

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050678	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/23/2013	
NAME OF PROVIDER OR SUPPLIER Orange Coast Memorial Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 9920 Talbert Ave, Fountain Valley, CA 92708-5153 ORANGE 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: CA00325325 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 22781, 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>Health and Safety Code Section 1279.1(c): The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.</p> <p>The CDPH verified that the facility had informed the patient or party responsible for the patient of the adverse event by the time the report was made.</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY:</p> <p>70213(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.</p>		<p>Plan of Correction for Complaint #CA00325325</p> <p>A. How the correction will be accomplished, both temporarily and permanently. What immediate measures and systemic changes will be put in place to ensure that the deficient practice does not recur?</p> <p>The following corrective actions have been taken:</p> <ol style="list-style-type: none"> The policy and procedure for the "FAST team, Inpatient" PTC-465 has been revised to include the following changes: <ul style="list-style-type: none"> Pharmacist attends all FAST team calls to the patient's room and ascertains patient name, allergies, age, height, and weight in anticipation of the possible need for Alteplase (t-PA) therapy. That Alteplase (t-PA) is administered as ordered by neurologist after patient is examined by a physician. That Alteplase (t-PA) for stroke is to be ordered by the neurologist using the Acute Ischemic Stroke Thrombolysis (OCM) [1675] order set in the electronic medical record. That all Alteplase (t-PA) orders require two (2) pharmacists checking accuracy of dose calculation prior to preparation. That all Alteplase (t-PA) preparations are delivered by a pharmacist and the dosage is re-checked with the administering nurse. 	<p>5/24/2013</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">2014 DEC 30 PM 12 20</p>

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

TITLE

(X6) DATE

Chris M. Shuman EXECUTIVE DIRECTOR OF PERFORMANCE IMPROVEMENT & PATIENT SAFETY 12/24/2014

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 10 *Accepted 12/24/15*

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>70213(d) Policies and Procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.</p> <p>70263(c)(1) 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. 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 regulations were NOT MET as evidenced by:</p> <p>Based on interview and medical record review, the hospital failed to ensure Patient A was evaluated per the hospital's P&Ps (Policies and Procedures) for the appropriate use and correct dose of t-PA (alteplase, a blood clot dissolving medication with a heightened risk of causing significant patient harm when used in error) medication that was ordered</p>		<ul style="list-style-type: none"> • That all Alteplase (t-PA) doses are checked by two (2) Registered Nurses prior to administering the medication. <p>2. The policy and procedure "High Alert/Risk Medications" MED-175 has been revised to add the double check processes to the entry for Alteplase (t-PA) in the "Thrombolytics" listing.</p> <p>3. Education of all critical care nurses has been completed with the following components:</p> <ul style="list-style-type: none"> • The revisions to the policy and procedures listed in (1.) above • Use of overhead paging of FAST team on all cases. • Uniform use of the NIH stroke scale. • Requirement to gather information for the neurologist on patient's history. • Requirement that t-PA is administered as ordered by neurologist after patient is examined by a physician. • Requirement of contacting the neurologist on call or patient's own neurologist if applicable. • Correct dosing of t-PA based upon weight. • Use of the Acute Ischemic Stroke Thrombolysis (OCM) [1675] order set <p>4. Education of all staff registered nurses has been completed to encompass the following components:</p>	<p>DEC 30 PM 12 20</p>

