

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050535	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/25/2008
NAME OF PROVIDER OR SUPPLIER COASTAL COMMUNITIES HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 2701 S. BRISTOL STREET, SANTA ANA, CA 92704 ORANGE COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
	<p>The following reflects the findings of the Department of Public Health during an investigation of COMPLAINT # CA00152441.</p> <p>Inspection was limited to the specific complaint(s) investigated and does not reflect the findings of a full inspection of the hospital.</p> <p>Representing the Department of Public Health (formerly Department of Health Services): [REDACTED], Pharmaceutical Consultant</p> <p>HSC 1280.1 (a)(c) (a) If a licensee of a health facility licensed under subdivision (a), (b) or (f) of Section 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. (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>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</p> <p>70263(c)(1) 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</p>			

Event ID:80UL11

8/14/2008

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

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	<p>Continued From page 1</p> <p>nursing service or her representative and the administrator or his representative.</p> <p>(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 shall be responsible for the development and implementation of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>The above regulation was NOT MET as evidenced by:</p> <p>Based on interview, record review and observation the facility failed to implement their policies and procedures on the safe administration of tPA (Tissue Plasminogen Activator), a clot dissolving drug, by accidentally administering an excessive dose of tPA to Patient 1 resulting in Patient 1's death.</p> <p>Findings:</p> <p>Record review on 6/12/08 at 1000 hours reveals that on 5/26/08 at 1336 hours, Patient 1 was brought to the Emergency Department (ED) by paramedics with a preliminary diagnosis of a possible cerebral vascular accident (bleeding in the brain). A CT (computerized tomography) scan, which is a specialized x-ray, was performed and did not show any contraindications for use of a thrombolytic</p>			

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	<p>Continued From page 2</p> <p>agent. A thrombolytic agent is a drug that dissolves blood clots. The ED physician consulted with a Neurologist at another hospital. The Neurologist recommended the administration of Labetolol, a drug used to bring down Patient 1's blood pressure, and then to administer tPA to dissolve the clot. A review of the "adverse reactions" in the approved package insert for tPA indicates that the most frequent adverse reaction associated with it, in all approved indications, is bleeding.</p> <p>On interview with Physician 1 on 6/12/08 at 1030 hours, he stated that on 5/26/08, he wrote orders for Labetolol 10 mg to be administered by intravenous push and a 83.5 mg dose of Alteplase, the brand name for tPA, to be administered intravenously in three doses of "15 mg bolus (immediately), then 41 mg over 30 minutes, then 27.5 mg over 60 minutes." He stated that he prescribed the 83.5 mg. dose based on the manufacturer's supplied dosing card located in the "clot box". The clot box is a sealed container containing tPA and the supplies necessary to administer the drug. At 6/12/08 at 1115 hours, observation of the manufacturer's supplied dosing card showed the card had dosing guides on both sides of the card. One side contained dosing guidelines for "Acute Ischemic Stroke" and the other side of the card had dosing guidelines for "Acute Myocardial Infarction." The physician stated that he and the nurse read the wrong side of the card and he mistakenly ordered the dose for "Acute Myocardial Infarction" instead of for "Acute Ischemic Stroke". Therefore, the patient received 83.5 mg of tPA instead of the proper dose of 50 mg</p>				

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	<p>Continued From page 3</p> <p>for acute ischemic stroke.</p> <p>Medical record review identified that on 5/26/08 at 2300 hours a CT scan was ordered for Patient 1 and showed subarachnoid bleeding (bleeding in the brain). On 5/27/08 at 0700 an EEG (a procedure to determine if the brain is functioning normally) was performed and read as "straight line" indicating the patient was brain dead. A cerebral perfusion study was performed which confirmed Patient 1 was brain dead. Patient 1 was taken off life support and died shortly thereafter. On 6/20/08 a review of the "Death Summary" in the medical record for Patient 1 stated, "....she developed a hemorrhage from the tPA."</p> <p>On 6/20/08 at 1044 hours, in an interview with Registered Nurse 1, she confirmed that she was involved in the administration of the tPA to Patient 1. She also confirmed that the wrong side of the manufacturer's dosage card was used by mistake to dose the patient.</p> <p>On 6/25/08 at 0810 hours, in an interview with Registered Nurse 2 it was confirmed that the facility's Policy and Procedure, entitled, "tPA Protocol For Stroke" contained a form entitled "Physicians Orders tPA for Stroke" which listed the calculation to be used for dosing tPA. She confirmed that the physician did not use this form to calculate or order the tPA for Patient 1.</p> <p>The violation(s) has caused or is likely to cause, serious injury or death to the patient(s).</p>			

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