CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050167	A. BUILDING _____ B. WING _____	04/15/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
San Joaquin General Hospital	500 W Hospital Rd, French Camp, CA 95231-9693 SAN JOAQUIN COUNTY

OKee 6/19/15

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00181306 - Substantiated Representing the Department of Public Health: Surveyor ID # 28407, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.3: 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. Health and Safety Code 1279.1 (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. The CDPH verified that the facility reported the adverse event to the Department no later than five days after the adverse event has been detected.		T22 DIV CH1 ART3 70213 Nursing Services **Corrective Action Plan** **New Work Group:** A Handoff Communication Improvement Workgroup was immediately formed. The following changes were implemented in regard to critically ill patient transfers from the Emergency Department (ED) to the Intensive Care Unit (ICU). 1. The nurse caring for the patient in the ED will keep the medical record with him/her and personally transport the patient to the ICU. 2. The transferring nurse and the receiving nurse will review ED and ICU Orders line by line. 3. The transferring and accepting nurses will initial each order reviewed. If there are any questions the accepting nurse will confer with the transferring nurse and the physicians involved in the care of the patient in both the ED and ICU to get clarification. 4. In the event the ED nurse is unable to transfer the patient and the ICU nurse is, the handoff described above will occur in the ED. **Person Responsible:** Chief Nursing Officer **Date Completed:** April 2, 2009	

Event ID:PN3G11 6/2/2015 11:32:11AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Carla Bomben Deputy Director, Standards & Compliance 6-19-15

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s). 1 thru 10

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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	Health and Safety Code 1279.1 (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following: (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose. The hospital detected the adverse event on 3/8/09. The hospital reported the adverse event to the Department on 3/13/09. The hospital notified the patient's family on 3/8/09. 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. The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code 1280.3 (g) 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.		**Education:** The Nursing *Communication – "Hand Off"* Policy was reviewed in Nursing Leadership meetings. Expectations of proper patient handoffs to ensure safe transfers were communicated to Department Managers who were made responsible for educating their staff members. The Chief of Internal Medicine also provided education to the Internal Medicine Residents in regard to the importance of thorough and systemic handoffs between care providers despite perceived lack of time. **Persons Responsible:** Chief Nursing Officer and Chief of Internal Medicine **Date Completed:** April – July 2009 and periodically thereafter. **Auditing:** After a period of education, auditing began in July. Nursing Administration visually audited random instances of patient transfers from the ED to the ICU to ensure handoffs were done face to face with orders reviewed and questions addressed. Compliance was expected to be greater than 95%. If necessary, coaching was provided to improve the process. **Person Responsible:** Chief Nursing Officer **Date Completed:** September 2009 and periodically thereafter.	

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	T22 DIV5 CH1 ART3 70213 Nursing Services Policies and Procedures (a) Written Policies and Procedures for patient care shall be developed, maintained, and implemented by nursing service These requirements were not met as evidenced by: Based on staff interviews and review of medical records and policies and procedures, the hospital staff failed to ensure their policies and procedures (P&P) for communication between caregivers (Communications - Hand Off) and for safe medication administration (Thrombolytic, Guidelines for the Use of) were followed when: 1. Registered Nurse (RN) 2 was not given details of what medications Patient 1 had already received in the Emergency Department (by either RN 1 or RN 3) when RN 2 assumed care of Patient 1, 2. An Intensive Care Unit (ICU) physician ordered and an ICU registered nurse (RN 2) administered thrombolytic medications (medications used to break up dangerous clots inside blood vessels) to Patient 1 that was not in accordance with the hospital's policies for use of thrombolytic medications. As a result, Patient 1 was given duplicate anticoagulant medications (which prevent blood clotting) in error. These failures resulted in Patient 1 suffering intracranial hemorrhage (bleeding into the brain) and subsequent death on 3/08/09, less than 24 hours after admission to the hospital. Findings:		**Other Improvement Actions:** The hospital implemented 24/7 Inpatient Pharmacy Services in May of 2011.	

