" which was conducted along with updating staff on changes made to policy	04/24/09 04/16/09 04/24/09

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	Continued From page 4 opaque or dull gray, and wrinkled, and later gray-white or yellowish-brown and may be deeply eroded and scarred... Harmful (moderately toxic) if its is absorbed through skin, phenol burns may be severe but painless due to damage to nerve ending causing numbness ... It may also cause kidney damage (renal failure, tubular necrosis), heart (necrosis of myocardium), and liver damage (jaundice), degenerative changes in the brain, and affect the blood (changes in red and white blood cell count, anemia)." The facility failed to dispense a solution in accordance with the physician's order. This failure allowed the administration of a corrosive chemical (89.5% phenol) to Patient K resulting in inflammation and fluid build-up in the muscles of both thighs which had the potential for muscle death. The facility's failure to dispense a solution in accordance with the physician's order is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1		ACTION ITEM #9 (continued) PM 9-53 "Medication Order Requirements". Monitoring of the above stated processes were incorporated into our ongoing medication error review through the Safety Reporting System. Medication errors are reviewed, reported and discussed at the Multidisciplinary Medication Management (3M), Pharmaceutics and Therapeutics (P&T), and Quality Improvement Committee (QIC) meetings quarterly.	04/24/09

Event ID:H6O611 2/18/2009 12:34.04PM

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1/Kalla PIC 1/20/2010 Kalla Director Pharmacy 1/7/2010

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