

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 050076	(X2) MULTIPLE CONSTRUCTION A BUILDING _____ B WING _____	(X3) DATE SURVEY COMPLETED 07/28/2010
NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL - SAN FRANCISCO		STREET ADDRESS, CITY, STATE, ZIP CODE 2425 GEARY BOULEVARD, SAN FRANCISCO, CA 94115 SAN FRANCISCO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00235034 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25732, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>Title 22 70263(l)</p> <p>(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.</p>		<p>Title 22 70263(l)</p> <p>Immediate Corrective Action: Immediately following this event, the following corrective measures were taken.</p> <p>1) Insulin Pumps were disallowed for use with hospitalized patients (until such time as an appropriate policy and procedure was developed to define parameters for safe use). 7/27/10</p> <p>2) Clarified expectation that patients presenting with an insulin pump would not only be instructed to turn the pump off, but that the pump must be removed from the patient's room while an alternate physician ordered insulin regimen is in place. All such patients would also receive an assessment by an Endocrinologist. 7/27/10</p> <p>3) The facility medication administration policy that addresses self-administered medications at the bedside was revised to specifically address the use of insulin pumps. Initial P&T 9/7/2010 Med Exec 11/17/10</p>	

Event ID: KLLX11 3/21/2011 12:17:35PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE
Andrea Caplan AQL for Christine Redisch Sr. VP, Area Mgr, Hospital Administration 4-6-2011

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	<p>Continued From page 1</p> <p>This regulation was not met evidenced by:</p> <p>Based on interview and record review the facility failed to implement their written policy and procedure on self-administered bedside medications in the management of Patient 1's Insulin Pump. This failed practice resulted in Patient 1's death which was related to hypoglycemia, the onset of which occurred while Patient 1 was being cared for in the facility.</p> <p>Patient 1 was admitted to the facility on [REDACTED] 0 for pyelonephritis (kidney infection). Review of Patient 1's clinical record indicates she had a history of Type 1 diabetes (insulin dependent diabetes), hypertension and kidney failure. Patient 1 was initially treated in the facility's emergency room during the night then admitted to the seventh floor medical-surgical unit for observation. Review of the emergency room medical record indicates Patient 1 had a Insulin Pump attached to her body from home. (Insulin Pump- device worn around the body that automatically delivers a set amount of insulin to a person, so person does not have to inject themselves with insulin). Patient 1 was alert and cooperative on admission to the floor.</p> <p>Review of the facility's medication policy dated 5/18/10 indicates: " Self -administered medications...If the medication has been brought from home by the patient, the contents of the containers must be examined and positively identified. after arrival at the hospital, by the patient's physician or the hospital pharmacist..The</p>		<p>Intermediate / Long Term corrective actions:</p> <p>A detailed policy addressing the use of insulin pumps in the hospital was developed. This policy was approved by the Pharmacy and Therapeutics Committee and the Quality Utilization Executive Oversight Committee (Medical Executive Committee) in December 2010 and was implemented in Maternal Child Health (MCH).</p> <p>MCH staff were trained by the MCH Director on the policy and the use of pumps in the hospital.</p> <p>This policy is now being implemented in the medical /surgical unit. Med / Surg Patients that are admitted on insulin pumps will be cohorted to one unit (7 So), in order to allow focused education of and competency by the staff in that unit. The Adult Services Director is responsible for assuring completion of the training.</p> <p>Pharmacy will be notified upon admission of any patient who meets criteria for continued use of their insulin pump during their hospital admission - Pharmacy staff were educated by the Inpatient Pharmacy Manager.</p>	<p>12/15/10</p> <p>Feb 2011</p> <p>4/1/11</p> <p>1/19/11</p>

