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 _____	11/26/2012

POC ACCEPTABLE YES ☐ NO ☐
Reviewed By: _____ Name
Fax: _____
Original: _____

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

Facility Notified
HSA - FRESNO COUNTY
Date: _____
Time: _____
Notified By: _____ Name

(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: CA00332399 - Substantiated Representing the Department of Public Health: Surveyor ID # 20365, 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. 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) 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		**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.** **Facility ID: 040000101** **Penalty #: 040009784** **1. Corrective actions accomplished for the patient affected and to identify others potentially affected:** **Immediate changes and systemic changes put in place:** On 11/1/12 an investigation was initiated and the event was reported to the Chief Quality Officer (CQO), Chief Executive Officer (CEO), Chief Nursing Officer (CNO), Chief Operating Officer (COO), Senior Vice President of Medical Affairs (SVPMA), President of the Medical Staff, Corporate CEO and COO, Chairperson of the Board of Trustees and two Board members, Chair of Committee on Interdisciplinary Practice (CIDP) and Chair of Surgery, Chair of Facility Executive Advisory Committee (FEAC) and referred to Peer Review. On 11/2/12 The Physician's Assistant involved was placed on administrative leave. On 11/6/12 a Case Review was completed with representatives of facility leadership, medical staff leadership, nursing staff leadership, Peer Review, Medical Staff Office, Patient Safety /Risk Management and Pharmacy leadership. Systems and process identified for improvement were: • Understanding of Physician and Allied Health Practitioner (AHP) privileging process by the medical and nursing staff • Policies and procedures regarding the care of patients with epidural catheters • Pharmacy review and verification process for anticoagulants • Physician ordering process in the electronic medical record	

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE AAPSRR TITLE (X6) DATE 4/15/13

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 6

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.

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	a patient, personnel, or visitor. Deficiency Constitutes Immediate Jeopardy Title 22 - Surgical Service General Requirements 70223(b) (2) (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures 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. Based on staff interview, clinical record and administrative document review, the hospital failed to have medical staff follow and implement Medical Staff Bylaws and rules and regulations when Physician (MD) 1 instructed Physician Assistant (PA) 1 to perform a procedure (removal of an epidural catheter - a tube placed in the back near the spinal cord) for which neither was privileged (allowed to perform). PA 1 removed the epidural catheter on Patient 1 on [redacted]/12 while the patient was on Lovenox (a blood thinner medication). Patient 1 subsequently suffered an epidural hematoma (collection of blood near the spinal cord). These failures resulted in Patient 1 suffering an avoidable surgical procedure (removal of the epidural hematoma) and subsequent paraplegia		On 11/6/12, during the case review, it was identified that physicians were placing medication related orders into the electronic medical record under "Nursing Communication Orders". A letter was sent to all medical staff from the President of the Medical Staff directing all practitioners to discontinue the practice of writing "Nursing Communication Orders" in the electronic medical record for ordering, changing or discontinuing medications. On 11/6/12 posters were created and distributed by the CNO to department leadership for placement at the head of the bed for all patients receiving therapeutic anti-coagulant therapy. (See Attachment) On 11/7/12 the CNO sent out a directive by E-Mail to all units instructing the nursing staff to contact the physician to obtain clarification on any medication related order placed in the electronic health record as a "Nursing Communication Order". A patient Safety Alert was issued on 11/7/12 to all nursing staff by the CNO reviewing the policy on epidural catheters with emphasis on appropriate privileging and the nursing staff's responsibilities when a patient is receiving therapeutic Lovenox and an epidural catheter is placed or removed. (See Attachment) The nurse involved received counseling on the incident on 11/8/12 by the Unit Director. On 11/8/12 Chair of Surgery discussed incident with surgeon and a letter was sent to the surgeon to cease and desist removing epidural catheters. On 11/8/12 Medical Executive Committee (MEC) reviewed the findings from the investigation. MEC membership has three (3) Board of Trustee members. The following actions were taken as a result: • The physician received a summary suspension for seven (7) days and was required to attend an Electronic Healthcare Record remediation class. • The Physician Assistant received a fourteen (14) day summary suspension On 11/9/12 The Physician's Assistant involved was terminated from hospital employment.	

