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

Complaint Intake Number: CA00432057 - Substantiated

Representing the Department of Public Health: Surveyor ID # 2694, 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.

Informed Adverse Event Notification

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 1279.1(b)

(b) For purposes of this section, "adverse event" includes any of the following:

- "event" includes any of the following:
Health and Safety Code 1279.1(b)(4)(A) Medication error

(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.

T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements

(g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnished. Orders for drugs should be written or transmitted by the prescriber or furnished.

Corrective Actions:
1. The electronic health record (eHR) order set for Heparin - Neurovascular has been revised to include an alert that the desired Xa level range is 0.3-0.5. If the Xa level is out of this range, the nurse will adjust the heparin rate and frequency of lab draws accordingly. 4/2015

2. A best practice alert (BPA) was created within the eHR to alert the clinical team as to which heparin order set is ordered (Neurovascular vs Cardiac vs VTE). 3/17/2015

3. The patient's Xa level is now included in nurse to nurse handoffs and in the daily clinical team rounds. 2/18/2015

4. The CPMC Procedure "Heparin titration Using Anti-Factor Xa Laboratory Test" was revised to require laboratory testing of Factor Xa level every 12 hours once the level is within target range. The previous policy required the lab testing be done every 24 hours once the Factor Xa level was within therapeutic range. 3/2015
Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnish shall countersign the order within 48 hours.

This RULE: is not met as evidenced by:

Based on interview, and record review, the Hospital failed to administer medication as prescribed when Patient 1 was ordered to be on a heparin infusion (heparin drip- to receive a medication that prevents the clotting of the blood through a vein) with instructions to keep the anti-factor Xa (a clinical test to measure heparin levels in the blood and monitor anticoagulant therapy) levels between 0.3-0.5 units/ ml (milliliters). Patient 1 continued to receive heparin without an adjustment in the infusion rate, as indicated in the Hospital's policy and procedure, when the anti-factor Xa was 0.58 units/ml. This failure led to Patient 1 receiving an amount of heparin higher than ordered, and could have potentially caused Patient 1 to have bloody drainage from his nose, blood in the urine, and contributed to Patient 1's death.

Findings:

Record review of a letter from the Hospital to the
California Department of Public Health, dated 2/18/15, indicated "...Report of Unusual Occurrence... (Patient 1) was started on heparin infusion (heparin drip - to receive a medication that prevents the clotting of the blood through a vein). On the 7th day of his ICU (Intensive Care Unit - designated area of a hospital that is dedicated to the care of patients who are seriously ill) stay (February 10, 2015) (Patient 1) was noted to have worsening neurological status and blood tinged urine. On February 11, 2015, he (Patient 1) was noted to have dark red urine and continued decline of his neurological status. On February 12, the heparin infusion was stopped, and (Patient 1) underwent a CT scan (x-ray images taken from different angles to create images of bones, blood vessels, and soft tissue in the body) of the head which showed previously identified petechial hemorrhage (bleeding in minute spots with the appearance of pinpoint flat round spots) as evolved into a large intraparenchymal hematoma (damage to a blood vessel causing bleeding in brain tissue). Unfortunately, on February 13, 2015 (Patient 1) met criteria for brain death... We are reporting this unusual occurrence because the heparin infusion may have been a contributing factor to the patient's death..."

Patient 1 was admitted to the Hospital on 1/22/15 with history of recent left Middle Cerebral Artery stroke (sudden onset of neurologic decline resulting from brain infarction (obstruction of blood supply to the brain causing death of tissue) or ischemia (inadequate blood supply to an organ)) on 1/19/15.

Responsible Persons:

Director of Nursing, Davies Campus
Nurse Manager, Intensive Care Unit, Davies Campus
RN Stroke Coordinators
Medical Director, Stroke Program
In an interview on 4/1/15 at 11:50 AM, the Director of Risk Management (DRM) was asked to provide a timeline of what happened. The DRM stated (Patient 1) was transferred back to ICU, and had heparin started on 2/4/15 (actual date 2/5/15). A petechial hemorrhage was identified on 2/4/15, and "neuro" (neurology - the medical specialty concerned with the diagnosis and treatment of disorders of the nervous system, which includes the brain, the spinal cord, and the nerves) recommended to proceed with heparin. The DRM stated the NOC RN (registered nurse who works the nighttime shift, typically 11:00 PM to 7:30 AM) on 2/11/15, noted bloody urine, Patient 1's neuro status (neurological status-assessment of overall condition of nervous system function) was getting worse, and the lab result for anti-factor Xa was 0.58. The DRM stated the nurse practitioner and physician thought the heparin was turned down after the reading of anti-factor Xa was 0.58, but it was not, and that nurses can turn down the heparin drip based on the Hospital's protocol/algorithm. The DRM stated the nurse thought Patient 1 was on the microvascular heparin protocol where the anti-factor Xa range would be 0.3 to 0.7 Units/ml, not the neurovascular heparin protocol where the range is 0.3 to 0.5 Units/ml. The DRM stated the nurse practitioner didn't recheck the level and dosage. She stated the intensivist (a medical doctor with special training and experience in treating critically ill patients) did not believe Patient 1's death was related to the heparin, while the neurologist (a physician who specializes in treating diseases of the nervous system, including the brain and spinal cord) did believe Patient 1's death was related to the heparin. The DRM stated on 2/12/15,
Patient 1's condition worsened, his anti-factor Xa level was 0.75, he had a CT scan, and the bleed in his brain was seen. She stated on 2/13/15, Patient 1 met the criteria for brain death.

