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FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICINCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000071	A. BUILDING _____ B. WING _____	C 07/30/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPTIAL – South Bay	25825 SOUTH VERMONT AVENUE HARBOR CITY, CA 90710

9X4 ID PREFIX TAG	SUMMARY STATEMENT OF DEFICINCIES (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 represents the findings of the Los Angeles County Depart of Public Health During the investigation of an entity reported Incident. Intake number: CA00236462 Representing the Department of Public Health [redacted], RN, HFEN The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility. 1280.1 (c) Health and Safety Code Section For purposes to this section, "Immediate Jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused or likely to cause, serious injury or death to the patient.	E 000	RECEIVED 2011 NOV 23 PM 12: 33 HEALTH FACILITIES INSPECTION DIVISION ADMINISTRATION	
E264	T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This Statute is not met as evidenced by: Based on interview and record review, the facility failed to implement its policy and procedure regarding administration of medication to ensure the correct medication was administered to Patient 1. Patient 1 underwent a surgery to repair	E264	Action: The correct process for responding to verbal orders in the OR suite was presented to the OR staff. The licensed healthcare practitioner receiving the verbal order will repeat back the medication name, dosage and route of administration, and wait for acknowledgement from the ordering physician. The instructions for repeating back verbal orders in the OR suite were incorporated into the Medical Center Policy #2144 "Processing Physician Orders (including verbal orders)" The revision was approved by the Medical Executive Committee. The Assistant Director (ADA) of Perioperative Services is responsible for the correction. The ADA or designee monitors all verbal orders by observation.	7/21/2010 8/6/2010

Licensing and Certification Division

Marion Schmidt — Director, Accreditation & Licensing (TITLE) — (X6) DATE 11/23/2011

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

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E 264	Continued From page 1 A bleeding of the gastrointestinal (digestive) tract during the surgery, the surgeon had asked for a medication (Factor VII) to aide in coagulation and to help stop Patient 1's bleeding; however, Patient 1 received Activase, an anticoagulant (blood thinner) in error. The facility staff's failure to ensure that Patient 1 was administered the correct medication as requested by the surgeon, resulted in Patient 1's death due to profuse bleeding from the abdominal wound. According to the death certificate, the immediate cause of death was "periprocedural administration of alteplase". (Activase is brand name and alteplase is generic name) Findings: On July 27, 2010, an unannounced visit was conducted to the facility to investigate an entity reported incident involving a medication error. The facility letter to the Department dated July 21, 2010, disclosed Patient 1 "underwent gastric repair in the OR (operating room)" and "the surgeon ordered Activated Factor VII" to control the bleeding. "It was discovered that the patient was not given Activated Factor VII in the OR, but, had been given Activase (TPA) in error." "The patient was treated with multiple units of blood products and medications but expired." Patient 1's medical record was reviewed on July 27, 2010. The Medical History and physical report dated [redacted] 2010, indicated Patient 1 was admitted to the facility on [redacted] 2010, after vomiting about two tablespoons of bright red blood. According to the Medical History and Physical report, Patient 1 had reported abdominal pain, had dark brown emesis, and black tarry stools. According to the report, the Physician's impression was that Patient 1 had gastric	E 264	Action: All OR & Pharmacy staffs received education on telephone orders. This included: The circulating RN in the OR suite is the person responsible for calling Pharmacy when a medication is needed and not available in the Perioperative area. The RN requests the medication and confirms the medication name, dosage and route of administration with the pharmacist on the phone. The Perioperative ADA and the Inpatient Pharmacy Director are responsible for the correction. Monitoring: Pharmacy documents the interaction with the OR RN on an audit sheet. The audit includes the medication name, dosage and route of administration. Auditing is ongoing and is reported to Medication Safety Committee and Pharmacy & Therapeutics Committee as appropriate. Action: All OR staffs were educated on the process for validating medications brought into the OR by Pharmacy during a case. The medication is verbally validated with the ordering physician and double-checked by two licensed healthcare practitioners using the following methods prior to administration: 1. Verbally to confirm the accuracy of the medication and dose ordered 2. Visually against the product label The Perioperative ADA and Director of Education are responsible for the correction.	7/21/2010-8/6/2010 (OR) 7/27/2010 (Pharmacy) 7/21/2010-8/6/2010