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	(paralysis below the waist and affecting both legs). Findings: Patient 1 was admitted on [redacted]12 with chronic severe pain. The hospitalist (MD 2) note on [redacted]12 documented the following information: On [redacted]12 Patient 1 underwent a procedure to place an epidural (the membrane covering the spinal cord) catheter (tube passed through the body to inject fluids) into the epidural space in her lower back to administer pain medication. The epidural catheter was removed by PA 1 on [redacted]12 at 2:03 p.m. by direct instruction from MD 1. This note also reflected Patient 1 had been placed on a systemic anti-coagulant medication (lovenox - a blood thinner) on [redacted]12 at 3:26 p.m. Subsequent to the removal of the epidural catheter, Patient 1 developed an epidural hematoma (mass of collected blood localized around the spinal cord). According to the medication insert, epidural catheters were not to be removed when patients were being treated with blood thinners because of the risk of uncontrolled localized bleeding. Review of medical staff privileging (formal process granting approval to perform a procedure) on 11/13/12 confirmed MD 1 and PA 1 were not privileged to perform placement or removal of epidural catheters. On 11/13/12 at 10:20 a.m., the Medical Staff Manager (MSM) stated Anesthesiologists		All unit managers were instructed by the CNO to perform a daily audit using a monitoring tool of all "Nursing Communication Orders" to ensure 100% compliance with no medication related orders. The audits were sent to the CNO's office weekly for review. The monitoring tool was updated 11/12/12 to include review of the Medication Administration Record (MAR) for the updated order and review for discontinuation of medication order placed in the nursing communication orders. Expectation is 100% compliance for updated order. On 11/12/12 the CNO designee met with all inpatient nursing management. Additional instructions were implemented with regard to medication orders placed under "Nursing Communication Orders". All nursing staff to now discontinue the nurse communication order after medications are entered appropriately under medication orders. A patient safety alert was issued the same day with education for nursing staff on what to do with medication orders received under "Nursing Communication Orders". Each unit was required to complete the education at the start of the shift and submit sign in sheets to the CNO. On 11/12/12 as a result of identified gaps in knowledge regarding privileges, letters were sent to all Allied Health Professionals from the CIDP Chair specifying their responsibility to know what is included in their privileges. In addition letters were sent to all supervising physicians specifying their responsibility for knowing what their AHP's privileges included. (See Attachment) On 11/12/12, MEC met with the physician and physician assistant to review the findings of the investigation. On 11/13/12 a notice was issued to all AHPs directing them to report to Medical Staff Office before 11/30/12 to review their privilege card and sign an attestation. This has been completed to 100% compliance of 211 AHP's. (See Attachment) On 11/13/12 the Chief Medical Informatics Officer (CMIO) instituted a hard stop on physician ordering of Lovenox and Heparin medication orders unless the response to a question is given when placing an order: "If patient has had any spinal procedures or epidural indwelling catheters in the last 48 hours please select from list, otherwise select none."	