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	<p>and administered on 8/29/12. As a result, Patient A received a dose of t-PA more than two times the required dose for the patient, which resulted in intracranial bleeding and subsequent death on 9/1/12.</p> <p>Findings:</p> <p>* The hospital's P&P titled FAST (Face/Arm/Speech/Time) Team, Inpatient (PTC-465), reviewed/revised as of 4/12, showed the following guidelines on how to care for patient exhibiting signs and symptoms of stroke. The purpose of the policy is to ensure a rapid response to patients presenting with signs of a stroke (disruption of blood flow to an area of the brain due to obstruction or bleeding). Patients who show signs of a stroke must receive immediate medical attention, and an assessment is done in order to make a diagnosis to determine the type of treatment needed. Immediate treatment may minimize the long-term effects of a stroke and prevent death.</p> <p>1. If a patient is identified by the nurse has having signs of a stroke (face drooping, weakness, speech difficulties, sudden confusion, vision problems in one or both eyes, sudden severe headache, dizziness, loss of balance or coordination), and was last seen normal less than six (6) hours before, the patient's nurse calls the Hospital's Critical Assessment Team (CAT). On arrival, the team performs an assessment of the patient. A stroke scale form of the patient's face/arm/speech/time assessment is completed</p>		<ul style="list-style-type: none"> • Review of the use of the Critical Assessment Team (CAT) and indications and procedure for its utilization • Use of the Critical Assessment Team specifically when changes in level of consciousness / weakness / verbal ability and the FAST screen, and that the CAT should be called when the criteria is met, and that the CAT responders will initiate the FAST team overhead page. The emergency department nurses will continue to directly page the FAST team. <p>5. Education of all pharmacist staff has been completed to encompass the following components:</p> <ul style="list-style-type: none"> • The revisions to the policy and procedure listed in (1. to 4.) above • The approved indications for Alteplase (t-PA) at the facility (acute ischemic stroke and pulmonary embolism) • Weight based dosing of t-PA for acute ischemic stroke and other indications. • Attendance at FAST team and changes to the policy and procedures to encompass double checking of dosage by a second pharmacist, delivery to the unit and checking with the nurse prior to administration. • Identification of the Acute Ischemic Stroke Thrombolysis 	<p>014 DEC 30 PM 12 20</p>

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	<p>and the results shared with the CAT team when they arrive.</p> <p>2. The CAT RN then performs another patient assessment and completes a NIH (National Institute of Health) stroke scale form showing the results of that assessment, and documents the time when the patient was last seen normal. If the patient was last seen within six hours, the following will be done:</p> <p>a. The CAT RN then overhead pages the FAST Team, calls the patient's attending physician and the on-call neurologist to notify them of a patient who may need t-PA administered. The FAST Team has a packet that contains the required forms (NIH stroke scale, Memorial Care t-PA Treatment in Acute Ischemic Stroke Inclusion/Exclusion Screening Tool), t-PA dosing guidelines, and t-PA order set (a computerized order set system used to calculate the correct dose of t-PA medication prior to dispensing the medication) to ensure the correct dosage of the t-PA is ordered for the patient.</p> <p>b. Regional Lab is alerted to expect blood specimens from a potential t-PA patient, which requires a 30 minute turnaround time.</p> <p>c. Radiology is alerted to expect a potential t-PA patient and to clear CT as soon as possible to give the FAST Team patient priority. Radiology informs radiologist that a priority FAST Team patient needs a CT interpretation as soon as possible.</p> <p>d. CAT RN then orders a non-contrast head CT and labs.</p> <p>e. FAST Team assists with CT transport, Critical Care Unit transfer, t-PA dosing (if ordered) and other urgent matters.</p>		<p>(OCM) [1675] order set that contains t-PA as a medication order.</p> <p>B. The title or position responsible for the correction:</p> <p>Vice President, Patient Care Services</p> <p>C. Plan for continued compliance and a description of the monitoring process to prevent recurrence of the deficiency:</p> <ol style="list-style-type: none"> 100% of FAST team calls will be reviewed by the Cardio-Pulmonary Advisory Team for compliance with the policies and procedures. Variations from the above are reported to the Performance Improvement and Patient Safety Committee, with reporting to the Medical Executive Committee and the Board of Directors. 100% of usage of Alteplase (t-PA) for stroke will be reviewed for compliance with the specified process components including the weight based dosage, double checking by pharmacist and nursing staff, and the ordering processes. This data will be reported to the Pharmacy, Therapeutic and Transfusion Committee and the Performance Improvement and Patient Safety Committee, with reporting to the Medical Executive Committee and the Board of Directors. 	