Record review of the Hospital's medication order for Patient 1, order date 2/5/15 at 1:06 AM, indicated "Heparin 25,000 units in D5W (5% dextrose in water- a fluid compatible with the body used in intravenous medication administration) 250 ml IV Drip...Start 2/5/15...Frequency: Titrate for See Admin (Administration) Instructions @ 12 ml/hr...Admin Instructions: Start at 15 Units/kg (kilogram)/ hr (hour)...Titrate (adjust to determine the concentration) between 0-2,500 Units/ hr per instructions below;...AntifactorXa 0.3-0.5 Units/ml: No change (in rate); AntifactorXa 0.51-0.59 Units/ml: Decrease by 140 units/hr; AntifactorXa 0.6-0.69 Units/ml: Decrease by 200 Units/hr; AntifactorXa 0.7 Units/ml or greater: HOLD infusion for 60 min (minutes) then restart at 200 Units/hr LESS than previous infusion..."

Record review of the Hospital's CarePlan Notes for Patient 1, dated 2/10/15 at 4:53 AM, Registered Nurse 1 (RN 1) documented "...Urine blood tinged and (Nurse Practitioner 1- NP 1) aware of it...Heparin gtt (drip) still running at 1740 units/hr..."

Record review of the Hospital's CarePlan Notes for Patient 1, dated 2/11/15 at 6:47 AM, Registered Nurse 1 (RN 1) documented "...Urine dark red, NP 1 notified. Urine specimen sent to the lab..."
2/11/15 at 5:53 AM (time posted in electronic health record), indicated "Results History...Heparin, Unfraction Xa...Component: Anti-Factor Xa Assay...Value: 0.58...Ref (Reference) Range: 0.3-0.7...Units: u(units)/ml..."

In an interview on 7/6/15 at 10:05 AM, RN 1 stated Patient 1 had blood tinged urine when she got on shift on 2/10/15, that she told NP 1 about it, and was instructed to just observe. On 2/11/15, RN 1 stated she told NP 1 Patient 1's urine was redder than earlier. A UA (urinalysis) was sent to make sure there wasn't an infection. When asked if she had seen the anti-factor Xa level posted on 2/11/15 at 5:53 AM, RN 1 stated "...did not see the lab at 0.58...sometimes did not get the result till late...didn't do any changes (rate of the heparin drip), because (I) didn't have the results..." When it was confirmed that the lab was posted at 5:53 AM, and her note was timed at 6:47 AM, RN 1 stated she may have checked the labs before the 0.58 lab value was posted. She did not remember seeing that result. When asked what she would have done if she saw the 0.58 lab value, RN 1 stated she would have made changes to the rate of heparin drip and refer to the Hospital's neurovascular protocol. RN 1 explained the protocol tells the nurse how much to change (the rate of heparin drip).

In an interview on 6/25/15 at 12:00 PM, NP 1 was asked what his interventions were when blood tinged urine was reported to him on 2/10/15, and dark red urine was reported on 2/11/15. NP 1 stated he had a urinalysis (analysis of the urine to test for abnormalities, including disease) sent for the blood...
tinged urine on 2/10/15, and dark red urine on 2/11/15. NP 1 was asked if he had seen the anti-factor Xa for 2/11/15 at 5:53 AM. It was clarified that the specimen was collected at 4:40 AM, the lab received the specimen at 5:16 AM, and the results were posted to the electronic health record at 5:53 AM. NP 1 stated, "...I did not get notified. I did not see the lab level. I did not get called..."

In an interview on 8/4/15 at 10:22 AM, Risk Management 1 (RM 1) stated there was no evidence that a urinalysis was ordered or sent on 2/10/15.

