

California Department of Public Health

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA220000031	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY 10/25/2008
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NAME OF PROVIDER OR SUPPLIER UCSF MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 505 PARNASSUS AVE SAN FRANCISCO, CA 94143
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JUL 19 2010
L & C DIVISION
DAILY CITY

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E 000 Initial Comments

The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. Entity reported incident: CA00166278.

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:
[REDACTED], Pharmaceutical Consultant

Health and Safety Code Section 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 000

The statements made on this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein.

This Plan of Correction constitutes UCSF Medical Center's written credible allegation of compliance for the deficiencies noted.

E 474 T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service General Requirements

(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.

This Statute is not met as evidenced by:

E 474

Corrective Action (E 475): On June 9, 2009, a policy on the use of anti-coagulation therapy, *Anticoagulation Therapy Management* was implemented. An Anti-Coagulation Management Program Reference Manual was implemented in September of 2009 and includes guidelines for ordering anti-coagulants, including Enoxaparin.

6/9/09

E 475 T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements

(1) The committee shall develop written policies

E 475

Immediately after the occurrence of this event, UCSF Medical Center contracted with a pharmacy software vendor to develop an enhanced label which includes the correct dose to be delivered and the correct volume of Enoxaparin required. All Enoxaparin orders prepared by the pharmacy now get a double check with a second pharmacist to ensure the information on the label is accurate. All pediatric Enoxaparin doses are now diluted to a larger volume to ensure accurate

10/2008

Licensing and Certification Division

Johanne Carnagey, RN Director, Regulatory Affairs

7/16/10 (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

accepted per plan. was not contact by vendor 7/29/10

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E 475	Continued From page 1 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. This Statute is not met as evidenced by: Based on observation, staff interview, and record review, the hospital Pharmacy and Therapeutics (P&T) committee failed to develop and implement a safe and effective system for the use of a high risk medication, Enoxaparin (Lovenox®), a blood thinning agent, for neonatal and pediatric patients, which resulted in Patient 1 receiving 3 doses of Enoxaparin in 10 times the prescribed dose from 10/8/08 to 10/9/08. In addition, the hospital failed to implement its medication administration and high risk medications policies and procedures to ensure the safe and effective administration of medications. Nursing staff in the Intensive Care Nursery Unit failed to follow the "5 Rights" of medication administration and perform dose verification by calculation prior the administrations of Enoxaparin to Patient 1. These systemic failures resulted in preventable medication errors involving Patient 1 receiving multiple doses of Enoxaparin in 10 times the prescribed dose. Patient 1 experienced bleeding complications from the overdose and required the administration of an antidote to reverse the effect of the drug to prevent serious injury or death. These violations caused, or were likely to cause, serious injury or death to Patient 1 who received	E 475	dosing. The process for dilution and labeling of Enoxaparin was initiated on 10/22/08, and a written procedure was distributed to pharmacy staff which summarized the new labeling and double checking requirements. All nursing staff in the ICN were educated on the revised process for Enoxaparin preparation and labeling by pharmacy and were re-educated on the requirement for medication dosage calculations as part of the 2-RN independent check for high risk medications. Education of all nursing staff was completed by 10/13/08. Every RN in the ICN completed a competency for calculation of correct medication dosage (for all medications) by December of 2008. Monitoring: The pharmacy maintains a log of Enoxaparin doses prepared by pharmacy. The log consists of a copy of each label for Enoxaparin doses that is signed by the pharmacist and a pharmacy technician. The log is reviewed by the Director of Pharmacy. Nursing drug calculations were audited from January to March of 2009. Results showed 100% accuracy. Preliminary results were reported to the Patient Safety Committee on 2/11/2009. Final results of the audit were reported to the ICN Patient Safety Committee on 3/17/09 High risk medication audits continue in the ICN at the rate of	10/22/08 10/13/08 12/2008 1/2009