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E 264	Continued From page 2 (stomach) bleeding. A review of a Nursing Note dated [redacted] 2010, at 11:53 p.m., revealed that between 11 p.m. and 11:30 p.m., Patient 1 was pale. According to the Nursing Note, Patient 1 had vomited a blood clot and the emesis (vomit) had bright red blood. Patient 1's physician was notified and the patient was transferred to the Intensive Care Unit (ICU). A review of a Surgeon Note dated [redacted] 2010, at 2:45 a.m., authored by MD 1, disclosed that Patient 1 was transferred to the ICU where she continued to vomit blood and received blood transfusions. According to the Surgeon Note, Patient 1 was intubated endotracheally (tube placed down the wind pipe to provide ventilation and connected to a breathing machine). The Surgeon Note indicated that the patient continued to bleed and had low blood pressure. Patient 1 was taken to the OR where she underwent a laparotomy (a surgical procedure involving an incision through the abdominal wall to gain access into the abdominal cavity.) According to the Surgeon Note, during the surgery, the patient had severe coagulopathy (problem with the body's blood clotting ability where heavy bleeding is seen). The Surgeon Note indicated Patient 1 was given "activated factor VII" and blood transfusions. Patient 1 was transferred back to the ICU in critical condition. According to the Food and Drug Administration (FDA), Factor VII is a medication used to treat bleeding episodes and for the prevention of bleeding in surgical interventions (http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm056954.pdf).	E 264		

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E 264	Continued From page 3 On July 27, 2010 at 12:15 p.m., during an interview, a certified registered nurse anesthetist (CRNA 1) stated he was the nurse anesthetist during Patient 1's surgery and was supervised by MD 2. CRNA 1 stated he heard MD 1 asking for "Factor VII." CRNA 1 stated he was handed a bottle of medication by MD 2 and he "put his trust in [my] supervisor and took the bottle of medication "and administered the drug. CRNA 1 stated he "assumed it was the correct medication" and he assumed the medication that was handed to him was Factor VII. CRNA 1 stated he did not look at the medication's label because he "put his trust" in his supervisor (MD 2) that the medication that was handed to him was Factor VII. CRNA 1 stated that patient was transferred to the ICU and MD 1 asked for more Factor VII from the pharmacist. According to CRNA 1, the pharmacist stated they had not sent Factor VII for Patient 1 yet. CRNA 1 stated he returned to the OR and discovered that the bottle of medication that he administered to Patient 1 was tissue plasminogen activator (tPA; activase; alteplase). According to the FDA, Activase is a tissue plasminogen activator used to dissolve clots during a heart attack, stroke, or lung clot. According to the FDA document, the most frequent adverse reaction is bleeding and can be critical (http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/alegen051502LB.pdf). A review of an Anesthetic Record dated [redacted] 2010, indicated Factor VII was administered to Patient 1. However, a review of an Anesthesia Post-Operative Note, dated [redacted] 2010 at 4:41 a.m., indicated it was discovered that the	E 264	Action : Medical Center Policy 2144, "Processing Physician Orders (including verbal orders)" was revised to include a section on verbal orders in the Surgical Suite. All staff were inserviced. Responsibilities of the RN order receiver and the ordering Physician are stipulated in the policy. The Perioperative ADA is responsible for the correction. The process is monitored by Pharmacy and the OR ADA and reported to P&T Committee. Action: Pharmacists and pharmacy staff have been inserviced to intervene in any order for Activase (t-PA) greater than 4 mg. The pharmacist calls the ordering physician to clarify the reason and dosage, prior to dispensing. All t-PA infusions, for use in all departments, must be prepared, labeled and checked by a pharmacist prior to leaving the pharmacy. These requirements have been added to the Medical Center Policy 2824, "High Alert Medication Policy" The Pharmacy Director is responsible for the correction. Monitoring of High Alert medication is documented on a Medication Safety Verification Record and reported to the Pharmacy and Therapeutics (P&T) Committee. Action: Anesthesia providers were provided re-education/review of Medical Center Policy 2824 and "High Alert Medication Safety Practices for Anesthesia". The Anesthesia Department Administrator and the Anesthesia Quality Improvement Chairman are responsible for the correction. High Alert medication ordering is monitored by Pharmacy and reported to P&T Committee.	18/6/2010 7/27/2010 8/6/2010 8/6/2010

