POC ACCEPTABLE YES ☒ NO ☐ Reviewed By: Steve Lopez
Name
Fax
Original X
Facility Notified
Name: Laura Malcomb 12/4/14

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	Name A. BUILDING _____ B. WING _____	04/17/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Community Regional Medical Center	2823 Fresno St, Fresno, CA 93721-1324 FRESNO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00306344 - Substantiated Representing the Department of Public Health: Surveyor ID # 27126, 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 NOVEMBER 25, 2014 TO REFLECT NEW EVIDENCE PROVIDED TO THE DEPARTMENT 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		**The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein. This plan of correction constitutes Community Regional Medical Centers written credible allegation of compliance for the deficiencies noted.** **Complaint #: CA00306344** **Penalty # 040009720** A. How the correction was accomplished, both temporarily and permanently for each individual affected by the deficient practice, including any system changes that were made. On 4/2/2012, an investigation was immediately authorized by the President of the Medical Staff and the Chair of Surgery. The Chairperson of the Board of Trustees (BOT) was notified by the Chief Quality Officer. On 4/6/2012, the Interim Director of Surgical Services and the Patient Safety Officer instructed the Cardiovascular surgical nursing staff leadership on the scope of practice for physician assistants and the requirements of a surgeon when a patient is in the operating room. Education on the scope of practice for physician assistants and the requirements of a surgeon was initiated by the Surgical Services Manager for all nursing surgical and cardiovascular staff. On 4/25/2012, the Interim Director of Surgical Services and the Patient Safety Officer instructed the nursing surgical staff clinical supervisors on the scope of practice for physician assistants and the requirements of a surgeon when a patient is in the operating room. All surgical and cardiovascular nursing staff were educated on the scope of practice for physician assistance and the requirements of a surgeon when a patient is in the operating room by Surgical Services Managers with 100% compliance. A nursing surgical services staff roster was utilized to ensure all nursing surgical staff were educated.	

Event ID: WGUB11 12/18/2014 10:37:32AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE 12/19/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

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-2567

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	(b) For purposes of this section, "adverse event" includes any of the following: (7) An adverse event or series of adverse events that cause the death or serious disability of a patient. Title 22 70443 Cardiovascular Surgery Service General Requirements (a) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Deficiency Constitutes Immediate Jeopardy Based on staff interviews, clinical record and administrative document review, the hospital failed to implement Cardiovascular Surgery Service policies and procedures and medical staff bylaws when Cardiovascular Surgeon 1 (CVS 1) left the Operating Room (OR) before Patient 1 fully stabilized following the conclusion of open heart surgery on [redacted]12. CVS 1 also directed Physician Assistant (PA) 1 to be left in-charge, an individual not qualified to be left in-charge of the cardiovascular (CV) surgery. After CVS 1 left the OR, Patient 1 suffered massive blood loss, cardiac arrest and loss of oxygen to the brain. The massive blood loss required re-opening the chest and manual massage of the heart. Patient 1 was placed		Compliance was measured by documentation of education to 100% of cardiovascular and surgical nursing staff by the Surgical Services Manger and Interim Director. As of April 30, 2012, compliance with those instructions was 100% for the nursing surgical staff. Compliance continues to be audited by the Surgical Services Manger and Interim Director and as of this date remains at 100% on the staff roster. On 4/12/2012, Medical Executive Committee (MEC) notified the physician by letter to comply with the medical staff bylaws requiring him to remain in the hospital and be available when patients are still in the Operating Room or to arrange for appropriate coverage. The President of the Medical Staff telephoned the physician and informed him of the same expectations and admonished him that failure to adhere to this directive would result in an immediate summary suspension. The Allied Health Professional (Physician Assistant) privilege card was modified in accordance with Title 16 to state that the personal presence of an approved supervising physician is required when performing surgical procedures under general anesthesia. The privilege card was approved at MEC on 5/10/2012 and Board of Trustees on 7/17/2012. After the event occurred, the Chair of the Department met individually with the practitioner and the Physician Assistant. They were directed that the personal presence of an approved supervising physician is required when performing surgical procedures under general anesthesia at all times. On 4/12/2012 the Medical Executive Committee determined it would be in the best interest of both the physician and the MEC if the case was reviewed by an outside expert. It immediately took steps to send the case in question out for an independent review by an experienced expert cardiovascular surgeon, even though it was recognized this would cause a time delay in resolution of the matter. On 7/18/2012 the practitioner and the assisting cardiovascular surgeon were directed by the President of the Medical Staff to amend their documentation in the patient record to reflect what accurately happened on 4/2/12.	

