...NT OF DEFICIENCIES ...N OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070001349	A. BUILDING _____ B. WING _____	C 12/20/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LUCILE SALTER PACKARD CHILDREN'S HSP	725 WELCH ROAD PALO ALTO, CA 94304

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	Initial Comments The following reflects the findings of the California Department of Public Health during investigation of an entity reported incident completed on 12/20/10. For entity reported incident CA00247777 regarding a Medication Error, state deficiencies were identified (see California Code of Regulations, Title 22, Sections 72015(b), 70263(g)(2), and California Health and Safety Code, Section 1280.1(c)). Inspection was limited to the specific entity reported incident and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health: 09714, Health Facilities Evaluator Nurse.	E 000	CALIFORNIA DEPARTMENT OF PUBLIC HEALTH AUG 24 2011 L & C DIVISION SAN JOSE	
E 294	T22 DIV5 CH1 ART3-70215(b) Planning and Implementing Patient Care (b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission. This Statute is not met as evidenced by: Based on interviews and record review, the nursing staff failed to revise the care plan for one sampled patient (1) who developed abnormal electrolytes and seizures. Findings: Record review on 12/15/10 indicated Patient 1 was a newborn admitted to the hospital on [redacted]/10. The patient had surgery on [redacted]/10 to repair a congenital heart defect. On [redacted]/10 at	E 294	**CORRECTIVE ACTIONS FOR PATIENT** Patient seizures ceased [redacted]/10. Patient continued on anticonvulsant medications. Seizure precautions implemented for patient. **CORRECTIVE ACTIONS FOR OTHER POTENTIAL PATIENTS** Nurse Manager/CNS reviewing with 90% of CVICU RN's during education huddles the need for updating care plans as patient clinical condition changes or at least every 24 hours. Changes include seizures, abnormal test results or values as well as clinical condition.	**COMPLETE DATE** [redacted]/10 **11/24/2010**

Licensing and Certification Division

Shefali Shah Clinical Accreditation Manager / 8/23/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE — (X6) DATE

POC accept TC to Shefali Shah 8/24/11

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E 294	Continued From page 1 3:30 a.m., the patient's laboratory results indicated a low chloride level of 88 milliequivalents/liter (mEq/L.) Normal range is 96-106 mEq/L. The physician ordered 5 mEq of ammonium chloride at 12:14 p.m. on [redacted]/10 to be given every twelve hours to treat the patient's abnormal level of chloride in the blood. The medication administration record (MAR) indicated the first intravenous (IV) dose of ammonium chloride was infused on [redacted]/10 at about 2:35 p.m. The nursing note on [redacted]/10 indicated the patient had a seizure 15 minutes after the start of the first dose of ammonium chloride. The infusion was stopped. The patient continued to have additional seizures. The MAR indicated a second IV dose of ammonium chloride was infused on [redacted]/10 at 11:30 p.m. On [redacted]/10 at 3:25 a.m., laboratory results indicated Patient 1's ammonia level was over 1000 micromoles per liter. Normal range for a newborn is 100-200 micromoles per liter. At 7:30 a.m. the ammonia level was 538 micromoles per liter. The nursing notes and the intensive care flow sheets on [redacted]/10 indicated the patient had seizures at 2:47 p.m. There were no care plans developed to address the seizures and the abnormal laboratory results. Patient 1 continued to have additional seizures. The physician ordered anticonvulsant medications including Ativan and phenobarbital to prevent the seizures. On 12/20/10 the hospital policy for Interdisciplinary Care Plan was reviewed. The policy stated the "care plan is designed to reflect the individualized patient care and progress...It is expected that the plan of care be evaluated and updated every 24 hours. The level of care a patient requires will influence the need and	E 294	**IMMEDIATE MEASURES AND SYSTEMIC CHANGES TO MITIGATE REOCCURRENCE** Identified improvements lead to the following actions taken: Nurse Manager/CNS conducted weekly care plan tracers for 5 weeks reviewing care plans for 4 RN's each week to validate compliance with updating care plans every 24 hours and updating as patient clinical condition changes. Results reported to Nurse Manager and to organization wide Regulatory Oversight Readiness Committee and Chapter Leader Group with monthly reporting to VP Operations Committee. **PERFORMANCE MONITORING PROCESS** Nurse Manager/CNS conducted weekly care plan for tracer for 5 weeks reviewing care plans for 4 RN's each week to validate compliance with updating care plans every 24 hours and updating as patient clinical condition changes. Nursing Care Plan tracers occurring monthly in 2011, performed by Quality. Results reported to Nurse Manager and organization wide Regulatory Oversight Readiness Committee and Chapter Leader Group with monthly reporting to VP Operations Committee. **PERSON RESPONSIBLE FOR MONITORING AND HOW RESULTS WILL BE REPORTED OUT** Nurse Manager/CNS conducted weekly care plan tracer; Quality performing monthly care plan tracer. Results reported out to Director of Nursing and VP/CNO of Nursing. Results reported to organization wide Regulatory Oversight Readiness Committee and Chapter Leader Group with monthly reporting to VP Operations Committee.	**11/24/2010** **11/24/2010** **12/31/2010**

