The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA00422666 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 1977, 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(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.

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Health and Safety Code section 1280.1 (d):
This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to one hundred thousand dollars ($100,000) per violation. With...
### Title 22, Section 70213: Plan of Correction:

1. The Medication Administration Policy and Procedure was reviewed and revised in December 2014. The revised policy and procedure was reviewed with the Cath Lab (CCL) Staff during the Staff Meeting on 1/6/15, and Huddles on 1/14/15 and 1/20/15. The importance of ensuring patient safety by following all the guidelines as established by the Medication Administration Policy and Procedure was emphasized with the staff. The noted highlights included:
   - a. to verify that the medication is correct upon removing from Pyxis;
   - b. to scan the correct medication vial upon removing from Pyxis;
   - c. to mix the correct medication for infusion;
   - d. to correctly label the medication bag;
   - e. to accept an IV medication bag, ensure it is the correct medication and labeled accordingly, prior to infusion.

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**California Code of Regulations, Title 22, Section 70213, Nursing Service Policies and Procedures**

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

**California Code of Regulations, Title 22, Section 70214, Nursing Staff Development**

(a): There shall be a written, organized in-service education program for all patient care personnel, including temporary staff as described in subsection 70217(m). The program shall include, but shall not
be limited to, orientation and the process of competency validation as described in subsection 70213(c).

(2) All patient care personnel, including temporary staff as described in subsection 70217(m), shall be subject to the process of competency validation for their assigned patient care unit or units. Prior to the completion of validation of the competency standards for a patient care unit, patient care assignments shall be subject to the following restrictions:

(A) Assignments shall include only those duties and responsibilities for which the competency has been validated.

California Code of Regulations, Title 22, Section 70217, Nursing Services Staff:

(a) Hospitals shall provide staffing by licensed nurses, within the scope of their licensure in accordance with the following nurse-to-patient ratios. Licensed nurse means a registered nurse, licensed vocational nurse and, in psychiatric units only a licensed psychiatric technician. Staffing for care not requiring a licensed nurse is not included within these ratios and shall be determined pursuant to the patient classification system.

No hospital shall assign a licensed nurse to a nursing unit or clinical area unless that hospital determines that the licensed nurse has demonstrated current competence in providing care in that area, and also has received orientation to

Title 22, Section 70213: Plan of Correction (Con’t):

2. A one to one discussion regarding the event occurred with the involved Registered Nurse (RN) staff. The Medication Administration Policy was reviewed with the involved RN staff in detail. The RN staff was educated regarding the importance of ensuring patient safety by following all the guidelines as established by the Medication Administration Policy and Procedure. In addition, a progressive disciplinary process was performed with the involved staff. The involved staff resigned with effective date of 12/15/14.

3. A quality monitoring process was developed based on the Medication Administration policy, MM 119, including observation of the licensed nurse during the process of medication preparation and administration. Deviations from the Medication Administration Policy are addressed immediately with the involved staff.

Responsible Person(s):
Director, Cardiac Cath Lab
that hospital's clinical area sufficient to provide competent care to patients in that area. The policies and procedures of the hospital shall contain the hospital's criteria for making this determination.

On January 7, 2015, at 10 a.m., an unannounced visit was conducted at the facility to investigate an entity reported incident regarding a patient who went into cardiac arrest during a routine cardiac procedure.

Patient 100 went into cardiac arrest during a routine right and left heart catheterization procedure when a Registered Nurse (RN 1) administered adrenaline (Epinephrine - a medication that causes the arteries to become smaller and increases the heart rate and blood pressure [BP]), instead of adenosine (a medication that opens the arteries), causing Patient 100 to become non-responsive and requiring a "code blue".

Based on interview and record review, the facility failed to ensure Registered Nurses (RNs) in the cardiac catheterization (cath) lab demonstrated competency in mixing critical intravenous (IV) medications for infusion during cardiac procedures. This failure was the direct cause of Patient 100 sustaining a cardiac arrest (heart stops beating), which required intubation (placed on a breathing machine), numerous life sustaining medications, and four days of critical care monitoring.