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	on life support after the subsequent CV surgery and as of [redacted]/12 remained on life support. Findings: On 4/11/12 at 3:46 p.m. the department received an anonymous complaint alleging the following: "... (CVS 1) left the operating room while the chest was still open (for Patient 1) and then left the hospital before the surgery was done leaving his (PA 1) to take over the surgery ...The patient arrested (cardiac arrest - the heart stopped beating) in the operating room and the surgeon was not in the hospital to attend to the patient..." The clinical record for Patient 1 was reviewed on 4/17/12. Patient 1 had a surgical repair of the Ascending Aortic Aneurysm (AAA) on [redacted]12. (Ascending Aortic Aneurysm is a serious condition where the main artery leaving the heart balloons out and may rupture. AAA requires open heart surgery in order to repair.) Surgery was started on [redacted]12 at 8:41 a.m. and due to complications, anesthesia was not stopped until 9:46 p.m. CVS 1 was the primary surgeon, assisted by PA 1 and MD 1 (general vascular surgeon). MD 2 was the anesthesiologist. Patient 1 came off of bypass at 11:45am. PA 1 and MD 1 proceeded to complete the surgery by closing Patient 1's chest. The closing of Patient 1's chest consists of closing several layers. CVS 1 left the OR shortly after 12:15pm. PA 1 and MD 1 left the OR after completing the surgery shortly thereafter. After PA 1 and MD 1 left the OR, Staff 1		The amended documentation was entered into the record on 7/19/2012. On 7/26/2012 the leadership of Surgical Services, Chairs of the Facility Executive Advisory Committees and the President of the Medical Staff sent a letter to all members of the medical staff notifying them of the Physician Assistant scope of practice and directing all to adhere to the California Code of Regulations Title 16. On 7/27/2012 the Medical Directorship for Cardiothoracic Services was reassigned to another physician. On 8/15/2012, the surgery staff orientation was amended to include the scope of practice for Physician Assistants and surgical practice and expectations of the surgeon when the patient is in the Operating Room. On 8/15/2012 a special MEC meeting was held to review the findings of the investigation. The following actions were taken regarding the physician: A. In regards to the issue of medical record documentation: • A summary of his documentation deficiencies identified during the external peer review will be provided to the practitioner to illustrate the types and severity of his documentation deficiencies. • In order to improve his documentation deficiencies, the physician must successfully complete a University of California San Diego (UCSD) Physician Assessment and Clinical Education (PACE) program in medical record documentation. • The practitioner must abide by all of the hospital policies, medical staff rules and regulations pertaining to medical records documentation. B. In regards to the issue of the chest closure following cardiac surgery, the physician shall remain in the operating room (OR) until the patient's chest is closed. C. Regarding the issue of leaving the OR and the hospital during the case of 4/2/2012: • There is evidence that the patient was unstable following the conclusion of surgery.	