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	<p>f. CAT RN completes inclusion/exclusion criteria to determine if the patient qualifies for t-PA administration.</p> <p>3. On-call neurologist is notified of all diagnostic results</p> <p>4. T-PA is administered as ordered after patient is examined by a physician and a neurologist is consulted.</p> <p>* The hospital's P&P titled High Alert/Risk Medications (MD-175), revised as of 6/11, showed t-PA is identified as high alert/risk medication and is treated with extra precaution in order to avoid the inadvertent use of the medication and inappropriate prescribing, dosing, and administration.</p> <p>* The hospital's P&P titled Pharmacist Medication Order Review (MED-117), revised as of 4/11, showed all medication orders are reviewed by a pharmacist. The guidelines included all drug orders are evaluated by the pharmacist for appropriateness of drug, dose, frequency, route of administration, therapeutic duplications, incompatibilities, allergies/drug sensitivities (actual or potential), interactions (actual or potential) between the medication and other medications, food and laboratory values, disease state appropriateness, patient height/weight, and etc. All concerns, issues, or questions are clarified by the individual prescriber before dispensing the medication.</p> <p>On 5/23/13 at 1000 hours, review of Patient A's medical record with the Pharmacy Director of Performance Improvement and Patient Safety was initiated.</p>		<p>D. Date when the immediate correction of the deficiency will be accomplished.</p> <p>The actions above have been completed and implemented prior to September 30, 2012</p>	<p>2014 DEC 30 PM 12 20</p>

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	<p>Patient A was a [REDACTED] female admitted to the hospital on 8/25/12, for generalized weakness and shortness of breath. The patient was transferred to the telemetry floor for continued medical care. On 8/29/12, the patient developed garbled speech with right-sided weakness and was diagnosed with a new onset stroke.</p> <p>The Outcome Eval form dated 8/29/12 at 0030 hours, documented by RN 1 showed Patient A was hard to arouse and presented with garbled speech, inability to speak needs, and a loss of cognitive abilities. The patient's right upper arm was flaccid, and there was loss of right leg movement. The patient's primary care physician was notified and ordered a CT (computerized tomography uses x-rays to make detailed pictures of structures inside of the body) scan of the head. The CT findings were "suspicious for large left MCA (middle cerebral artery) territory acute infarct" (stroke). Documentation by RN 1 at 0205 hours, showed the patient was transferred to the critical care unit (provides intensive care medicine for patients with most severe and life-threatening illnesses and injuries).</p> <p>Further review of the medical record showed no documented evidence the RN had called and informed the CAT Team and FAST Team regarding the patient's new onset stroke to assess and evaluate the patient for timely treatment as per the hospital's P&P, including utilizing toolkits containing NIH stroke scale, Memorial Care t-PA Treatment in Acute Ischemic Stroke</p>			2014 DEC 30 PM 12 20

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	<p>Inclusion/Exclusion Screening Tool, t-PA dosing guidelines, and order set and to notify the on-call neurologist of the CT scan result.</p> <p>On 8/29/12 at 0245 hours, a physician's order was obtained to administer t-PA 90 mg (milligrams) intravenously STAT (immediately) to the patient. However, the administration instruction from this same physician's order showed to calculate the t-PA dosage based on 0.90 mg/kg intravenously over 60 minutes.</p> <p>Medical record showed Patient A weighed 48.4 kg, and as per the 8/29/12 physician's order for the t-PA dosage calculation of 0.90 mg/kg, the total dosage of t-PA for Patient A should have been 43.56 mg; however, the patient was administered 90 mg of t-PA, more than two times the required dosage.</p> <p>According to the t-PA manufacturer's guidelines, the recommended medication dosage of t-PA is 0.9 mg/kg (milligrams per kilogram) with 10% of the total dose given as an intravenous bolus over one minute, and the balance given over 60 minutes. The total dose of t-PA for treatment of an acute ischemic stroke should not exceed 90 mg.</p> <p>Also according to the t-PA manufacturer's guidelines, a study of another t-PA product in acute ischemic stroke suggested that doses greater than 0.9mg/kg may be associated with an increased incidence of intracranial hemorrhage (bleeding within the skull) and doses greater than 0.9mg/kg (maximum 90 mg) should not be used in the</p>			

