CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH  

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<th>ID</th>
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<th>REVIEWED BY</th>
<th>PLAN OF CORRECTION</th>
<th>COMPLETE DATE</th>
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The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number: 
CA00252552 - Substantiated

Representing the Department of Public Health: 
Surveyor ID # 28531, 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 1280.1(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.

AMENDED TO CORRECT TYPING ERRORS  
7/29/11.

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

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<th>Event ID: MBN011</th>
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<tr>
<td>7/29/2011</td>
<td>8:14:34AM</td>
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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.

State-2357
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(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.

DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY

T22 DIV 5 CH 1 ART 3-70263(g)(2) - Pharmaceutical Service General Requirement. Medications and Treatments shall be administered as ordered.

This RULE is not met as evidenced by:

Based on staff interview, clinical record and administrative document review, the facility failed to administer medication safely when the wrong dose (50 times the amount ordered) of heparin (a drug used to slow the time it takes blood to clot) was given to Patient 1. This failure caused blood vessels in Patient’s brain to bleed. This is known

a. High Risk High Alert Medication Administration as defined in HRHA policy to include; pharmacy involvement in medication preparation, independent double checks, medication storage, and medication administration. HRHA medications include: Chemotherapeutic agents, Insulin (intravenous infusion/subcutaneous), Heparin infusion and bolus, Electrolytes (concentrated intravenous preparation), Neumoscular blocking agents, Vasoactive agents (applies only to intravenous Epinephrine, Dopamine, Norepinephrine, Phenylephrine, and Vasopressin), Citrate for Continuous Renal Replacement Therapy, Prostacyclins, Alteplase, Warfarin.

b. Alarms SMART Pump Guardrail usage with return demonstration to their supervisor or designee

c. Patient Hand-off-as defined in policy to include communication from one healthcare team member to another so that pertinent care, treatment, or needs as well as the patient’s current condition and any recent or anticipated changes are accurately communicated whenever there is a transfer of responsibility for the care of the patient.

C. December 16, 2010: All licensed staff during their first shift worked on or after December 16, 2010 received the following education:

12/16/2010
**continued from page 2**

as an intracranial (inside the skull) bleed. Patient 1's intracranial bleed resulted in a coma, and then death.

Findings:

The clinical record was reviewed on 12/17/10 and showed Patient 1 arrived at the Emergency Department on [redacted] at 11:11 a.m., with the chief complaint of pain in her left arm. Patient 1 was diagnosed with a blood clot blocking an artery (vessel which carries blood away from the heart) in her left arm. Alteplase (a drug used to breakdown blood clots) was administered intravenously (IV) into Patient 1's clotted artery. Heparin was then administered into the same artery. The heparin was used to prevent clots from forming around the catheter (tubing) directing the flow of the alteplase. There was no documented evidence in Patient 1's clinical record to indicate exactly when the initial heparin infusion was started, or by whom. There was no documentation by the second nurse verifying the accuracy of the pump settings per facility policy. A Radiology Report dated [redacted], [without a time] indicated the heparin was started at 300 units per hour during the Interventional Radiology (IR) procedure. According to the Intra-Procedure Record, the procedure was conducted from 6:36 p.m. to 6:58 p.m. The post-procedure order dated [redacted] at 7:30 p.m. was: heparin premix - 25,000 units/500 milliliters (ml- a liquid measurement) 5% dextrose (sugar solution) in water to infuse at 300 units/ hour. An activity report from the automated medication dispensing cabinet (ADC) was reviewed on 5/18/11.

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<tr>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY)</th>
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<tr>
<td>a. High Risk High Alert Medication Administration as defined in HRHA policy to include; pharmacy involvement in medication preparation, independent double checks, medication storage, and medication administration. HRHA medications include; Chemotherapeutic agents, Insulin (Intravenous Infusion/subcutaneous), Heparin infusion and bolus, Electrolytes (concentrated intravenous preparation), Neurumuscular blocking agents, Vasoactive agents (applies only to Intravenous Epinephrine, Dopamine, Norepinephrine, Phenylephrine, and Vasopressin), Citrate for Continuous Renal Replacement Therapy, Prostacyclins, Alteplase, Warfarin.</td>
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<td>b. Alaris SMART Pump Guardrail usage with return demonstration to their supervisor or designee</td>
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<td>c. Chain of Command activation for problem solving</td>
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<td>d. Patient Hand-off as defined in policy to include communication from one healthcare team member to another so that pertinent care, treatment, or needs as well as the patient's current condition and any recent or anticipated changes are accurately communicated whenever there is a transfer of responsibility for the care of the patient.</td>
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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH
STATEMENT
OF DEFICIENCIES
AND PLAN
OF CORRECTION

PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:
050060

T1PLE CONSMUCTI()N
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COMPLETED
050060
A BUILDING
B. WING
12/21/2010

NAME OF PROVIDER OR SUPPLIER
COMMUNITY REGIONAL MEDICAL CENTER
STREET ADDRESS, CITY, STATE, ZIP CODE
2823 FRENSO STREET, FRENSO, CA 93721-1324 FRENSO COUNTY

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
REGULATORY OR LSC IDENTIFYING INFORMATION)

PREFIX
TAG

D. December 15, 2010: The Radiology Manager counseled the nurse who administered the Heparin and Alteplace to the patient and failed to properly complete the Procedural Record.