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	(perfusionist - a specialized health professional trained to monitor the heart-lung machine during cardiovascular open heart surgery) noted Patient 1 continued to bleed. At this time Registered Nurse (RN) 1 (circulating registered nurse) called CVS 1 about the continued bleeding. By phone, CVS 1 ordered blood products (for example, red blood cells and plasma) to be administered to Patient 1; multiple administrations of blood products were given with continued bleeding from the chest. At approximately 12:45 p.m. the anesthesiologist noted Patient 1 to be in ventricular fibrillation (uncoordinated heart contractions causing the heart to quiver and cause of cardiac arrest) and code blue was called. (Code blue is an emergent situation where the heart stops beating and requires immediate intervention.) PA 1 responded to the code blue and rushed back into the OR and opened the chest (cut the wire sutures holding the chest together) and started manually massaging the heart. Patient 1 did not respond to the manual massage of the heart. Patient 1 continued to suffer massive blood loss. PA 1 and MD 2 attempted to place a cannula (a hollow tube) into the heart in preparation to re-start the heart bypass machine. All attempts to place the cannula were unsuccessful. CVS 1 re-entered the OR at 1:29 p.m. and adjusted the cannulas successfully. Patient 1 was placed on full heart bypass at this time. CVS 1 attempted to stabilize patient's vital signs and stop the blood loss in order to wean from the heart bypass machine. Attempts to take Patient 1 off the bypass		• As a result the patient was not ready to leave the OR. • The responsibility for the patient's care under these circumstances rests clearly with this physician. • In leaving the OR and the hospital, he failed to designate another physician qualified to provide the necessary coverage or care. • As a result, there was an untimely response to the patient's deteriorating condition. • The physician has been directed to either be present or to provide suitable coverage (presence of a privileged cardiothoracic surgeon) following cardiac surgery cases until the patient is stable in the Intensive Care Unit (ICU). • Therefore, a fourteen (14) day medical staff suspension was imposed. *B. The title of position of the person responsible for correction, e.g. Administrator, Director of Nursing or other responsible supervisory personnel.* President of Medical Staff and Chief Quality Officer *C. A description of the monitoring process to prevent recurrences of the deficiency, the frequency of the monitoring and the individuates) responsible for the monitoring.* All Cardiovascular surgeries under the care of the physician were monitored concurrently for 2 months by the Patient Safety Department from April 3, 2012 through June 1, 2012 for compliance with surgeon attendance during surgery as specified by our bylaws. All cases were referred to Peer Review for Medical Staff oversight. All Cardiovascular surgeries under the care of the physician were monitored for compliance with surgeon attendance during surgery as specified by our bylaws retrospectively within 1 week began June 2, 2012 and continued for 6 months until December 1, 2012 and referred to Peer Review for Medical Staff oversight.	

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	machine were unsuccessful. CVS 1 decided to place Patient 1 on ECMO (extra corporeal membrane oxygenation - a machine designed to help oxygenate blood when the heart and lungs are severely damaged) at 3:53 p.m. Patient 1 continued to bleed heavily after Patient 1 was placed on ECMO. At approximately 7:10 p.m. CVS 1 asked another cardiovascular surgeon (CVS 2) to evaluate Patient 1's continued bleeding. CVS 2 managed Patient 1's surgical bleeding and Patient 1 was admitted to the Cardiovascular Intensive Care Unit (CVICU) in critical condition at approximately 10:40 p.m. on [redacted]2. On 4/18/12 at 1:30 p.m., during an interview, Staff 1 (perfusionist) stated to the effect that CVS 1 left the OR prior to the complete closure of Patient 1's chest and that (PA 1) and (MD 1) closed up the chest and then left the OR. Staff 1 stated that as PA1 and MD1 were closing, "there was still bleeding, enough to MD1" and that "[a]t about 12:50pm blood started pouring out of the patient's chest. At the initial time, ...almost 250ml of blood lose. [F]rom 12:45-12:55 about 1250ml." (RN 1) called (CVS 1) and he ordered another round of blood products given to Patient 1. (MD 2) was giving the blood products. Patient 1 was bleeding so much that (MD 2) could not replace the blood fast enough and Patient 1 coded at 12:55 p.m. Staff 1 stated, "When we called the code ... (PA 1) came rushing back in while CPR (cardiopulmonary resuscitation) was in process. (PA 1) decided to open up the chest with chest compressions being given. When she opened up the chest blood was		On 8/15/2012, 10 cases per month were randomly selected for all Cardiovascular and Surgical procedures and reviewed by Peer Review for compliance with surgeon attendance during surgery as specified by our bylaws and surgical documentation including surgery times, attendance and the Operating Room report. The review occurred for 3 months with the goal of 100% compliance. Monitoring results was reported to Surgery Advisory, MEC and BOT for September, October and November 2012. On 8/15/2012, 10 cases per month were randomly selected and reviewed by Peer Review for appropriate utilization of Physician Assistants and surgical documentation including surgery times, attendance and the Operating Room report. The review occurred for 3 months with 100% compliance. Monitoring results were reported to Surgery Advisory, MEC and BOT for September, October and November 2012. On 8/15/2012, 2 cardiovascular and 2 surgical cases were randomly selected for observation per month by Quality and Patient Safety RN's. The review occurred for 3 months with 100% compliance of adherence to medical staff bylaw expectation of surgeon attendance and Physician Assistant scope of practice. Monitoring results was reported to Surgery Advisory, MEC and BOT for September, October and November 2012. *D. The date when the immediate correction of the deficiency was accomplished. Normally this will be no more than thirty (30) days from the date of the exit conference.* August 15, 2012	08/15/2012