POC accepted 8/24/11

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E 294	Continued From page 2 frequency of updating the care plan more often than every 24 hours."	E 294		
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (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. (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: HSC 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.	E 485	**CORRECTIVE ACTIONS FOR PATIENT** Patient seizures ceased [redacted]/10. Patient continued on anticonvulsant medications. Laboratory results followed for abnormal levels. **CORRECTIVE ACTIONS FOR OTHER POTENTIAL PATIENTS** 1. Computer-generated patient label was changed to more clearly specify "Dilution" on 10/26/10. 2. Products compounded by dilution are recorded on a dilution log implemented on 10/28/10. 3. Procedure was reviewed to remind staff that a technician must check the drug name and concentration and compare this to the patient label prior to preparing doses, completed by 11/2/10. 4. Competency training implemented to validate that all staff know how to prepare and verify that the correct drug product is compounded, completed by 12/31/10. 5. Log initiated on 11/15/10 to record all products prepared in the IV room. Log will include patient identification, and patient dose, drug name, concentration, manufacturer, and lot number. 6. Use of cell phones, internet, and e-mail during work hours will be restricted to work-related issues only, implemented on 10/28/10.	**COMPLETE DATE** [redacted]/10 **All corrective actions identified implemented by 12/31/10**

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E 485	Continued From page 3 DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY Based on interview and record review, medication for Patient 1 was not administered as ordered. A hospital pharmacy technician failed to implement pharmacy procedure for dilution of ammonium chloride per manufacturer's recommendations. The supervising pharmacist failed to verify accurate preparation of compounded medications according to the hospital's policy to use the California Board of Pharmacy standards and according to the hospital pharmacy procedure for dilution of ammonium chloride. Findings: Record review on 12/15/10 indicated Patient 1 was a newborn admitted to the hospital on [redacted]/10. The patient had surgery on [redacted]/10 to repair a congenital heart defect. On [redacted]/10 the physician ordered 5 mEq (milliequivalents) of ammonium chloride at 12:14 p.m. to be given every twelve hours. On 12/15/10 at 9 a.m., during an interview, the director of the pharmacy stated the hospital had been notified by the manufacturer there was a drug shortage of arginine hydrochloride. An e-mail was sent on [redacted]/10 to inform the pharmacists and technicians. The e-mail reported ammonium chloride would be substituted for arginine hydrochloride to treat hypochloremia (low chloride levels) and metabolic alkalosis. The e-mail also stated "a new dilution card has been made and will be available in the IV room." On 12/15/10 at 9 a.m. during an interview, the director of the pharmacy stated on [redacted]/10 a hospital pharmacy technician and a pharmacist	E 485	7. Dose Edge, workflow manager software has received hospital funding approval as of 10/29/10 and will be implemented in the IV room. This system promotes best-practice workflow in the IV and integrates drug verification, dose and dilution calculations, and provides an audit trail of doses prepared and checked. 8. Ammonium Chloride supply labeled in RED with instructions: "MUST BE DILUTED", implemented on 11/2/10. 9. In-service education for all pharmacists staffing inpatient pharmacy on the treatment of hypochloremic alkalosis including staff involved in occurrence, implemented on 12/23/10 and continues in 2011. 10. Pharmacy newsletter to all staff on the use of Ammonium Chloride distributed in December 2010. 11. Re-evaluate work flow and location of label printers occurred in December 2010. **IMMEDIATE MEASURES AND SYSTEMIC CHANGES TO MITIGATE REOCURRANCE** Identified improvements lead to the following actions taken: 1. Computer-generated patient label was changed to more clearly specify "Dilution" on 10/26/10. 2. Products compounded by dilution are recorded on a dilution log, implemented on 10/28/10. 3. Procedure was reviewed to remind staff that a technician must check the drug name and concentration and compare this to the patient label prior to preparing doses, implemented by 12/31/10. 4. Competency training implemented to validate that all staff know how to prepare and verify that the correct drug product is compounded, implemented by 11/15/10.	**12/31/10**

