11/28/4 EST

California Department of Public Health

PRINTED: 11/08/2011 FORM APPROVED

STATEMENT OF DEFICINCIES PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY IDENTIFICATION NUMBER AND PLAN OF CORRECTION COMPLETED A. BUILDING C B. WING_ CA930000071 07/30/2010 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 25825 SOUTH VERMONT AVENUE KAISER FOUNDATION HOSPTIAL - South Bay HARBOR CITY, CA 90710 9X4 ID SUMMARY STATEMENT OF DEFICINCIES PROVIDER'S PLAN OF CORRECTION (EACH (X5)COMPLETE **PREFIX** (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 000 **Initial Comments** E 000 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 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 Action: licensee's noncompliance with one or more The correct process for responding to verbal 7/21/2010 requirements of licensure has caused or likely to orders in the OR suite was presented to the cause, serious injury or death to the patient. OR staff. The licensed healthcare practitioner receiving the verbal order will repeat back the T22 DIV5 CH1 ART3-70213(a) Nursing Service F264 E264 medication name, dosage and route of Policies and Procedures administration, and wait for acknowledgement from the ordering physician. (a) Written policies and procedures for patient care shall be developed, maintained and The instructions for repeating back verbal implemented by the nursing service. 8/6/2010 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 This Statute is not met as evidenced by: **Executive Committee.** Based on interview and record review, the facility The Assistant Director (ADA) of Perioperative failed to implement its policy and procedure Services is responsible for the correction. regarding administration of medication to ensure The ADA or designee monitors all verbal the correct medication was administered to orders by observation. Patient 1. Patient 1 underwent a surgery to repair

Licensing and Certification Division

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California Department of Public Health

NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPTIAL – South Bay STREET ADDRESS, CITY, STATE, ZIP CODE 25825 SOUTH VERMONT AVENUE HARBOR CITY, CA 90710 SUMMARY STATEMENT OF DEFICINCIES TAG SUMMARY STATEMENT OF DEFICINCIES REGULATORY OR LSC IDENTIFYING INFORMATION) 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 are quested 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 alteplases". (Activase is brand name and alteplase is generic name) Findings: On July 27, 2010, an unannounced visit was	STATEMENT OF DEFICINCIES (X1) PROVIDER/SUPPLIER/CLI/ AND PLAN OF CORRECTION IDENTIFICATION NUMBER		₹ ``		TIPLE CONSTRUCTION NG	(X3) DATE SURVEY COMPLETED			
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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 2010, indicated Patient 1 was admitted to the facility on 2010, after vomiting about two tablespoons of bright red blood. According to the Medical History and Physical report, Patient 1 had reported 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 ordening 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.	E 264	A bleeding of the g during the surgery, medication (Factor and to help stop Pa Patient 1 received (blood thinner) in e to ensure that Patiet correct medication resulted in Patient bleeding from the ato the death certific death was "peripro alteplase". (Activas alteplase is generic Findings: On July 27, 2010, a conducted to the fareported incident in The facility letter to 21, 2010, disclosed repair in the OR (of surgeon ordered Active bleeding. "It was not given Active but, had been given "The patient was the blood products and Patient 1's medical 27, 2010. 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Accordate, the immediate caus cedural administration of the is brand name and coname) an unannounced visit was acility to investigate an envolving a medication error the Department dated Jid Patient 1 "underwent gaperating room)" and "the civated Factor VII" to coast discovered that the payated Factor VII in the Olin Activase (TPA) in error eated with multiple units it medications but expired I record was reviewed on dical History and physical 2010, indicated Patient and Eatility on the Medical History and tient 1 had reported and dark brown emesis, and the province and dark brown emesis, and the surgeon in the province and dark brown emesis, and the surgeon in the province and dark brown emesis, and the surgeon in the province and dark brown emesis, and the surgeon in the province and dark brown emesis, and the surgeon in the province and the provi	for a property of the second o	E 264	Action: All OR & Pharmacy staffs received on telephone orders. 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California Department of Public Health STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION COMPLETED IDENTIFICATION NUMBER: A. BUILDING B. WING CA93000071 07/30/2010 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 25825 SOUTH VERMONT AVENUE KAISER FOUNDATION HOSPITAL - SOUTH BA HARBOR CITY, CA 90710 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PRÉFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG **DEFICIENCY**) E 264 E 264 Continued From page 2 (stomach) bleeding. A review of a Nursing Note dated 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 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/BiologicsBloodVa ccines/BloodBloodProducts/ApprovedProducts/Li censedProductsBLAs/FractionatedPlasmaProduc ts/ucm056954.pdf).