Findings:

<table>
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<tr>
<th>(X4) ID</th>
<th>PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID</th>
<th>PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>Title 22, Section 70213: Plan of Correction (Con't):</td>
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<td>Two (2) Cath Lab charts were audited per day for five (5) days per week for three (3) months (4/6/15 – 7/6/15) with results of 100% compliance, to ensure correct process of medication preparation and administration, including:</td>
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<td>• Receive medication order;</td>
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<td>• Select and withdraw medication from Rx dispenser (Pyxis);</td>
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<td>• Follow the scanning process;</td>
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<td>• Administer Medication.</td>
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<td>Results of all monitoring are aggregated, analyzed, reported to and reviewed at the Quality and Safety Committee, MEC and the Board of Trustees.</td>
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<td>Responsible Person(s):</td>
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<td>Director, Cardiac Cath Lab</td>
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<td>Charge Nurse, Cardiac Cath Lab</td>
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During the investigation of an entity reported incident on January 7, 2015, a review of the patient's clinical record the following was revealed:

Patient 100 was admitted to the facility on December 3, 2014, with diagnoses that included diabetes, hypertension (HTN), hyperlipidemia (high levels of fat in the blood), left bundle branch block (LBBB - cardiac rhythm abnormality), and worsening of previously diagnosed congestive heart failure (CHF).

The document entitled "The Heart Care Institute at ... (name of facility)" indicated Patient 100 was taken to the cardiac cath lab on December 5, 2014, at 8:45 a.m., for a right and left heart catheterization (using catheters and contrast to measure pressures in the heart, view the coronary arteries and assess for blockages, and determine the pumping effectiveness of the ventricle).

The document indicated "9:29 a.m. MD present and aware of medication error. 9:36 a.m. Patient is intubated and non-responsive."

The document entitled "Code Blue (a medical emergency when a patient's heart stops beating or when the lungs stop functioning) Report", dictated December 5, 2014, at 12:08 p.m., indicated "In the cath lab, getting a routine right and left heart catheterization. While attempting to do a FFR procedure (a test to determine how significant a blockage was) ... instead of adenosine (a medication that causes vasodilation where arteries open up bigger), the patient received adrenaline (Epinephrine.

**Title 22, Section 70214: Plan of Correction:**

1. The current RCH Cath Lab Intravenous (IV) Admixture Competency in HealthStream was reviewed with the Education Dept. and was assigned to all Cath Lab licensed RN staff. The assigned program includes a post-test section to assess competency. As of 4/6/15, 100% of licensed CCL RN staff completed the assigned program to demonstrate competency. IV Admixture Competency has been added to the Cath Lab RN annual competencies (100% completed for 2016, and October is expected completion date for 2017). Competency assessment will be an ongoing process of maintenance of knowledge and skills, educational consultation, remediation, and redevelopment. Competency assessment will include competency skills days, Performance Based Development System and online programs (HealthStream).
A medication that causes a sudden onset of vasoconstriction [arteries become smaller] with an increase in heart rate and blood pressure (BP).

After 50 seconds of infusion the patient started complaining of chest pain. The infusion was stopped immediately. Chest pain was severe. His pressure (blood pressure) went up to approximately 300 systolic (the pressure in the arteries when the heart beats, normal is less than 120) Then he started having shortness of breath. He started coughing up blood. The blood was copious (large amount). Procedure was stopped immediately.

During an interview with the Cath Lab Director (CLD) on January 7, 2015, at 10:20 a.m., and on February 26, 2015, at 12:40 p.m., the director stated Patient 100 had a heart cath done in mid-December. The director stated a blockage was identified, and the cardiologist wanted to perform an FFR to determine the severity of the blockage and the possible need for intervention to open the vessel. The director stated the physician ordered RN 1 to proceed with preparation of angiomax (brand name for Bivalindin-to prevent blood from clotting) and adenosine infusions.

According to the director, after the infusion was started, RN 1 went to scan the medication and label the bag, and realized she had mixed an adrenaline infusion instead of an adenosine infusion. The infusion was stopped, and the patient condition began to deteriorate, requiring intubation (placement a tube into the airway to assist with breathing), Cardiopulmonary Resuscitation (CPR), and a

Title 22, Section 70214: Plan of Correction (Con’t):

2. A one to one discussion regarding the event occurred with the involved Registered Nurse (RN) staff. The requirements of the RCH Cath Lab Intravenous (IV) Admixture Competency was reviewed with the involved RN staff in detail. The RN staff was educated regarding the importance of ensuring patient safety by following all the guidelines as established by the IV Admixture Competency. In addition, a progressive disciplinary process was performed with the involved Nursing staff. The involved staff resigned with effective date of 12/15/14.

3. New hires to the Cath Lab will be required to complete IV Admixture Competency prior to receiving a patient care assignment in the Cath Lab. State dates of new hires & dates/% of completion for new hires.

Responsible Person(s);
Director, Cardiac Cath Lab

Monitoring:

100% of all licensed Cath Lab procedural RN staff completed the RCH Cath Lab Intravenous Admixture Competency. Audit all 90-day evaluations on Cath Lab RN new hires to ensure completion of the IV Admixture Competency.
transfer to the Intensive Care Unit (ICU).