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	<p>Continued From page 2</p> <p>registered nurse is to evaluate the patient's ability to self-administer medications before the patient is allowed to administer medications.. "</p> <p>In an interview on 7/28/10 at 1:00 PM, Nurse Manager 1 [NM-1] said, " On [REDACTED] 10 at 9:52 PM Patient 1 had a High Critical Blood Sugar over 400 mg/dl (milligrams per deciliter) (normal blood sugar 70-105 mg/dl) RN-1 [Registered Nurse 1] gave Patient 1 an injection of Insulin Regular at a dose of 5 Units (medication to lower blood sugar in diabetes) per the Insulin Sliding Scale [ISS] (a doctor's order on the amount of insulin to give based on the blood sugar checks at the bedside) then called the doctor. The doctor ordered a blood sample be sent to the lab to confirm the bedside blood sugar reading. That blood sugar value was 447 mg/dl which was phoned to the doctor. Per doctor's order RN-1 gave Patient 1 another injection of a different type of Insulin, Aspart-Novalog Insulin at a dose of 10 Units (a rapid acting insulin, to lower blood sugar). At 12:30 AM on 6/12/10 Registered Nurse-2 [RN-2] rechecked Patient 1's blood sugar value at the bedside which was 178 mg/dl. RN-2 notified the doctor who ordered no more Insulin at this time but to check the blood sugar at 4 AM. RN-1 went into Patient 1's room at 4 AM to recheck her blood sugar. RN-1 found Patient 1 unresponsive and unconsciousness with a blood sugar level of 7 mg/dl. RN-1 called for a "Code Blue"(rapid response emergency team to help resuscitate a patient who is suddenly unresponsive). Patient 1 was given Dextrose 50-IV (drug to counteract the effects of a dangerously low blood sugar injected into the vein) and intubated (</p>		<p>Monitoring: Monitoring will consist of a 100% chart review of all patients who meet criteria for continued use of their insulin pump during their hospital admission. 100% review will be completed for a minimum of 6 months post implementation, until sustained compliance is demonstrated. Results of the monitoring process will be reported to medication Safety, Pharmacy and Therapeutics, QUEOC (Medical Executive) committees and hospital administration.</p> <p>Monitoring will be done by the Risk Management / Patient Safety and Pharmacy departments.</p>	Ongoing	



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	<p>Continued From page 3</p> <p>emergency artificial tube inserted into the throat to maintain breathing) and was transferred to the ICU [Intensive Care Unit]. Patient 1 never regained consciousness."</p> <p>Record review of Patient 1's 6/12/10 ICU Physician note indicated: "Unresponsive blood sugar of 7 but still breathing, pulse palpable. Code called at 4:20 AM this morning but unclear how long patient was down. Intubated 22 minutes later. Noted to have Insulin Pump still attached. However, on checking chart the pump was supposedly d/c'd (discontinued) and patient was instructed to d/c pump. Unclear if patient also received insulin from pump in addition to ISS."</p> <p>Record review of Patient 1's [REDACTED] 10 Death Certificate Work sheet indicated: "Cause of Death...cardiopulmonary arrest due to anoxic encephalopathy due to hypoglycemia..."(brain injury and death due to a low blood sugar). Discharge Summary Note indicated the date of death was [REDACTED] 10 at 5:02 AM.</p> <p>In an interview, on 7/29/10 at 7:30 AM, RN-1 was asked what she knew about Patient 1's Insulin Pump RN-1 said, "When I came to work that evening at 7 PM ([REDACTED] 10) I was told by RN-3 in report that the Insulin Pump had been discontinued During the Code Blue at 4 AM the next morning when we were working on Patient 1 I noticed the Insulin Pump was still in place on the patient's abdomen. The Critical Care Nurse on the code team removed it at that time."</p>			

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	<p>Continued From page 4</p> <p>In an interview, on 8/13/10 at 3:30 PM ,RN-3 was asked what she knew about Patient 1's Insulin Pump. RN-3 said," I admitted Patient 1 to our floor from the Emergency Room on [REDACTED]10,during my assessment when I was listening to her lungs and checking her abdomen I felt a bump on her body. Patient 1 told me it was her Insulin Pump."</p> <p>In the same interview RN-3 was asked if she knew the Insulin Pump was on. RN-3 said," I really don't know. The patient's nephrologist (kidney doctor) came by an told the patient to turn it off. I think the patient turned it off but she still had it on her body at the end of my shift."</p> <p>In an interview on 7/28/10 at 3:30 PM, NM-1 was asked for a policy and procedure for managing a patient using her own Insulin Pump in the hospital. NM-1 said,"We don't have a written policy. It has been our practice not to allow the use of the patient's own Insulin Pump in the hospital."</p> <p>In the same interview NM-1 was asked if Patient 1's competency for self-administration of medication by insulin pump was evaluated according to facility policy. NM-1 said,"We did not check on the medication competency of Patient 1 because we don't allow the use of the pump in the hospital."</p> <p>NM-1 was then asked if the pump was pumping insulin into Patient 1 during her stay on the seventh floor. NM-1 said,"Well it is hard to say if it was pumping on her body or at the bedside. We never physically removed the pump from her body on admission. We told her not to use it. We never took</p>			

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