PREFIX
TAG

E. June 1, 2011: All Radiology nurses were reeducated about complete documentation including:

a. Documentation of medication administration
b. Do not leave blanks. If a component doesn't apply, write "N/A".
c. Document baseline vital signs if not already completed by the previous unit.
d. Complete the Post-Procedural checklist for outpatients.
e. Complete the In-Patient Report for inpatients.
f. Complete the Procedural Patient Care Plan and Education.

2. The title or position of the person responsible for the correction.

Chief Nursing Officer
Medical Imaging Director
Burn Unit Director

Event ID: M8NO11
7/29/2011 8:14:34AM
LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE

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State-2067
Continued From page 4
greater than 38.5 seconds are considered excessive). Narrative nurses notes dated 10 at 11:30 p.m., written by RN 2 contained documentation, "pump noted to have improper programming for Heparin..." This note indicated the discovery of heparin being administered incorrectly. A late entry on 10 at 6:14 a.m., RN 2 documented the heparin was stopped on 10 at 10:35 p.m.

Review of Patient 1's Intake and Output record dated 10, showed hourly totals of heparin Patient 1 received. Patient 1 received 826 ml or 41,500 units of heparin between 6:30 p.m. and 10:35 p.m. Patient 1 should have received 6 ml an hour for the three to four hour period the heparin infused. Therefore, Patient 1 received 60 times the dose of heparin that was ordered by the physician.

A Physician's Progress note dated 10 at 12:55 p.m., contained the following: "Disclosure Note - was called to the patient bedside at approximately [10 p.m.] due to critical lab value ... discovered that the patient received a higher dose of heparin than ordered, at 300 ml/hr. rather than 300 units/hr... Pl. (patient) continued to be stable but now had an occipital [back of head] headache, at this point; I disclosed to the patient that she had received a higher dose of heparin than ordered by MD 2..." MD 1 documented concern that Patient 1 may have a bleed in her head. He wrote that the Computed Tomography (CT) (high definition computer tomography- scanned views) results indicated there was bleeding in Patient 1's brain.

3. A description of the monitoring process to prevent recurrence of the deficiency.

A. The manager or designee of each patient care unit performed daily audits for documentation of independent double checks and compliance with use of the Alaris SMART Pump Guardrail system on all High Risk High Alert medications which per policy to include Chemotherapeutic agents, Insulin (intravenous infusion/subcutaneous), Heparin infusion and bolus, Electrolytes (concentrated intravenous preparation), Neuromuscular blocking agents, Vasoactive agents (applies only to intravenous Epinephrine, Dopamine, Norepinephrine, Phenylephrine, and Vasopressin), Citrate for Continuous Renal Replacement Therapy, Prostacyclins, Atteplase, and Warfarin being delivered from 12/17/10 to 12/31/10, weekly audits from 1/1/11 for four weeks and until 100% compliance was achieved. Once 100% compliance was achieved, the manager or designee of each patient care unit performed the audits monthly. The audits continue to be done on a monthly basis.

B. The manager or designee of each patient care unit ensured that all RN's demonstrated competency in the use of the Alaris SMART Pump Guardrail System and completed the education and signed the attestation form at 100% compliance rate. Completed by 12/31/10.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<th>ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
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<th>(X5) COMPLETE DATE</th>
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<tr>
<td>1</td>
<td>C. Education and audits have been monitored by the Chief Nursing Officer for 100% compliance in all patient care areas that use High Risk High alert medications and Alaris SMART Pumps. This was completed by 12/31/10.</td>
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<td>2</td>
<td>D. 2/20/11: An Alaris consultant independently reviewed Alaris SMART Pump settings and use of Guardrails with random audits. 100% compliance was found which included correct settings on all Alaris SMART Pumps audited along with 100% of appropriate pump guardrails use.</td>
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<td>E. The Radiology Manager monitored for 100% compliance by Radiology nurses for education on documentation beginning June 1, 2011. Compliance rate is 100%.</td>
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<td>06/02/2011</td>
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<td>F. Beginning June 1, 2011 through September 1, 2011 the Radiology Manager or his designee will perform audits on all inpatient thrombolysis procedures to ensure complete documentation by the procedural nurse.</td>
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<td>09/01/2011</td>
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<td>5</td>
<td>G. Beginning June 1, 2011 through September 1, 2011 the Radiology Manager or his designee will perform 30 random audits a month on IR procedures to ensure complete documentation by the procedural nurse.</td>
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<td>09/01/2011</td>
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<td>H. Audit results will be reviewed by the Chief Nursing Officer and Quality Patient Safety Committee.</td>
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### LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

**Event ID:** MBND11

**Date:** 06/02/2011

**Title:** (X6) DATE

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**State:** CA

**Facility:** Community Regional Medical Center

**Address:** 2823 Fresno Street, Fresno, CA 93721-1224

**City:** Fresno

**State:** CA

**ZIP Code:** 93721

**Telephone:** (X6) DATE

**Fax:** (X6) DATE

**Email:** (X6) DATE

**Website:** (X6) DATE

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Continued From page 5

A CT of Patient 1's brain dated 10/10 at 7:46 a.m. indicated Patient 1's condition had worsened with a decreased level of consciousness. The CT report concluded the bleeding in Patient's brain had developed into a very large subdural hematoma (a space in the brain created by an abnormal collection of blood). The subdural hematoma had grown and was crowding Patient 1's brain.