The director stated the facility investigation revealed RN 1 removed adrenaline from the automated drug dispensing cabinet (Pyxis) instead of adenosine, assumed it was the correct medication, and did not check the vial. The director stated RN 1 did not scan the medication until after she mixed the infusion, and did not label the bag until after the infusion was started.

The manufacturer's insert for the medication adrenaline (epinephrine) indicates contraindications (should not be used when certain conditions exist due to the harm it would cause the patient) for use this medication include high blood pressure and irregular heartbeat, which were conditions present in Patient A's diagnosis.

The facility policy titled, "Medication Administration," was reviewed on January 7 and February 26, 2015. The policy indicated, under the section Policy Statement, section D, "When a medication is administered, the patient's identity will be verified by two of the four indicators. The patient's armband will be scanned as one indicator and used with one of the remaining indicators: (name, date of birth or medical record number) to complete identity verification."

Under the section titled Competency Expectations, "(1) All staff administering or dispensing medication at Riverside Community Hospital will have their competence validated prior to dispensing or administering medications and periodically

**Title 22, Section 70214: Plan of Correction (Con't):**

**Monitoring (Con't):**

Results of all monitoring are aggregated, analyzed, reported to and reviewed at the Quality and Safety Committee, MEC and the Board of Trustees.

Responsible Person(s):
Director, Cardiac Cath Lab
Charge Nurse, Cardiac Cath Lab

**Title 22, Section 70217: Plan of Correction:**

1. A one to one discussion regarding the event occurred with the involved Registered Nurse (RN) staff. The Medication Administration Policy was reviewed with the involved RN staff in detail. The RN staff was educated regarding the importance of ensuring patient safety by following all the guidelines as established by the Medication Administration Policy and Procedure. In addition, a progressive disciplinary process was performed with the involved staff. The involved staff resigned with effective date of 12/15/14.
thereafter. (2) Initial competency validation includes all of the following elements... (a) Application of the 7 (seven) rights of patient medication administration, (c) Demonstration/verbalization of clinical knowledge of Department and/or Unit specific medications, (g) Demonstration/verbalization of the ability to follow [sic] all steps in this medication administration policy and procedure., (h) Demonstration of the ability to use eMAR to document and scan medications correctly."

Then, section 7. Electronic Medication Administration Record (eMAR), indicates "(c) All documentation should be done through the "Scan Medication" route. 1. Scan the patient's armband. Verify patient's second identifier. 2. Scan barcodes of all medications administered at this time. Complete any screen presented... 3. Click the "Submit" button. 4 Save documentation by clicking "Save and Recompile" button or "Save and Exit" button." A review of cath lab education records that indicated nurses who had demonstrated competency in mixing/preparing IV infusions was reviewed. The list did not include RN 1. There was no evidence the facility verified RN 1 was competent to mix/prepare IV infusions. There was no evidence other cath lab nurses had demonstrated competence in mixing/preparing IV infusions for the past three years.

On February 26, 2015, RN 1’s personnel file was reviewed and it indicated RN 1 did not meet the required competencies for eight competencies, and

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e. to accept an IV medication bag, ensure it is the correct medication and labeled accordingly, prior to infusion.
that she did not have the medication administration competency. In the cardiac cath lab this is a required competency because all medications are mixed pursuant to the "Aseptic Practical for IV Admixture Competency Staff."

During an interview with the CLD on February 26, 2015, at 12:40 p.m., the director stated the department had not done competency verification for nurses preparing IV infusions since he started working there (for two years). The director stated RN 1 had been disciplined in July [of 2014] for a medication error, and there was no remediation or monitoring done after the discipline.

This failure 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 1280.3(g).

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 1280.3(g).

Title 22, Section 70217: Plan of Correction (Con’t):

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**Title 22, Section 70217: Plan of Correction (Con’t):**

5. A quality monitoring process was developed based on the Medication Administration policy, MM 119, including observation of the licensed nurse during the process of medication preparation and administration. Deviations from the Medication Administration Policy are addressed immediately with the involved staff.

   Responsible Person(s);
   Director, Cardiac Cath Lab

**Monitoring:**

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Numerator: # correct med prep/admin
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Title 22, Section 70217: Plan of Correction (Con't):

Monitoring (Con't):

2. 100% of all licensed Cath Lab procedural RN staff completed the RCH Cath Lab Intravenous Admixture Competency. Audit all 90-day evaluations on Cath Lab RN new hires to ensure completion of the IV Admixture Competency.

Results of all monitoring are aggregated, analyzed, reported to and reviewed at the Quality and Safety Committee, MEC and the Board of Trustees.

Responsible Person(s):
Director, Cardiac Cath Lab
Charge Nurse, Cardiac Cath Lab

| Event ID: G1XF11 | 7/11/2017 8:23:44AM |  |  |