Record review of the Hospital's Urinalysis Results, dated 2/11/15 at 7:47 AM (time posted in electronic health record), indicated: "...Component: Urine Red Blood Cells (blood in urine)...Value: 500 (H) (high)...Ref Range & Units: 0-5/ (hpf) (high powered field- when the amount of red blood cells in the urine is determined microscopically)..."

Record review of the Hospital's Progress Notes for Patient 1, dated 2/11/15 at 7:57 AM, Physician 1 completed an Attending Physician Attestation (to certify or affirm to be true) indicating key portions of the history and physical examination, and laboratory results were reviewed with a second physician. The Events/Chief Complaint portion of the Progress Notes indicated: "...HEParin...Last Rate: 1,740 Units/hr (2/11/15 0700 (7:00 AM)...Recent Labs...2/11/15 0440 (4:40 AM)...FACTORXACT (antifactor Xa level)...0.58...Impression/Plan/Recommendations...Neurological:...heparin gtt, neurovascular protocol Xa level 0.3 to 0.5..."
In an interview on 8/26/15 at 1:17 PM, Physician 1 confirmed her specialty was neurology. Physician 1 stated the heparin rate was pre-populated by a template, the computer filled it in, and she doesn't routinely enter the flow. Physician 1 stated she did see the anti-factor Xa level at 0.58 when it was reviewed on rounds (a interdisciplinary team discussion that includes patients' status, assessments, and plan of care), and that the level greater than 0.5 was not red flagged. She stated it was normal for the level to not be perfect, there was a protocol for the rate of heparin to be adjusted by the nurse, and confirmed that nurses do attend rounds. When asked what should have happened if the anti-factor Xa was out of range, Physician 1 stated, "It should have been brought back into range." She did not recall seeing the urinalysis with the urine red blood cell count at 500 hpf, and stated "...don't normally look at it..." When asked what symptoms of supratherapeutic heparin (heparin administered at levels greater that would be used in the actual treatment) would look like, Physician 1 stated "...result in bleeding anywhere in the body..."

Record review of the Hospital's Progress Notes by Nurse Practitioner 2 (NP 2) for Patient 1, dated 2/11/15 at 8:50 AM, indicated "...Labs Reviewed...Recent Labs/2/11/15 0440... FACTORXACT...0.58... Impression/Plan/Recommendations...Neurological:...continue heparin gtt, neurovascular protocol Xa level 0.3 to 0.5..."

In an interview on 8/4/15 at 2:30 PM, NP 2 was asked if he had seen the anti-factor Xa level of 0.58.
NP 2 stated it might have been missed during rounds, and that he could not remember. When asked if he had seen the urinalysis value of 500 hpf, NP 2 stated NPs do get notification for abnormal results, but he could not remember if anyone saw it. He could not recall seeing it before. When asked what should have happened with an anti-factor Xa level of 0.58 with someone on the neurovascular protocol for heparin, NP 2 stated "...when (the) nurse gets value at 4:40 in AM, there should have been adjustments to the drip...rechecked the antifactor Xa...nurses prompted to notify NP at the time...should have been brought up at rounds..." When asked what would have resulted from the anti-factor Xa level being out of range, NP 2 stated a supratherapeutic level of heparin could cause bleeding in the urine or IV site.

Record review of the Hospital's Progress Notes by Physician 2 for Patient 1, dated 2/11/15 at 11:08 AM, indicated "...Infusions:...HEParin...Last Rate: 1,740 Units/hr (2/11/15 1000 (10:00 AM)...Recent Labs...2/11/15 0440 (4:40 AM)...FACTORXACT (antifactor Xa level)...0.58...Other Diagnostics: 24-hour events reviewed with nursing staff...Chart, labs, and imaging studies reviewed. Case discussed with (Physician 1) and the entire neurocritical care team...

In an interview on 8/26/15 at 2:00 PM, Physician 2 stated Patient 1 had an ischemic stroke on 1/19, and a second stroke on 2/4/15 with petechial symptoms. He couldn't remember why Patient 1 was heparinized, but in his opinion, heparin was used for everything. Physician 2 stated the
anti-factor Xa did drift up a little bit, but he could not say if Patient 1's death was related to high heparin or bleeding from a new stroke. Physician 2 stated Patient 1 was at risk for bleeding with the heparin drip. When asked if he was aware of Patient 1's hematuria (blood in urine) and epistaxis (bloody nose), Physician 2 stated, "...I don't know...nothing done...no interventions...would I lower or stop heparin?...yeah, maybe..." When asked if he saw the anti-factor Xa level of 0.58, Physician 2 stated, "...saw it...didn't react to it." He stated the Hospital had an automatic protocol, and the nurses titrate up and down. Physician 2 stated the nurses check the value and adjust, and "...tended to go on autopilot...assumed (heparin was) being titrated properly..."

