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

Complaint Intake Number: CA00340450 - Substantiated

Representing the Department of Public Health:
Surveyor ID #28851, Pharmacy Consultant

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 1280.1(c): For Purposes of this section "immediate jeopardy" mean 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.

**TITLe 22 DIVS CHI ART-70263 (C)(1)**

(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 implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

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<th>INITIAL COMMENTS</th>
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<tr>
<td>Preparation and execution of this plan of correction does not constitute admission or agreement of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared and executed solely because it is required by state law.</td>
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**Actions Taken**

1. Hospital Leadership discussed the survey findings. The "Checking High Alert Medication" and "Anticoagulant Therapy and Improving the Safe Use of Medications" Policies were reviewed and revised to clarify the process for nurses in reviewing heparin orders and dosing. Intravenous heparin orders and doses are verified by two Registered Nurses (RN), with the nurses initialing their verification in the medical
Based on review of a facility incident report, patient clinical records and interview with staff, the facility failed to protect Patient 1 from an adverse medication consequence. The facility failed to consistently implement and establish policies and procedures for the safe and effective use of an anticoagulant, heparin (a blood thinner for treatment and/or prevention of blood clots in the veins, arteries, or lungs). The facility failed to ensure the correct dose and infusion rate of the heparin drip were ordered, prepared, and administered for Patient 1.

On 92013, at 4:40 p.m., the prescribing physician ordered "Heparin IV protocol for DVT [deep vein thrombosis, blood clots in the veins]" to be started at "800 units/hr [units per hour]". Based on the facility’s anticoagulation protocol, dated 10/2012, 800 units/hr translates to an infusion rate of 8 mL/hr (milliliter per hour). However, at 5:20 p.m. and at 11 p.m., the pharmacist failed to transcribe the order correctly and ordered the heparin drip dosing to be started at "8 mL/hr", which was ten times over the correct infusion rate. The nursing staff failed to "double check" the correct infusion rate prior to administering this "High Alert" medication. The facility staff failed to obtain and report the critically high lab value, due to the excessive dose of heparin, prior to Patient 1’s scheduled surgery. The patient received two heparin drips on 92013 at 12:30 a.m. and 5:20 a.m. Subsequently, the patient experienced bleeding from orifices around the surgical site, decreased blood pressure, and event.

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respiratory distress that eventually required resuscitation and mechanical ventilation support. The patient also received Protamine to reverse the anticoagulant effects of heparin.

Findings:

On 2/6/2013, a review of the clinical records revealed Patient 1 was admitted on 2/2013 with a chief complaint of gangrenous right foot. A review of the physician order dated 2/2013, at 4:40 p.m., indicated the prescribing physician ordered "Heparin IV protocol for DVT to be started at 800 units/hr..." A review of Patient 1’s pharmacy protocol order for heparin drip, dated 2/2013, at 5:20 p.m., indicated "start heparin drip at 800 units/hr (= 80 ml/hr)..." Another pharmacy protocol order dated 2/2013, at 11 p.m., also indicated "start heparin drip at 800 units/hr (at 80 ml/hr)...

According to the facility’s anticoagulation protocol policy, dated 10/2012, the infusion rate for the concentration of 800 units/hr should be at 8 ml/hr (milliliter per hour).

During an interview on 2/6/2013, at 2:30 p.m., Pharm 1 indicated the first clinical pharmacist misinterpreted the concentration of the heparin IV (intravenous) bag, hence, the miscalculation of the infusion rate. Pharm 1 further stated the same order was later re-written again incorrectly by another clinical pharmacist. Pharm 1 also

3. The Chief Nursing Officer discussed the survey findings with the identified nurses, with special emphasis on the verification of heparin process and reviewing and reporting applicable lab results.

4. Nursing and Pharmacy Leadership reviewed all IV heparin orders/dosing at the time of the survey and no issues were identified.

5. The MEC sent a memo to all physicians regarding the revised policies, the heparin pre-set order form and compliance with pre-op assessments.

6. The Pre-Operative Checklist was revised for additional space to document issues with lab results (e.g., lab, result, date of results). Applicable staff were inserviced on the revised form.

7. The Corporate VP of Pharmacy reviewed and revised the "Anticoagulant Therapy and Improving the Safe Use of Medications" Policy to clarify the process for IV heparin orders, including the pre-printed heparin order sheet. The F & T Committee, Quality Council, MEC and Governing Board approved the policy revision. Pharmacists were reinserviced, with special
confirmed that Patient 1 received a total of two bags of heparin drips (250ml each).

A review of Patient 1's medication administration record (MAR), dated 2/6/2013, indicated one nurse's initial signifying the administration of heparin drip at 12:30 a.m. and at 5:20 a.m.

During an interview, at 3 p.m., Pharm I stated heparin drip had always been considered a high alert medication and, as such, would require two nurses to double check before administering the medication.

During a concurrent interview, the chief nursing officer stated one nurse administered heparin and did not ask another nurse to check or witness the administration of the heparin drip.

A review of the facility's policy and procedure, titled "HIGH ALERT MEDICATION SAFETY," dated 10/2012, indicated heparin as one of the high alert medications. The procedure also indicated "High alert medications require documentation of the double-checking process. Two nurses double checking a High Alert Medication must provide their initials on the Medication Administration Record...."

According to Patient 1's clinical records, an abnormal reading of PTT (partial thromboplastin time, a blood test to look at how long it takes for blood to clot) of 192.4 was deemed "Critical High" (normal reference range between 21.0 – 32.0). The lab result was reported on...

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### Statement of Deficiencies and Plan of Correction

**ID: 4KHV11**

**Event ID:** 4KHV11  8/7/2013  8:31:56 AM

**Summary Statement of Deficiencies**

- **Event ID: 4KHV11**
- **Completion Date:** 8/7/2013
- **Compliance and Monitoring:**
  - The Chief Nursing Officer or qualified designee shall perform a 100% review of all IV heparin drips (for six months and then re-evaluate) to achieve the goal of 100% compliance with IV heparin administration. Corrective action is taken as necessary, including immediate correction of dosing if applicable and 1:1 reeducation of nursing staff. The Corporate VP of Pharmacy or qualified designee completes a 100% review of all IV heparin dosing orders to achieve the goal of 100% compliance with heparin IV dosing. Corrective action is taken as necessary, including 1:1 reeducation of pharmacy staff. The Director of Laboratory Services or qualified designee reviews all reporting of critical lab values daily to achieve the goal of 100% compliance with reporting of critical lab values. Corrective action is taken.

**Provider's Plan of Correction**

- **Correction Action:**
  - Education on reporting critical lab values is provided to lab personnel on hire and annually.
  - Education on high-alert medication dosing, including the heparin pre-printed order set, is provided to pharmacists upon hire and annually.
  - Monitoring of high-alert medication administration and reporting of critical lab values is part of QAPI.
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- **Persons Responsible**
  - Chief Nursing Officer
  - Nurse Manager, Surgical Services
  - Corporate VP of Pharmacy
  - Director of Laboratory Services

As necessary, including 1:1 reeducation of staff. Data on compliance is tracked, trended, analyzed, and reported monthly at the Quality Council and MEC. Compliance is reported quarterly to the Governing Board, and is used for performance improvement measures.