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E 475	<p>Continued From page 2</p> <p>the wrong doses of medication. The systemic practices involving these failures to follow hospital policies & protocols also had a potential to affect all patients in the hospital.</p> <p>Findings:</p> <p>During an interview at approximately 11:55 a.m. on 10/23/08, the hospital Director of Pharmacy (DOP) provided a summary of the incident as follow: Patient 1 was a pre-term baby admitted to the hospital with multiple health problems on 9/23/08. Enoxaparin 1.1mg/kg subcutaneously (under the skin) every 12 hours was ordered by the physician on 10/8/08 for thrombus (blood clot) in descending aorta (a blood vessel). Patient 1's weight was 1.87kg (4.1 lb). The calculated Enoxaparin dose for Patient 1 based on his weight was 2mg. The ICN satellite pharmacy erroneously prepared 3 syringes of 0.2ml of Enoxaparin 100mg/ml (each syringe contained 20mg instead of 2mg of Enoxaparin, 10 times the prescribed dose) on 10/8/08. Patient 1 received 3 doses of Enoxaparin 20mg from 10/8/08 to 10/9/08. On 10/9/08, an elevated level of Antifactor Xa (a test to monitor heparin levels in patients being treated with Enoxaparin) was reported by the laboratory. Protamine (an antidote to reverse the effect of Enoxaparin) was administered twice to reverse the effect of Enoxaparin.</p> <p>Enoxaparin (Lovenox®) is a blood thinner that belongs to a class of drugs known as low-molecular-weight heparin and is indicated for the treatment and prevention of blood clots in blood vessels. Enoxaparin is commercially available in 2 concentrations: 100mg/ml and 150mg/ml. Lexi-Comp®, a provider of drug information for health care professionals,</p>	E 475	<p>approximately 10 medication administration records (aMARs) per month. Audits include a check for completion of a 2-RN double check.</p> <p>Responsible Party: Director of Pharmacy, Chief Nursing Officer</p>	
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E 475	<p>Continued From page 3</p> <p>indicated that the dose of Enoxaparin for infant under 2 months old should be 1.5mg/kg subcutaneously every 12 hours. Overdosage of Enoxaparin may cause severe bleeding. Some of the bleeding cases associated with the use of Enoxaparin have been fatal.</p> <p>The Institute for Safe Medication Practices (ISMP) listed anticoagulants (blood thinners) including low-molecular weight heparin as a class of high-alert medications in since 2005. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.</p> <p>A review of Patient 1's clinical record on 10/23/08 showed that Patient 1 was a preterm baby admitted to the hospital on 9/23/08 for surgical management of necrotizing enterocolitis (death of intestinal tissue). At 10:05 a.m. on 10/8/08, Patient 1's physician wrote the following orders:</p> <p>Lovenox (Enoxaparin) 2mg (1.1mg/kg) sc (subcutaneously) every 12 hours. Send Anti-Xa level four hours following second Lovenox injection.</p> <p>Anti-Xa level measures anti-activated factor X (anti-Xa) in blood. The amount of factor Xa in blood is affected by the amount of heparin in the body. This test is used to monitor heparin levels in patients being treated with standard heparin or low molecular weight heparin.</p> <p>A review of Patient 1's MAR on 10/23/08 showed that Patient 1 received 3 doses of Enoxaparin as follows: RN 2 administered the first dose of</p>	E 475		

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E 475	<p>Continued From page 4</p> <p>Enoxaparin at 12:30 p.m. on 10/8/08 and the administration was cosigned by RN 3. RN 4 administered the second dose of Enoxaparin at 9:00p.m. on 10/8/08 and there was no record of another RN cosigning the administration. RN5 administered the third dose of Enoxaparin at 9:45 a.m. on 10/9/08 and the administration was cosigned by RN6.</p> <p>A physician's notes dated 10/10/08 at 12:01 a.m. documented the following:</p> <p>" ... However, due to a medication error, the infant was provided with ten times the requested dose of Lovenox. This was noticed after the baby's anti-10A level came back elevated at 1.92 (u/ml) with a goal range of 0.5 to 0.7. Unfortunately, by the time this level had come back, a third dose of Lovenox was already given at the tenfold elevated dose."</p> <p>Patient 1 required two administrations of an injectable antidote, Protamine Sulfate, 20mg at 1:45 p.m. and 10mg at 6:50 p.m. on 10/9/08 respectively, to reverse the overdosage of Enoxaparin. A head ultrasound was done to ensure that Patient 1 ' s over-anticoagulated state did not cause intraventricular hemorrhage (bleeding into the ventricles of the brain). A physician ' s note dated 10/10/08 at 1:39 p.m. documented that the overdosage of Enoxaparin had resulted in symptoms of bleeding including hematoma (a collection of blood outside the blood vessels) at wrist and blood on dressing.</p> <p>During interviews at approximately 11:50 a.m. and 2:00 p.m. on 10/23/08, the hospital Director of Pharmacy (DOP) stated that a pharmacist made a key stroke error and entered "0.2ml"</p>	E 475		