Record review of the Hospital's Medication Administration Record (MAR) for Patient 1, order start time 2/5/15 and order end time 2/12/15, indicated "Heparin 25,000 units in D5W(5% dextrose in water- a fluid compatible with the body used in intravenous medication administration) 250 ml IV Drip...Start 2/5/15...Frequency: Titrate for See Admin (Administration) Instructions @ 12 ml/hr...Admin Instructions: Start at 15 Units/kg (kilogram)/ hr (hour)...Titrate (adjust to determine the concentration) between 0-2,500 Units/hr per instructions below:...Antifactor Xa 0.3-0.5 Units/ml: No change (in rate); Antifactor Xa 0.51-0.59 Units/ml: Decrease by 140 units/hr; Antifactor Xa 0.6-0.69 Units/ml: Decrease by 200 Units/hr; Antifactor Xa 0.7 Units/ml or greater: HOLD infusion for 60 min (minutes) then restart at 200 Units/hr LESS than previous infusion..."
In an interview on 8/4/15 at 9:40 AM, Risk Management 2 (RM 2) stated it was more important to keep the anti-factor Xa in goal, than the actual rate of units being given.

In an interview on 8/4/15 at 9:48 AM, the DRM stated nurses's can view the physician's orders, including the neurovascular protocol.

In an interview on 8/4/15 at 11:15 AM, RM 2 confirmed nurses could see the neurovascular protocol on the MAR.

In a concurrent interview, and record review on 8/19/15 at 1:05 PM, RN 2 stated she did see the lab value at 0.58 for the anti-factor Xa. RN 2 stated, "...Looking at the reference range of 0.3 to 0.7 that comes up when the labs were posted, to me, it was in range..." When asked if she saw the urinalysis (UA) result of 500 hpf for red blood cells in the urine, RN 2 stated she did not remember looking at the UA, and that usually nurses don't look at the urinalysis. When asked if she remembered seeing the neurovascular protocol with the anti-factor Xa range as 0.3 to 0.5 on the MAR for Patient 1, RN 2 stated she did not remember seeing the value on the MAR, and "...just went by the lab reference range..." When asked what should have happened if it had been noticed that the anti-factor Xa level was out of range, RN 2 stated the NP or doctor should have been notified, and the drip should have been adjusted. When asked what kind of assessments she performed, RN 2 stated she assessed Patient 1's oral cavity and urine, because
### Summary Statement of Deficiencies

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction</th>
<th>Complete Date</th>
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<tbody>
<tr>
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<td>(Each corrective action should be cross-referenced to the appropriate deficiency)</td>
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#### Provider/Supplier/Clinic Information

**Name of Provider or Supplier**: California Pacific Medical Center – Davies Campus Hospital

**Street Address, City, State, Zip Code**: 601 Duboce Ave, San Francisco, CA 94117-3389, SAN FRANCISCO COUNTY

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**Event ID**: SCS11

**4/19/2017 2:46:23PM**
Record review of the Hospital's Progress Notes by NP 1 for Patient 1, dated 2/11/15 at 9:27 PM, indicated "...Events/Chief Complaint...slight nasal oozing of blood out of right nare (right nostril)...0615am change in neuro exam: emesis (vomiting)...blown right pupil (when the pupil doesn't react to light)...stat CT obtained...Impression/Plan/Recommendations...Neurological:...continue heparin gtt, neurovascular protocol Xa level 0.3 to 0.5..."

Record review of the Hospital's CarePlan Notes for Patient 1, dated 2/12/15 at 3:10 AM, Registered Nurse 3 (RN 3) documented "...Aphasia worsening, decrease in verbal communication- still saying yes/no...Small amount bloody drainage noted from right nare..."

In an interview on 6/24/15 at 10:30 AM, RN 3 stated he came on shift at 7:00 PM, got report, and reviewed Patient 1's labs. He saw the anti-factor Xa level at 0.58, the reference range as 0.3 to 0.7, and...
stated it wasn't flagged as irregular. RN 3 verified the heparin drip was still running at 1740 u/hr from 2/11/15 to 2/12/15, and wasn't turned off until 6:00 AM to 6:10 AM on 2/12/15. He stated at 6:00 AM on 2/12/15, Patient 1 had worsening aphasia, his right pupil was blown, he had emesis on the right shoulder, and bloody drainage on his nose around the nostril.