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E 485	Continued From page 4 failed to dilute ammonium chloride as required before preparing doses for intravenous administration for Patient 1. Pharmacy Technician A received the physician's order and 20 ml (milliliter) vials of ammonium chloride from Pharmacist B. The pharmacy technician prepared the patient's medication without following the hospital procedure to dilute the medication according to the drug's dilution card. A 20 ml vial containing 100 mEq of ammonium chloride was not diluted. The pharmacy technician withdrew 12.5 cc (cubic centimeters) from the 20 ml vial. One cc is equivalent to one ml when measuring volume. Pharmacist B failed to verify the doses prepared by the pharmacy technician were diluted as prescribed by the physician before the medication was sent out for patient administration. Each dose contained 62.5 mEq of ammonium chloride instead of 5 mEq. The medication administration record (MAR) indicated the first intravenous (IV) dose of ammonium chloride was infused on [redacted]/10 via a syringe pump starting at about 2:35 p.m. The nursing note indicated the patient had a seizure 15 minutes after the start of the first dose of ammonium chloride. The infusion was stopped. The MAR indicated a second dose of ammonium chloride was infused on [redacted]/10 at 11:30 p.m. Patient 1 continued to have more seizures. The physician ordered anticonvulsant medications including Ativan and phenobarbital to prevent the seizures. The patient had not required these medications prior to the overdose of ammonium chloride. On [redacted]/10 at 3:25 a.m. laboratory results indicated Patient 1's ammonia level was over 1000 micromoles per liter. Normal range for a newborn is 100-200 micromoles per liter. At 7:30	E 485	5. Log initiated on 10/28/10 to record all products prepared in the IV room. Log will include patient identification, and patient dose, drug name, concentration, manufacturer, and lot number. 6. Use of cell phones, internet, and e-mail during work hours will be restricted to work-related issues only, implemented on 10/29/10. 7. Dose Edge, workflow manager software has received hospital funding approval as of 10/29/10 and will be implemented in the IV room. This system promotes best-practice workflow in the IV and integrates drug verification, dose and dilution calculations, and provides an audit trail of doses prepared and checked. 8. Ammonium Chloride supply labeled in RED with instructions: "MUST BE DILUTED", implemented on 12/23/10. 9. In-service education for all pharmacy staff on the treatment of hypochloremic alkalosis including staff involved in occurrence, implemented in December 2010. 10. Pharmacy newsletter distributed to all staff on the use of Ammonium Chloride in December 2010. 11. Re-evaluate work flow and location of label printers, implemented in 2010.	

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E 485	Continued From page 5	E 485	**PERFORMANCE MONITORING PROCESS**	
			Audits performed for compliance with process by Director of Pharmacy. 30/30 doses logged appropriately from12/1/10 – 12/30/10 None reported for Ammonium Chloride from 1/1/11 thru 2/28/11, when drug no longer available Daily monitoring of Quantros for error reporting by Director of Pharmacy.	**12/30/2010**
			PERSON RESPONSIBLE FOR MONITORING AND HOW RESULTS WILL BE REPORTED OUT	
			Director of Pharmacy responsible for monitoring and reporting results monthly to Medication Management Steering Committee, reporting to Patient Safety Committee which reports to Quality Improvement Committee. Drug not available after 2/28/11	**1/11/11**

a.m. the ammonia level was 538 micromoles per liter. According to the IP Discharge Summary dated [redacted]/10, Patient 1 had seizures and mental status changes requiring intubation for several days following the medication error.

The director of pharmacy stated a pharmacist reviewed Patient 1's laboratory results the morning of [redacted]/10, saw the elevated ammonia level, and initiated an investigation. The pharmacist discovered the patient received higher doses of ammonium chloride than ordered by the physician. The hospital's investigation determined the error occurred because the pharmacist and the pharmacy technician failed to follow the pharmacy procedure established to ensure safe dispensing of medications. The dilution card referenced in the e-mail sent to staff was not used for preparing the medication.

On 12/15/10 when asked to review the policies and procedures for medication preparation, the associate director of pharmacy stated the pharmacists followed standards of practice determined by the Board of Pharmacy Regulations. The policies provided referred only to procedures to follow during drug shortages (March 2010) and for safe medication administration (October 2010) at the patient's bedside. There were no policies or procedures provided specific to compounding medications.

The director of pharmacy described the pharmacy procedure which required the pharmacist to obtain the medication as supplied by the manufacturer, then provide the pharmacy technician with the medication and the physician order. The dilution card was kept in the IV pharmacy. The technician was to read the card, dilute the medication according to the instructions

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E 485	Continued From page 6 for medication dilution, and fill the individual dose syringes with the prescribed amount of medication. The Board of Pharmacy Regulations (California Code of Regulations, Title 16, Section 1735.2) states the pharmacist performing, or supervising, compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product. The pharmacist failed to ensure ammonium chloride was diluted according to the procedure developed by the pharmacy. Failure to dilute the medication resulted in higher doses of medication administered to Patient 1 than ordered by the physician. Patient 1 suffered multiple seizures following administration of the medication and required treatment with anticonvulsant medications which were continued after discharge home. The failure of the facility to administer medication as ordered by the physician caused, or is likely to cause, serious injury or death to the patient.	E 485		