California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDERISUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING B.WING	(X3) DATE SURVEY COMPLETED
			03/21/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, liP CODE
KAISER FOUNDATION HOSPITAL - SANTA CLARA	900 KIELY BLVD SANTA CLARA, CA 95051

CA220001022

(X4) 10 PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	10 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	E 000		

The following reflects the findings of the California Department of Public Health during a complaint validation survey conducted from 3/19/07 to 3/21/07.

Representing the California Department of Public Health were [redacted]

1280.1(a) HSC Section 1280

If a licensee of a health facility licensed under subdivision (a), (b), or (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 dollars ($25,000) per violation.

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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY. .

E 4741	T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be .	E 474	

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

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E 4741	Continued From Page 1 . 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.	E 474		
E 4751	T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements (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 shaH 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. !.Theabove regulation was not met as evidenced by: . Based on observation, staff interviews, and document reviews, the hospital failed to provide patient safety by ensuring written policies and procedures for the distribution of all drugs were developed and implemented to ensure for the safe use of all medications. Findings include: 1. On 3/19/07 at 9:30 a.m., Administrative and Clinical Pharmacy Staff were interviewed about	E475		

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E 4751	Continued From Page 2	E 475		

the investigation alleging an overdose of two pharmaceutical products administered to Patient 1.

Patient 1 was a 1-month-old neonate diagnosed with a genetic metabolic deficiency (carbamoyl phosphate synthetase deficiency) a few days after his birth on 1/6/07, and had been transferred to Lucile Salter Packard (LSP) Children's Hospital At Stanford for the stabilization of this condition.

On 2/2/07 Patient 1 returned to Kaiser Hospital for continued treatment prior to being discharged home. Patient 1 was receiving enteral feedings and supplemental nutritional supplements including L-citrulline (a non-essential amino acid). Patient 1 was also receiving phenylbutyrate to reduce high levels of ammonia in the blood ..

On 2/13/07, Patient 1 returned to LSP after a medication overdose and fulminant liver failure requiring dialysis, and liver transplant evaluation and the management of his metabolic deficiency.
On 2/24/07, Patient 1 expired.

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E 4751	Continued From Page 3	E475		

blood.

c. On 2/7/07 Pharmacy staff had repackaged the dry powder doses L-citrulline and phenylbutyrate incorrectly. The repackaging did not take into consideration the weight of the container. Citrulline was packaged as 3.77 gram (g) doses instead of 150 milligram (mg) doses, and . phenyl butyrate was packaged as 4.1 g doses instead of 450mg doses. The repackaging error was not identified by the pharmacy technician repackaging the dry powder or by the pharmacist checking the accuracy of the repackaged product prior to distribution and administration to the patient.

On 3/19/07 at 9:50 a.m., the Pharmacy Director said corrective action was taken to ensure the accurate measurement of dry powders, and stated all pharmacists and technicians 'were to be "tested" and "oriented" to the correct use of the dry powder scale to ensure the accuracy of its use so as to prevent further repackaging medication errors. The Pharmacy Director said new policy and procedures for the "Weighing of Dry Powdered Substances" (policy number PHAR2.22 last revised 3/07) had been implemented to ensure for the improved oversight of weight-based products. The procedures identified competency testing will be done for "all pharmacists and technicians". The Pharmacy Director said only pharmacists had been in-serviced on the new procedures.

By *3/21/07,* approximately 5 weeks after the error was detected, the pharmacy technicians had not been inserviced to the proper usage of the scale and for accurate weight-based procedures, which was not in accordance with the facility's policies and procedures and corrective action taken.

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E 4751	Continued From Page 4 The violation(s) has caused or is fikely to cause serious injury or death to a patient(s).	E 475		