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	rushing out. She couldn't insert the chest tube and (MD 2) had to glove up and assist inserting the chest tube. (PA 1) and (MD 2) never inserted a chest tube. (CVS 1) wasn't in and they had to do something. (RN 1) got (CVS 1) on the phone and got the phone to (PA 1's) ear so he could talk to her. He instructed (PA 1) how to cannulate (insert a tube into the chest cavity) but she could not do it. (CVS 1) came in at 1:29 p.m. and adjusted the cannulas. He took over from (PA 1) and started repairing the bleeding points. At 3:28 p.m., (Patient 1) was still bleeding and (CVS 1) decided to put him on ECMO. (CVS 1) said, 'At this point there is nothing else that can be done surgically,' that we should send (Patient 1) to Cardiac ICU." On 7/13/12 at 10:35 a.m., during an interview, CVS 1 stated he directed PA 1 to finish the case which meant she was to perform the remainder of the surgery - closure of the chest with wires. CVS 1 stated he had checked all the tubes and all was routine. CVS 1 stated he allowed PA 1 to practice above her privilege card as PA 1was preparing for an Advanced Quality Practice Exam and for that, she needed so many cases with opening and closing the chest and to cannulate (the insertion of a cannula or tube into a hollow body organ) the heart. CVS 1 stated he left the surgery and went up to the unit to complete orders. Patient 1's medical records indicate that CVS 1 was in the OR until 12:15pm. On 7/16/12 at 11:30 a.m., MD 4 (Chief Officer for Quality) and Administrative (Admin) 1, both stated			

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	CVS 1 left the OR prior to complete closure of the chest skin. MD 4 and Admin Staff 1 stated that CVS 1 violated the hospital's Rules and Regulations under the Bylaws which do not permit the primary surgeon to leave the OR prior to the patient being established as stable. The Rules and Regulations and Policies of the Medical Staff dated 2011 were reviewed on 7/12/12 and contained the following documentation under section D: "... Coverage Arrangement - Each attending physician shall personally provide or otherwise arrange for continuous care and coverage for each of his or her patients... Failure to arrange appropriate coverage shall be grounds for corrective action as defined in articles VI and VII of the Medical Staff Bylaws...If a physician is unable to provide care for his or her patients, then the physician must provide coverage through another appropriately credentialed physician. The covering physician must be available and qualified to assume responsibility for the patients during the entirety of the attending physician's absence...It is expected that a physician on call will respond to pages regarding a hospital inpatient within fifteen (15) minutes of being called and will be available in the hospital within thirty (30) minutes of any call to provide necessary medical evaluation treatment and stabilizing treatments. In certain specialties more restrictive availability may be required. Under Article VI Corrective Action and section 6.1.1 the following documentation was noted: When a member may have exhibited conduct likely to be (1) detrimental to patient safety or to the delivery of quality patient care within the hospital; ... (4) below applicable			

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	professional standards...may be initiated by the President of the Committee:.." CVS 1 left the open heart surgery on Patient 1 prior to complete closure of the chest and before Patient 1 fully stabilized. CVS1 violated the hospital medical staff rules and regulations when. CVS 1 failed to arrange appropriate coverage for Patient 1 by leaving in-charge individuals not qualified to assume responsibility for Patient 1. . As a result, Patient 1 suffered massive blood loss after CVS 1 left the OR and subsequently suffered cardiac arrest. Because of the massive blood loss and loss of oxygen to the brain, Patient 1 was placed on life support. Patient 1 remained on life support as of [redacted]12. 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). 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).			