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	<p>management of acute ischemic stroke. The adverse reaction of the t-PA included serious intracranial and gastrointestinal bleeding which could result in significant disability or death.</p> <p>Medical record review showed the pharmacist had reviewed and verified the t-PA medication order on 8/29/12 at 0255 hours and 0305 hours. However, the pharmacist failed to clarify with the physician regarding the physician's ordered dose of t-PA 90 mg while the physician's ordered instruction and the manufacturer's guidelines to calculate the t-PA dosage was 0.9ml/kg (which was 43.56 mg, not 90 mg, more than doubling of the required dosage). In addition, the pharmacist failed to clarify as to whether the 10% of the total dose should be administered as an initial intravenous bolus over one minute and the balance given over 60 minutes as per the t-PA manufacturer's guidelines during the medication order review to ensure the use of the medication was appropriate and safe for the patient.</p> <p>On 8/29/12 at 0308 hours, the medical record showed RN 2 had administered t-PA 90 mg intravenously to the patient as ordered, which was more than two times the appropriate t-PA dose for the patient's weight. There was no documented evidence 10% of total dose was administered as initial bolus dose and the balance given over 60 minutes as per the t-PA manufacturer's guidelines. In addition, there was no documented evidence the physician had examined the patient and the neurologist was consulted prior to the t-PA administration as per the hospital's P&P.</p>			2014 DEC 30 PM 12:20

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	<p>The Progress Notes dated 8/29/12 at 0605 hours, documented by RN 2 showed the patient was still aphasic (unable to talk), and the right extremities were flaccid with no signs of bleeding. The patient developed increased lethargy, and another CT scan of the head was done on 8/29/12 at 0845 hours. The CT scan result showed the patient had interval development of significant bleeding measuring 6.5 cm X 4.1 cm that required the patient to have a left-sided craniotomy (a surgical operation in which a bone flap is temporarily removed from the skull to access the brain) surgery. Patient A continued to have increased bleeding after the surgery, developed gastrointestinal bleeding, and became increasingly lethargic and comatose.</p> <p>The Discharge Summary report dated 9/6/12, documented by the physician showed the patient's neurological status had deteriorated and remained comatose after the craniotomy surgery. The patient was extubated (removal of the tube after intubation of the larynx or trachea) on 8/31/12, and expired on 9/1/12. The Discharge Summary report also showed documentation the patient had developed intracranial hemorrhage after receiving t-PA, and the cause of death was cerebrovascular accident (stroke) with intracranial hemorrhage.</p> <p>On 5/23/13 at 1000 hours, during an interview with the Pharmacy Director of Performance Improvement and Patient Safety, he confirmed the pharmacist reviewing the t-PA medication order did not comply with the hospital's Pharmacist Medication Order Review policy, High Alert/Risk Medication policy, and FAST Team Inpatient policy to question the</p>				2014 DEC 30 PM 12 20

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	<p>ordered t-PA dosing in relation to Patient 1's weight per physician's order and manufacturer's guidelines and did not use the hospital's computerized order set system to calculate the correct dose of t-PA medication prior to dispensing the medication.</p> <p>On 5/23/13 at 1300 hours, during an interview with RN 3, she stated the RN or physician must calculate the medication dose for the patient to receive. The drug order entry showed no documented evidence the medication dose was calculated based on the patient's weight. She further stated the hospital's computer system contained an order set (a grouping of orders, used to standardize and expedite the ordering process for a common clinical scenario) for t-PA that automatically calculated the correct dosage of medication when given for patients with strokes. However, there was no documented evidence the t-PA order set was utilized.</p> <p>The hospital's failure to ensure their P&Ps were followed resulting in Patient A'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 Section 1280.1(c).</p> <p>This facility failed to prevent the deficiency(ies) as described above that 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 Section 1280.1(c).</p>				

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