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	A review of Patient 1's medical record disclosed that she was admitted to the Emergency Department (ED) via ambulance on 3/7/09 at 11:35 p.m., complaining of chest pain. Patient 1, who was 78 years old, had a history of a stroke, high blood pressure, heart blood vessel disease, and dementia (a general term for a decline in mental ability). Both the ED physician and ED RN assessed Patient 1 as being alert and oriented to person, place, time, and situation. According to a document titled, Death Summary, dictated on 5/1/09 (electronically signed by the physician on 5/25/09), Patient 1 had an electrocardiogram (ECG- a test that checks for problems with the electrical activity of the heart) on 3/7/09 at 11:43 p.m. in the ED. The ECG showed she had experienced a heart attack (MI). The Summary also disclosed that, while the ED physician performed a rectal exam, Patient 1's heart began to beat with a potentially fatal, rapid, irregular rhythm (this rhythm inhibits the ability of the heart to circulate blood throughout the body and soon, the heart stops beating). Documentation by the ED physician and ED RN (RN 1) in Patient 1's Emergency Department records dated 3/8/09, disclosed that at 12:08 a.m., the ED staff began advanced life support to resuscitate her. At 12:14 a.m., Patient 1 was given tenecteplase (TNK) 40 milligrams (mg) intravenously (IV). TNK is a thrombolytic drug which dissolves blood clots. At 12:20 a.m., Patient 1 was given Lovenox (an anticoagulant, e.g. blood thinner)			

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30 mg IV. At 12:22 a.m., Patient 1 was given Lovenox 70 mg subcutaneously (SC - into the fat layer between the skin and muscle; more slowly absorbed than when given IV). RN 1 documented that she administered the TNK and both doses of Lovenox in the Critical Care (ICU) Flowsheet Progress Notes.

A hospital P&P titled, "Thrombolytic, Guidelines for the Use Of," effective 10/04, indicated that thrombolytic therapy was normally initiated using either TNK or tPA (Tissue Plasminogen Activator, a thrombolytic), in the ED or ICU for such conditions as an acute MI. The P&P included procedures for the administration of TNK, the drug of choice for an acute heart attack, which is initiated with a rapid IV infusion of the medication immediately followed by an anticoagulant, either Lovenox or Heparin (given per hospital Heparin Protocol).

Patient 1 was transferred from the ED and admitted to the hospital's Intensive Care Unit at 12:47 a.m. RN 1 documented at 1:03 a.m. on the ICU Progress Notes that she had "given report" to ICU RN 3. There were no details of the content of her report to RN 3. At 1 a.m., ICU RN 2 documented on the same ICU Progress Notes that she had received Patient 1. There was no documentation in the ICU Progress Notes that RN 2 had received a report of Patient 1's status, her current condition, nor what treatments and medications she had received.

A P&P titled, "Communications - Hand Off" (dated

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	effective on 7/2008), maintained that, "... for ... transfers ... accurate information must be shared ... to be effective [hand - off information should include] ... up-to-date information regarding patient's treatment and services, condition, and any recent or anticipated changes ... [and] interventions taken or need[ed] to be taken ..." An ICU Admission Assessment dated 3/8/09 at 1 a.m., indicated Patient 1's speech was clear; her social interaction, affect, and speech pattern were appropriate; she was alert and oriented to person, place, and time but with a short term memory deficit; and was independent in all her activities of daily living including dressing, grooming, bathing, and toileting. On 3/8/09 at 1 a.m., an ICU resident (MD 3) ordered the hospital's Heparin Protocol to be initiated. At 1:30 a.m., RN 2 documented that she had started a continuous IV infusion of Heparin after she had given an IV bolus (a high dose of medication to raise its concentration in the bloodstream to an effective level) of Heparin 2700 units. At 2 a.m., RN 2 gave Patient 1 Plavix (which prevents the formation of blood clots) 300 mg by mouth, ordered as a "Now" dose by MD 3. A review was done of the ICU MD 3's orders and progress notes and RN 2's medication administration records and progress notes dated 3/8/09. There was no indication in the records that MD 3 or RN 2 were aware of the TNK or Lovenox that had been administered to Patient 1 in the ED.			