Progress Notes dated 10/10 at 11:35 p.m. were reviewed. MD 3 documented in the progress notes that Patient 1 died on 10/10. The time of death was 11:20 p.m. MD 3 indicated the immediate cause of death was due to brain hemorrhage.

Risk Manager 1 was interviewed on 12/17/10 at 10:20 a.m. She stated the amount of heparin ordered for Patient 1 was 300 units an hour. The Risk Manager 1 stated, "The IR nurse programmed the pump (equipment used to precisely administer IV medication) to administer 300 mL an hour, instead of 300 units an hour. The error was discovered on 10/10 at 10:35 p.m." During the interview, Risk Manager 1 stated the following: By that time, Patient 1 had been receiving 15,000 units of heparin an hour for approximately three hours. The amount of heparin the physician ordered for Patient 1 was 300 units an hour. Patient 1 received an overdose of 40,500 units of heparin over a three to four hour time period.

During a second interview on 12/17/10 at 11:30 a.m., Risk Manager 1 stated the nurse that programmed the pump to infuse Patient 1's heparin...
Continued From page 6

did not use the "guardrails." The guardrails are a built in safety mechanism that recognize when safe parameters (doses too high or too low) of high risk medications, such as heparin, are not met. The pumps will not accept doses that are outside the pre-set safe parameters. Risk Manager 1 stated, "Our policy is to use the guard rails. RN 1 bypassed the guard rails. RN 1 programmed Patient 1's pump as if he were going to give a regular IV, not a high risk medication like heparin."

On 5/23/11 at 2:20 p.m., during an interview the Burn Unit Director stated RN's were responsible for certain checks when they took over the care of a patient. Those checks included: physical assessment of the patient, checking the doctor's orders, and checking the settings on the pumps. Double checks were required when patient care was handed-off from one nurse to another. Hand off communication and checks were not required to be documented. The start of a High Alert High Risk (HAHR) medication required two nurses to verify the dose settings. This double check was to be documented - meaning both nurses would sign that they verified it to be accurate. The same double check should have occurred when a new container of the HAHR medication replaced an empty container. It was the receiving nurse's responsibility to double check. The Burn Unit Director stated, "[RN 2] admitted this was not done [for Patient 1]."

The facility policy and procedure titled "High Alert / High Risk [HAHR] Medications - Patient Care"

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Policy Manuel #11992, Effective Date 2/23/09, indicated, "... DEFINITION - HIGH ALERT/ HIGH RISK medications and/or administration techniques are defined as: Those that have been shown to actually or potentially cause significant harm to the patient, even when used as intended... HRHA Medications include: ...Heparin infusion (steady drip) and bolus [single, larger dose]... HAND OFF Communication is the provision of communication from one healthcare team member to another... Whenever there is a transfer of responsibility for the care of the patient. Independent Double check at Hand off is done but does not require co-signature. INDEPENDENT DOUBLE CHECK - Is a check of the factors below performed independently by a second qualified healthcare practitioner. Checks include, but are not limited to: ... - Right dose of drug... - IV pump setting (if applicable) - Rate of infusion (if applicable) INDEPENDENT DOUBLE CHECK WHO? Two registered nurses... WHEN? Upon initial pump programming, Medication bag replacement... Double Check will be co-signed on MAR or medication flow sheet as appropriate... Use of Guardrails Safety System- All drugs must be run through Alaris [Manufacturer's brand name] Guardrails System... DO NOT RUN DRUG IN BASIC INFUSION MODE, this violates corporate policy and jeopardizes patient safety."

The facility failed to: document Patient 1's clinical record to indicate when the initial heparin infusion was started, or by whom; ensure healthcare

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<tr>
<td>Karen Buckley  Chief Nursing Officer</td>
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<td>TITLE</td>
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professionals administered heparin at the ordered dose; follow manufacturer's instructions for the administration of heparin; ensure healthcare professionals documented treatment and signed notes; ensure that equipment (IV pump) was properly programmed and operated by staff; ensure healthcare professionals communicated at hand-off per facility policies and procedures; ensure healthcare professionals independently double-checked correct drug dose, IV pump setting and rate of infusion per facility policy and procedure.

Patient 1 developed a large intracranial bleed and expired within 25 hours from the discovery of the overdose.

This 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 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).