In an interview on 6/25/15 at 12:00 PM, NP 1 stated the heparin drip was stopped on 2/12/15 at 6:15 AM, due to a change in Patient 1's neuro exam.

Record review of the Hospital's Intake and Output Flowsheet for Heparin Drip, dated 2/11/15 at 4:00 AM to 2/11/15 at 11:00 PM, indicated Patient 1 received heparin at a rate of 1740 u/hr with no changes in rate after the anti-factor Xa level of 0.58.

Record review of the Hospital's Progress Notes for Patient 1, dated 2/12/15 at 7:38 AM, indicated "...Studies Reviewed: CT this AM: Impression: transformation of small petechial hemorrhagic infarct...on prior study performed one week ago into large intraparenchymal hematoma with intraventricular hemorrhage (bleeding in the brain's ventricular system, where cerebrospinal fluid is produced) on the current study...

Record review of the Hospital's Lab Results, dated 2/12/15 at 6:37 AM, documents the specimen was collected on 12/12/15 at 5:00 AM, and posted to the Hospital's electronic health record at 6:37 AM. The record indicated "Results History...Heparin, Unfraction Xa...Component: Anti-Factor Xa..."
| Event ID: SCS11 | 4/19/2017 2:46:23PM |

<table>
<thead>
<tr>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
</tr>
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<tbody>
<tr>
<td>Assay...Value: 0.75...Flag: (H)...Ref (Reference) Range: 0.3-0.7...Units: u(units)/ml...&quot;</td>
</tr>
<tr>
<td>Record review of the Hospital's CarePlan Notes for Patient 1, dated 2/12/15 at 8:30 AM, Registered Nurse 4 (RN 4) documented &quot;...Foley draining dark red urine...&quot;</td>
</tr>
<tr>
<td>Record review of the Hospital's Progress Notes by Physician 2 for Patient 1, dated 2/12/15 at 9:12 AM, indicated &quot;...Events of Past 24 Hours: Catastrophic change in status overnight with massive hemorrhagic transformation and rapid decline in neuro status...Assessment: Prognosis is nil. Likely will progress to brain death...Massive intracerebral and intraventricular hemorrhage-2/12...Recent Labs...2/12/15 0500 (5:00 AM)...FACTORXACT (antifactor Xa level)...0.75 H...&quot;</td>
</tr>
<tr>
<td>Record review of the Hospital's Discharge Summary Notes for Patient 1, dated 2/20/15, Physician 2 documented &quot;...Death Summary...Final Diagnoses: Massive intracerebral and intraventricular hemorrhage-2/12...Brain Death-2/13...&quot;</td>
</tr>
<tr>
<td>Record review of the Hospital's &quot;Heparin Titration Using Anti-Factor Xa Laboratory Test&quot; policy and procedure, review date 1/14, indicated &quot;...Policy: 1. To outline the management of unfractionated heparin (UFH) using the anti-factor Xa laboratory test. This protocol is used ONLY when the UFH is ordered to treat:...Neurovascular patients...Medication Interventions per MD Order: 1. Adjust heparin infusion drip rate according to titration&quot;</td>
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## SUMMARY STATEMENT OF DEFICIENCIES

Table...Reportable Conditions: 3. Any signs and symptoms of bleeding, clotting, or altered mental status. Neurovascular Protocol (Anti-factor Xa level goal 0.3-0.5 units/ml)... Anti-factor Xa level (units/ml): 0.3-0.5...Goal...Change drip rate (units/hr): No Change...Anti-factor Xa level (units/ml): 0.51-0.59...Change drip rate (units/hr): decrease rate by 140...Anti-factor Xa level (units/ml): 0.6-0.69...Change drip rate (units/hr): decrease rate by 200...Anti-factor Xa level (units/ml): >0.7...Hold (minutes): 60...Change drip rate (units/hr): decrease rate by 200 less than previous infusion. Notify prescriber: 3. Any signs and symptoms of bleeding, clotting, or altered mental status...

According to Lexicomp Online (a collection of clinical databases and clinical decision support tools that provides users with an extensive medical library), no date available, clinical information indicated "Heparin (Lexi-Drugs)...High alert medication: The Institute for Safe Medication Practices (ISMP) includes this medication among its list of drugs which have a heightened risk of causing significant patient harm when used in error...Warnings/Precautions- Concerns related to adverse effects: Bleeding: Monitor patients closely for signs or symptoms of bleeding...Adverse Reactions (any unexpected or dangerous reaction caused by the administration of a drug):...Gastrointestinal: vomiting...Hematologic:...epistaxis (nose bleed)...Renal: Hematuria (blood in the urine)...Effects on Bleeding: The most serious adverse effect is bleeding..."
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).