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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 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.	STATEMENT OF DEFICINCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER CA930000071			(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED C 07/30/2010		
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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 2010, indicated Factor VII was administered to Patient 1. However, a review of an Anesthesia Post-Operative Note, dated 2010 at 4:41 a.m., indicated it was discovered that the Action: Action: Anesthesia providers were provided reeducation/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	E 264	On July 27, 2010 a interview, a certified (CRNA 1) stated he during Patient 1's s MD 2. CRNA 1 sta "Factor VII." CRNA bottle of medicatior in [my] supervisor a medication "and ad stated he "assumed medication" and he was handed to him stated he did not lo because he "put his 2) that the medicati was Factor VII. CR transferred to the IC Factor VII from the CRNA 1, the pharm Factor VII for Patier returned to the OR of medication that h was tissue plasminal teplase). According to the FI plasminogen activaduring a heart attack According to the FI frequent adverse recritical (http://www.accesslabel/2002/alegen0 A review of an Anece 2010, indicated Face Patient 1. However Post-Operative Not	t 12:15 p.m., during an d registered nurse anesthet was the nurse anesthet was the nurse anesthet was the heard MD 1 askin 1 stated he was handed by MD 2 and he "put his and took the bottle of liministered the drug. CR dit was the correct was Factor VII. CRNA 1 ok at the medication's lates trust" in his supervisor (ion that was handed to his trust" in his supervisor (ion that was handed to his trust" in his supervisor (ion that was handed to his trust and MD 1 asked for me pharmacist. According to hacist stated they had not not 1 yet. CRNA 1 stated and discovered that the line administered to Patientogen activator (tPA; activated to dissolve clots ock, stroke, or lung clot. DA document, the most eaction is bleeding and calculated and discovered that the line administered to Patientogen activator (tPA; activated to dissolve clots ock, stroke, or lung clot. DA document, the most eaction is bleeding and calculated and discovered dated cor VII was administered to view of an Anesthe te, dated and an Anesthe te, dated an Anesthe te, dated and an Anesthe te, dated an Anesthe te	netist ist ed by g for I a strust NA 1 n that oel MD m was nore o t sent he bottle t 1 vase; an be docs/	E 264	Action: Medical Center Policy 2144, "Processing Orders (including verbal orders)" was reinclude a section on verbal orders in the Suite. All staff were inserviced. Responsible RN order receiver and the ordering Fare stipulated in the policy. The Perioperative ADA is responsible for correction. The process is monitored by Pharmacy ADA and reported to P&T Committee. Action: Pharmacists and pharmacy staff have be inserviced to intervene in any order for APA) greater than 4 mg. The pharmacist ordering physician to clarify the reason a dosage, prior to dispensing. All t-PA infuse in all departments, must be prepare and checked by a pharmacist prior to leapharmacy. These requirements have been added to Medical Center Policy 2824, "High Alert Policy" The Pharmacy Director is responsible for correction. Monitoring of High Alert medication is do on a Medication Safety Verification Recorreported to the Pharmacy and Therapeu Committee. Action: Anesthesia providers were provided reeducation/review of Medical Center Policand "High Alert Medication Safety Practi Anesthesia". The Anesthesia Department Administrat Anesthesia Quality Improvement Chairm responsible for the correction. High Alert Alerthesia Quality Improvement Chairm responsible for the correction. High Alerthesia Correction.	vised to Surgical sibilities of Physician r the and the OR een Activase (t- calls the and fusions, for d, labeled aving the o the Medication r the cumented ord and tics (P&T) cy 2824 ces for or and the nan are	

