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
	050060	A. BUILDING _____ B. WING _____	12/21/2010

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	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:		POC ACCEPTABLE YES ☒ NO ☐ Reviewed By: Campbell Name Facility Notified Name: Karen Buckley Date: 8/9/11 Time: 8:35am Verified By: Campbell Name Amended 8/9/11 1.B.a 1.B.c 1.C.a 1.C.d 3. A 3. D Plan of Correction CA00252552 *The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein.* *The plan of correction constitutes Community Regional Medical Center's written credible allegation of compliance for the deficiencies noted.* **1. How the correction will be accomplished, both temporarily and permanently.** A. December 15, 2010: The Burn Center Director reviewed all patients receiving High Risk High Alert medications in the unit for 100% compliance with independent double check performance and Alaris SMART Pump guardrail usage. B. December 16, 2010: All Interventional Radiology nurses were educated on the High Risk / High Alert Medication Policy and Procedure. Education included:	12/15/2010 12/16/2010

Event ID:M8ND11 7/29/2011 8:14:34AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Buckley RN — TITLE: Chief Nursing Officer — (X6) DATE: 8/9/11

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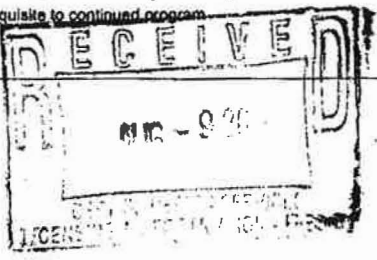

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	Continued From page 1 (4) Care management events, including the following: (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, 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. A012 1280.1(c) Health & Safety Code 1280 (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. 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 Patient1'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), Neuromuscular blocking agents, Vasoactive agents (applies only to intravenous Epinephrine, Dopamine, Norepinephrine, Phenylephrine, and Vasopressin), Citrate for Continuous Renal Replacement Therapy, Prostacyclins, Alteplase, Warfarin. b. Alaris 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

Event ID:M8ND11 7/29/2011 8:14:34AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Karen Buckley RN	Chief Nursing Officer	8/9/11

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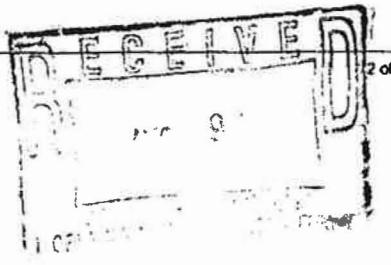

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	Continued From page 2 as an intracranial (inside the skull) bleed. Patient 1's intracranial bleed resulted in a coma, and then death. Findings: The clinical record was reviewed on 12/17/10 and showed Patient 1 arrived at the Emergency Department on [redacted]10 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]10, [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]10 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		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), Neuromuscular blocking agents, Vasoactive agents (applies only to intravenous Epinephrine, Dopamine, Norepinephrine, Phenylephrine, and Vasopressin), Citrate for Continuous Renal Replacement Therapy, Prostacyclins, Alteplase, Warfarin. b. Alaris SMART Pump Guardrail usage with return demonstration to their supervisor or designee c. Chain of Command activation for problem solving 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.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Buckley RN TITLE: Chief Nursing Officer (X6) DATE: 8/9/11

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	Continued From page 3 at 4 p.m. The report indicated on [redacted]10 at 6:22 p.m., Registered Nurse (RN) 1 removed heparin from the ADC for Patient 1. The report indicated the heparin was premixed with Heparin 25,000 units in 500 ml of solution. The nurse's note written by RN 2, dated [redacted]10 at 7:50 p.m., noted Patient 1 was transferred to the burn unit after the IR procedure and that "IR nurse stated, Heparin gtt [drip or IV infusion] @ sub therapeutic level @ 300/ hr..." There was no documented evidence to clarify if the 300 referred to units or ml per hour. Patient 1's Medication Administration Record (MAR) dated [redacted]10, indicated the first container of heparin solution had been administered to Patient 1. RN 2 documented on the MAR that she had begun administering a second container of heparin at 9:10 p.m. The following pre-printed information was on Patient 1's MAR: Heparin: 25,000 units in 500 ml of solution, resulting in a concentration of "50 UNITS/ML, INFUSION RATE: 300 UNITS/HR = 6 ML/HR... *** HIGH ALERT / HIGH RISK MED [HAHR] ***" This order showed how the heparin was to be administered. There were no signatures or initials on the MAR except RN 2's. There was no documented evidence that double checks were performed per facility policy. On [redacted]10 at 10:05 p.m., RN 2 received notification that Patient 1's Partial Thromboplastin Time (PTT) was greater than 120 seconds. (PTT was a test to measure clotting time - Lab values		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. 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	12/15/2010 06/01/2011

Event ID:M8ND11 7/29/2011 8:14:34AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Buckley RN — TITLE: Chief Nursing Officer — (X8) DATE: 8/9/11

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State-2567

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	Continued From page 4 greater than 36.5 seconds are considered excessive). Narrative nurses notes dated [redacted]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 [redacted]10 at 6:14 a.m., RN 2 documented the heparin was stopped on [redacted]10 at 10:35 p.m. Review of Patient 1's intake and Output record dated [redacted]10, showed hourly totals of heparin Patient 1 received. Patient 1 received 829 ml or 41,500 units of heparin between 6:36 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 50 times the dose of heparin that was ordered by the physician. A Physician's Progress note dated [redacted]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... Pt. (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, Alteplase, 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.	~~Ongoing~~ SC 12/31/2010

Event ID:M8ND11 7/29/2011 8:14:34AM

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	Continued From page 5 A CT of Patient 1's brain dated [redacted]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 [redacted]10 at 11:35 p.m. were reviewed. MD 3 documented in the progress notes that Patient 1 died on [redacted]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 [redacted]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 1was 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		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. 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. E. The Radiology Manager monitored for 100% compliance by Radiology nurses for education on documentation beginning June 1, 2011. Compliance rate is 100%. F. Beginning June 1, 2011 through September 1, 2011 the Radiology Manager or his designee will perform audits on all inpatient thrombolysis procedures in IR to ensure complete documentation by the procedural nurse. 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. H. Audit results will be reviewed by the Chief Nursing Officer and Quality Patient Safety Committee.	12/31/2010 02/20/2011 06/02/2011 09/01/2011 09/01/2011 ~~Ongoing~~ SC

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	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		**4. The date the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty days (30) from the date of the exit conference.** December 31, 2010	12/31/2010

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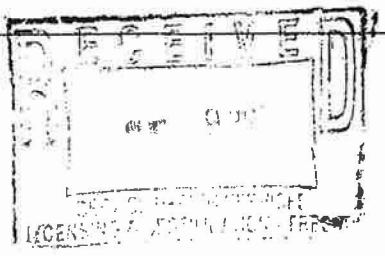

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	Continued From page 7 Policy Manuel #11992, Effective Date 2/23/09, indicated, "... DEFINITION - HIGH ALERT/ HIGH RISK medications and/ or administration techniques are defined as: Those that have been shown to actually or potentially cause significant 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			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Buckley RN | TITLE: Chief Nursing Officer | (X6) DATE: 8/9/11

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	050060	A. BUILDING _____ B. WING _____	12/21/2010

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 8 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).			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Buckley RN — TITLE: Chief Nursing Officer — (X6) DATE: 8/9/11

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.