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.

(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 10. The patient had surgery on to repair a congenital heart defect. On 10 at

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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 12/10 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 12/10 at about 2:35 p.m. The nursing note on 12/10 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 12/10 at 11:30 p.m.

On 12/10 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 12/10 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
## STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

### PROVIDER/SUPPLIER/CALIA IDENTIFICATION NUMBER

CA070001349

### MULTIPLE CONSTRUCTION

A. BUILDING
B. WING

### DATE SURVEY COMPLETED

12/20/2010

### NAME OF PROVIDER OR SUPPLIER

LUCILE SALTER PACKARD CHILDREN'S HOSPITAL

### STREET ADDRESS, CITY, STATE, ZIP CODE

725 WELCH ROAD
PALO ALTO, CA 94304

### ID PREFIX TAG

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### SUMMARY STATEMENT OF DEFICIENCIES

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

#### E 294

Continued From page 2

> frequency of updating the care plan more often than every 24 hours.

#### 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 furnish. Orders for drugs should be written or transmitted by the prescriber or furnish. 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 furnish 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.

### CORRECTIVE ACTIONS FOR PATIENT

Patient seizures ceased on 10/26/10.
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.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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**NAME OF PROVIDER OR SUPPLIER**

LUCILE SALTER PACKARD CHILDREN'S HSP

**STREET ADDRESS, CITY, STATE, ZIP CODE**

725 WELCH ROAD
PALO ALTO, CA 94304

**IDENTIFICATION NUMBER**

(A) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070001349

(B) MULTIPLE CONSTRUCTION

1. A. BUILDING
2. B. WING

**DATE SURVEY COMPLETED**

C 12/20/2010

**NAME OF PROVIDER OR SUPPLIER**

LUCILE SALTER PACKARD CHILDREN'S HSP

**STREET ADDRESS, CITY, STATE, ZIP CODE**

725 WELCH ROAD
PALO ALTO, CA 94304

**ID SUMMARY STATEMENT OF DEFICIENCIES ID**

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**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 11/10. The patient had surgery on 11/10 to repair a congenital heart defect. On 11/10 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 was notified by the manufacturer there was a drug shortage of arginine hydrochloride. An e-mail was sent on 12/10 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 12/10 a hospital pharmacy technician and a pharmacist

**PROVIDER'S PLAN OF CORRECTION**

(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

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.


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 workflow and location of label printers occurred in December 2010.

**IMMEDIATE MEASURES AND SYSTEMIC CHANGES TO MITIGATE REOCCURRENCE**

1. Computer-generated patient label was changed to more clearly specify "Dilution" on 10/26/10.

2. Product 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.

**COMPLETE DATE**

12/31/10
California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER:
CA070001349

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
C 12/20/2010

NAME OF PROVIDER OR SUPPLIER
LUCILE SALTER PACKARD CHILDREN'S HOSPITAL

STREET ADDRESS, CITY, STATE, ZIP CODE
725 WELCH ROAD
PALO ALTO, CA 94304

The medication administration record (MAR) indicated the first intravenous (IV) dose of ammonium chloride was infused on 12/10 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 12/10 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 did not require these medications prior to the overdose of ammonium chloride.

On 12/10 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

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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.


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.
E 485  Continued From page 5

a.m. the ammonia level was 538 micromoles per liter. According to the IP Discharge Summary dated 12/10, 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 12/10, 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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<td>for medication dilution, and fill the individual dose syringes with the prescribed amount of medication.</td>
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The Board of Pharmacy Regulations (California Code of Regulations, Title 16, Section 17352) 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.