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PRINTED: 11/08/2011 FORM APPROVED California Department of Public Health (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICINCIES PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A. BUILDING C B. WING CA930000071 07/30/2010 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 25825 SOUTH VERMONT AVENUE KAISER FOUNDATION HOSPTIAL - South Bay HARBOR CITY, CA 90710 PROVIDER'S PLAN OF CORRECTION (EACH 9X4 ID SUMMARY STATEMENT OF DEFICINCIES (X5)**PREFIX** PREFIX COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL CORRECTIVE ACTION SHOULD BE TAG REGULATORY OR LSC IDENTIFYING INFORMATION). TAG CROSS-REFERENCED TO THE APPROPRIATE DATE **DEFICIENCY**) E 264 8/06/2010 Continued From page 4 E 264 Action: Re-education was presented to OR staff Medication that was administered to Patient 1 regarding the process for handling verbal was Activase instead of Factor VII. orders in the OR with emphasis on "repeat back" and obtaining confirmation from the On July 27, 2010, when interviewed at 12:30 ordering physician. p.m., RN 1 stated he was the nurse assisting The ADA of Perioperative Services is during the surgery. RN 1 stated he heard MD 3 responsible for correction and monitoring by "call out" for Activase. RN 1 stated he wrote the observation. 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 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. Action: Only July 30, 2010 at 10 a.m. during a telephone Interview at 10 a.m., MD 2 stated he was the All High Alert medications must be venified by anesthesiologist during Patient 1's surgery. 7/27/2010 Pharmacy prior to dispensing. All t-PA During the surgery, MD2 stated he head MD 1 infusions are prepared by a pharmacist, in the 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.

pharmacy where they are labeled with a "High

Alert" label. This information has been added

to the Medical Center Policy #2824

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E 264	A review of a Prograt 2:53 p.m., indical exploratory laparoto vessel, but the intra after Activase was the OR. According 1 had multi-organ f. hemorrhagic shock blood transfusions products. The progpatient had bleedin very poor prognosis. A review of the Deat 4:57 p.m., indical bradycardia (slowing emergency cardiace the patient. However, progressed to asystem products. The progressed to asystem progressed progresse	the did not do what he did." Tess Notes dated an omy for repair of a bleeding worse given instead of Factor V to the Progress Notes, Paailure and persistent that did not improve with and infusions of clotting gress Notes revealed that g that worsened and had so at the Notice dated at the Patient 1 progressed ag of the heart rate) and drugs were administered for the patient rapidly tole (cardiac standstill). The determinant dead at 4:: at 1:35 p.m., during an atted that he told the reare going to need Factor wever, the OR staff did not the standstill of the stand	ened II in atient the a 2010 to I to The 26 or VII ot ed the VII, ral and	E 264	Re-education presented to the OR semphasis on "repeat back" and obtate confirmation from the ordering physical the medication order was understood correct. The Perioperative ADA is responsible correction. The ADA monitors the verbal order probservation. Reports are made to the Committee.	ining cian that d and is e for process by	8/6/2010	

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E 264	administering the nensuring the six rig administration which medication, the right route, right time and The facility's staff fand procedure on "ensure that the patimedication resulted deficiency that has serious injury or de therefore constituted.	patient care provider nedication is responsible hts of medication th included: the right nt patient, right dose, righ	for t licy n" to	E 264	Kaiser Permanente Policy, Anesthese "High Alert Medication Safety Practic Anesthesia" and Medical Center Poli "High –Alert Medication Policy" prese Anesthesia providers. The Administrator of the Department Anesthesia and the Physician QI Charesponsible for the correction. Pharmacy monitors medication admit and reports to P&T Committee.	ces for cy #2824, ented to of air are	8/6/2010	

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