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E 475	<p>Continued From page 5</p> <p>instead of "0.02 ml" during order entry. The DOP also stated that the hospital did not have any protocols or guidelines on the preparation of Enoxaparin for neonatal and pediatric patients as well as guidelines on the dilution of medications for neonatal and pediatric patients use. When asked about how nursing staff could accurately measure 0.02ml using an 1-ml syringe, the DOP replied that 0.02 ml was very unlikely to be measured accurately using an 1-ml syringe and such practice would likely yield a high error rate. The DOP added that the pharmacist should have diluted Enoxaparin to prepare Patient 1's order to ensure that the volume to be administered can be accurately measured. The DOP also stated that guidelines on the dispensation of Enoxaparin for neonatal and pediatric patients had been created and distributed to pharmacy staff on 10/22/08 to ensure the safe use of Enoxaparin in neonatal and pediatric patients.</p> <p>During an interview at approximately 1:00p.m. on 10/23/08, Pharmacist 1 stated that there was no hospital protocol or guidelines on the preparation of Enoxaparin for neonatal and pediatric patients prior to the discovery of the incident.</p> <p>During an interview at approximately 1:20 p.m. on 10/23/08, RN Manager 1 stated that Enoxaparin was considered a high risk medication in the ICN unit and administration of Enoxaparin required a second registered nurse (RN) to perform an independent check to ensure that the following were right: patient, dose, weight, volume and concentration.</p> <p>During an interview at approximately 1:45 p.m. on 10/23/08, RN 3 stated that she could not remember if Patient 1's Enoxaparin was labeled</p>	E 475		
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E 475	<p>Continued From page 6</p> <p>with drug concentration and she did not do a calculation to verify the dose before administration. RN 3 also stated that drug concentrations were not always printed on the drug labels.</p> <p>During a telephone interview at approximately 7:45 a.m. on 2/3/09, RN4 stated that Enoxaparin was a high risk medication in ICN. RN 4 also stated that she did not do a calculation to verify the dose prior to administration and she did not recall seeing the drug concentration on Patient 1's Enoxaparin label. RN 4 further stated that calculation should be done to verify the dose if the drug concentration was printed on the drug label.</p> <p>During a telephone interview at approximately 8:00 a.m. on 2/3/09, RN2 stated that Enoxaparin was a high risk medication in ICN. RN2 also stated that she did not do a dose verification of Patient 1's Enoxaparin dose by calculation. RN 2 added that she did not remember seeing the drug concentration on Patient 1's Enoxaparin label and that drug concentrations were not always printed on medication labels. RN 2 further stated that it was not a general practice by nursing staff to verify dose by calculation prior to administration of medication in ICN and she thought she was not trained adequately to do dose calculation.</p> <p>RN 5 and RN 6 were not available for interview during the investigation and there was no record indicating that dose verification by calculation was performed by the nurses prior to the administrations of Enoxaparin to Patient 1.</p> <p>A review of a reprint of Patient 1's Enoxaparin label on 10/23/08 showed the following information was on the label:</p>	E 475		

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E 475	<p>Continued From page 7</p> <p>Enoxaparin Sodium Enoxaparin injection 2mg/0.2ml (Concentration: 100mg/ml) IN TB SYRINGE WITH 27G ½ NEEDLE *NO OVERFILL Frequency: Q12H</p> <p>The label showed that drug concentration of Enoxaparin was printed on the label.</p> <p>A review of the hospital's medication administration policy and procedure on 10/23/08 showed that medications should be administered only after all five "rights" have been checked by the licensed person administering the drug. The five rights are: right patient, right drug, right dose, right time and right dose. The nursing staff who provided care to Patient 1 failed to adhere to the hospital policy to ensure that the 3 doses of Enoxaparin that Patient 1 received were right.</p> <p>A review of the hospital's high risk medication policy and procedure on 10/23/08 showed that all routes of heparin were identified as high risk medications for neonatal and pediatric patients and administration of such high risk medications required a 2-RN independent check. The policy indicated that a 2-RN independent check required each RN to independently calculate and verify the dose to be administered prior to administration. In addition, documentation of RNs completing the 2-RN independent check on MAR was required. The nursing staff who provided care to Patient 1 failed to adhere to the hospital's policy on the administration of high risk medications.</p> <p>These systemic, unsafe medication practices by the hospital had resulted in medication errors that involved Patient 1 receiving 3 doses of</p>	E 475		

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E 475	<p>Continued From page 8</p> <p>Enoxaparin 10 times the prescribed dose. Patient 1 experienced bleeding complication from the overdosage and required immediate monitoring and intervention including the administration of a reversing agent, protamine sulfate, to prevent serious injury or death. The violations involved the failure of the hospital to develop and implement a system to ensure the safe use of Enoxaparin in neonatal and pediatric patients as well as multiple failures of the facility to adhere to established policies & procedures for safe medication use. A policy and procedure involving the 5 Rights of medication administration including the administration of the right medication at the right dose to the right patient was not followed. A policy and procedure involving the requirement for a second registered nurse to independently check the calculation and dose of high risk medications for all neonatal and pediatric patients prior to administration was not followed. These violations caused, or were likely to cause, serious injury or death to Patient 1 who received multiple doses of wrong medications. The facility's systemic practices involving these failures to follow facility policies & protocols also had a potential to affect all patients in the hospital.</p> <p>The hospital's failure to develop and implement a policy and procedure to ensure the safe use of Enoxaparin in neonatal and pediatric patients; and to adhere to the hospital medication administration policy and procedure and high risk medication policy and procedure to ensure the safe administration of medication are deficiencies that have caused, or are 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.</p>	E 475		
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