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E 264	Continued From page 4 Medication that was administered to Patient 1 was Activase instead of Factor VII. On July 27, 2010, when interviewed at 12:30 p.m., RN 1 stated he was the nurse assisting during the surgery. RN 1 stated he heard MD 3 "call out" for Activase. RN 1 stated he wrote the name of the drug down on a piece of paper and read back aloud "Activase." RN 1 stated he received the medication from the pharmacy and raised the box and stated "Activase 100 milligrams" at least three times and handed it to MD 2. A review of the Nursing notes dated [redacted] 2010 at 5:30 a.m., indicated Patient 1 was received from the post anesthesia care unit and the patient was "very unstable/critical, unresponsive to stimulation." According to the notes, Patient 1 was "bleeding profusely (from the) abdominal wound" and the suction canisters (collection device that collects the blood that was suctioned from the wound) was changed several times. The notes indicated the towel dressings were constantly saturated with blood. Patient 1 received several units of blood and fresh frozen plasma (liquid portion of human blood that has components for coagulation) transfusions. Only July 30, 2010 at 10 a.m. during a telephone Interview at 10 a.m., MD 2 stated he was the anesthesiologist during Patient 1's surgery. During the surgery, MD2 stated he head MD 1 ask for Factor VII. According to MD 2, the bottle of medication was placed on the anesthesia cart by the circulating nurse and he mixed the medication. MD 2 stated he did not read the medication label and did not verify the medication name. MD 2 state it was his common practice to read a medication label prior to mixing a drug.	E 264	Action: Re-education was presented to OR staff regarding the process for handling verbal orders in the OR with emphasis on "repeat back" and obtaining confirmation from the ordering physician. The ADA of Perioperative Services is responsible for correction and monitoring by observation. Action: All High Alert medications must be verified by Pharmacy prior to dispensing. All t-PA infusions are prepared by a pharmacist, in the pharmacy where they are labeled with a "High Alert" label. This information has been added to the Medical Center Policy #2824	8/06/2010 7/27/2010

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E 264	Continued From page 5 But "unfortunately [he] did not do what he commonly practiced." A review of a Progress Notes dated [redacted]2010 at 2:53 p.m., indicated Patient 1 had an exploratory laparotomy for repair of a bleeding vessel, but the intraoperatvie bleeding worsened after Activase was given instead of Factor VII in the OR. According to the Progress Notes, Patient 1 had multi-organ failure and persistent hemorrhagic shock that did not improve with blood transfusions and infusions of clotting products. The progress Notes revealed that the patient had bleeding that worsened and had a very poor prognosis. A review of the Death Notice dated [redacted]2010 at 4:57 p.m., indicated Patient 1 progressed to bradycardia (slowing of the heart rate) and emergency cardiac drugs were administered to the patient. However, the patient rapidly progressed to asystole (cardiac standstill). The physician pronounced the patient dead at 4:26 p.m. On July 27, 2010, at 1:35 p.m., during an interview, MD 1 stated that he told the anesthesiologist "we are going to need Factor VII for this patient;" however, the OR staff did not confirm the medication with him. MD 1 stated the error of infusing Activase, instead of Factor VII, contributed to Patient 1's demise. Patient 1's Certificate of Death revealed the immediate cause of death was "Periprocedural administration of alteplase". (Activase is brand name and alteplase is generic name) A review of the facility's policy and procedure titled, "Medication Administration" dated February	E 264	Re-education presented to the OR staff with emphasis on "repeat back" and obtaining confirmation from the ordering physician that the medication order was understood and is correct. The Perioperative ADA is responsible for correction. The ADA monitors the verbal order process by observation. Reports are made to the P&T Committee.	8/6/2010

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E 264	Continued From page 6 2010 stipulated the patient care provider administering the medication is responsible for ensuring the six rights of medication administration which included: the right medication, the right patient, right dose, right route, right time and the right reason. The facility's staff failure to implement its policy and procedure on "Medication Administration" to ensure that the patient received the correct medication resulted in Patient 1's death, is a deficiency that has caused, or is likely to cause serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code §1280.1	E 264	Kaiser Permanente Policy, Anesthesia 7040, "High Alert Medication Safety Practices for Anesthesia" and Medical Center Policy #2824, "High –Alert Medication Policy" presented to Anesthesia providers. The Administrator of the Department of Anesthesia and the Physician QI Chair are responsible for the correction. Pharmacy monitors medication administration and reports to P&T Committee.	8/6/2010