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	Review of Patient 1's medication administration record showed that Patient 1 was given Plavix 75 mg and aspirin (another medication which prevents the formation of blood clots) 81 mg by mouth at 9 a.m. In a telephone interview on 4/2/14 at 8:30 a.m., RN 2 confirmed that she initiated the continuous infusion of Heparin for Patient 1 at 1:30 a.m. on 3/8/09 per MD 3's orders, as documented in the ICU Progress Notes. RN 2 stated that before she started the Heparin infusion, she had not reviewed what medications were documented as given by ED RN 1. RN 2 confirmed that the Lovenox given by RN 1 was clearly documented in the medication administration record and in the ICU Progress Notes. RN 2 stated that had she reviewed the pertinent records, she would have questioned MD 3's order for the heparin infusion because the order was not in accordance with the hospital's thrombolytic therapy protocol. The drug information reference, Lexicomp, indicated that Plavix is an antiplatelet that decreases platelet aggregation (clumping together) and inhibits clot formation. Aspirin has similar effects. Both medications increase the risk for bleeding. The Warning/Precautions for Heparin and Lovenox showed both have adverse effects such as increased risk of bleeding. The warning directed that patients should be monitored closely for signs or symptoms of bleeding especially if two or more anticoagulants are used at the same time. When used in patients older than 75 or with the addition of antiplatelet medications the risks are even greater.			

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A review of ICU Nursing Progress Notes showed in an entry on 3/8/09 at 8 a.m., that Patient 1 was observed to have a large bruise on her left breast and multiple bruises on her body. The Progress Note entry disclosed Patient 1 had bleeding from discontinued IV site (the location of the bleeding site was not documented) and was vomiting dark grey fluid with blood. The RN also noted at that time that the Heparin infusion was stopped. At 10 a.m., the RN documented that Patient 1 was "talking - (complained) of being hungry." At 10:30 a.m., the day shift ICU RN documented that Patient 1 had suddenly became limp, felt cold and clammy, and that MD 3 was at the bedside.

On 3/08/09 at 10:20 a.m., MD 3 ordered an immediate CT scan (computerized x-ray) of Patient 1's head to check for intracranial bleeding. Patient 1 was taken to radiology for the CT scan at 11 a.m. When she returned at 11:40 a.m., Patient 1 was unresponsive. Patient 1 had a breathing tube inserted into lungs and was placed on a ventilator (a breathing machine).

The CT scan analysis by a physician on 3/8/09 at 11:45 a.m., confirmed that Patient 1 had suffered extensive intracranial bleeding. After a discussion with Patient 1's family, MD 3 wrote an order for no resuscitation measures should her heart or lungs stop functioning. Patient 1 continued to deteriorate and expired on 3/8/09 at 4:50 p.m.

Patient 1's Death Certificate, dated 3/11/09, listed the immediate cause of death as intracranial

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	hemorrhage due to thrombolytic, anticoagulation therapy with underlying cerebrovascular disease. In an interview on 10/28/13 at 10:50 a.m., Administrative Staff (AS) 1 and AS 2 confirmed that Patient 1 was started on thrombolytic therapy in the ED per hospital protocol. The hospital's review of the case indicated that when Patient 1 was transferred to the ICU, MD 3 initiated the Heparin protocol in error which was not in accordance with the hospital's established protocol. Both AS 1 and AS 2 confirmed that the Heparin bolus and continuous infusion ordered by MD 3 and administered by RN 2, constituted a preventable medication error. AS 1 and AS 2 both stated that the thrombolytic medications ordered by MD 3 for Patient 1 were not reviewed by a pharmacist prior to administration. AS 1 and AS 2 stated that at that time the hospital did not have 24 hour pharmacy services available. In an interview on 10/28/13 at 12:30 p.m., the Chief of Staff (MD 1) stated that the hospital's protocol for treatment of an acute MI at the time Patient 1 was hospitalized was to give either Lovenox or heparin in conjunction with the thrombolytic agent but not both. The MD 1 confirmed that the Lovenox ordered and given in the ED and the heparin ordered and given in the ICU, was a preventable medication error that directly contributed to Patient 1's intracranial bleed and subsequent death. The hospital's failure to order and administer thrombolytic medications per their "Thrombolytic, Guidelines for the use Of" policy and procedure and			

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	follow the policy for communication between caregivers (Communications - Hand Off) resulted in Patient 1 receiving duplicate thrombolytic medication therapy, which was a deficient practice that caused, or was 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. 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).			