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	(specially trained physicians in blocking pain with medications) and Certified Registered Nurse Anesthetists (CRNAs - specially trained nurses) are the only ones who have privileges to pull epidurals. And that should have been apparent to all staff." On 11/13/12 at 2:00 p.m., the Vice President of Medical Staff (VPMS) stated MD 1 and PA 1 did not have privileges to place or remove epidural catheters and did not act within their approved privileges. The VPMS stated the expectation for supervising physicians was not to direct physician assistants to perform procedures outside of the scope of practice or outside of their privileges. On 11/13/12 at 1:40 p.m., during an interview, MD 1 stated he instructed PA 1 to remove the epidural catheter for Patient 1 on [redacted]12. MD 1 stated he was unaware Patient 1 was on lovenox at the time he instructed PA 1 to remove it. MD 1 stated "pulling (removal of) the epidural catheter while on lovenox is contraindicated...if I would have looked at the literature (for lovenox), I would not have had the epidural catheter pulled." MD 1 stated he did not realize he was not privileged to remove (and place) epidural catheters. On 11/13/12 at 4:15 p.m. during an interview, PA 1 stated that MD 1 instructed him to remove the epidural catheter for Patient 1 on [redacted]12. PA 1 stated he took out Patient 1's epidural catheter at 2:03 p.m., and 20 to 30 minutes later RN 13 contacted him that Patient 1 was having decreased sensation and movement in her lower body. PA 1		Pharmacist must review answers to a mandatory ordering question and consult with the ordering physician for any questions or concerns, especially if patient has a history of epidural or spinal anesthesia, prior to medication release for administration. This conversation is documented in a pharmacist note in the electronic health record. On 11/14/12 the CMIO, Chief Nursing Information Officer (CNIO), MD Quality Improvement physicians, Quality, Pharmacy, and Nursing met to review options in the electronic medical record for revising order reconciliation and the use of "Nursing Communication Orders". Starting 11/14/12 Orange stickers with "Anti-coagulant Therapy" are able to be placed on all epidural dressings by the nurse after insertion. On 11/15/12, a thorough review of affected current policies was completed. The policies affected and the revisions made are as follows; Epidural Injections & Continuous Infusions. (See attached policy --Attachment 4) The policy was amended to include: • PATIENT SAFETY ALERT - Administration of medications that affect normal coagulation may significantly increase the risk of neuraxial bleeding with serious complications. Each patient's medication history must be reviewed prior to placement of epidural catheters, during infusion and prior to removal of epidural catheter. Refer to the Epidurals with Anticoagulants Reference Table. • NOTE: Therapeutic Lovenox (e.g., Enoxaparin 1mg/kg Q12H) is not recommended for use on patients with epidural catheters. • If patient is on anticoagulation therapy, place an anticoagulation therapy label on the epidural dressing. • If patient is on therapeutic anticoagulation therapy, ensure a therapeutic anticoagulation therapy poster is at the head of the bed. During the case review completed 11/6/12 it was determined the electronic medical record contained an option (button) allowing the physician to renew all orders at once increasing the chance of reordering medication no longer indicated for the patient. On 11/20/12 the CMIO sent a letter notifying all physicians the "continue all" button for renewing orders was removed. All orders must be reviewed and renewed individually.	

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	stated he was unaware Patient 1 was on lovenox and stated "...the decision to remove the epidural catheter was made believing the patient was not on lovenox." PA 1 stated he was not privileged to perform epidural catheters. On 11/13/12, a signed copy of the hospital's Medical staff Bylaws dated 2011 was reviewed and Page 48 indicated "ARTICLE V CLINICAL PRIVILEGES 5.1 EXERCISE OF PRIVILEGES A practitioner shall be entitled to exercise only those clinical privileges or practice prerogatives specifically granted. ...Clinical privileges shall be exercised pursuant to these Medical Staff Bylaws, Rules and Regulations, and Medical Staff and hospital policy, and subject to the authority of the Department Chairpersons and the Medical Executive Committee." On 11/13/12 at 9:30 a.m., a signed copy of the hospital's Department of Cardiology Rules and Regulations dated 2012 was reviewed and Page 6 indicated"5.1 - SCOPE OF CLINICAL PRIVILEGES Appointment to the Department of Cardiology shall confer on the appointee only such privileges as have been granted by the Board of Trustees as recommended by the Medical Staff, ... which shall be in accordance with the Medical Staff Bylaws, Rules and Regulations... specific to clinical privileges." The hospital failed to ensure MD 1 and PA 1		The revised policy was submitted and approved by Anesthesia Subcommittee of Surgical Advisory, Pharmacy and Therapeutic Committee, Medical Executive Committee, Interdisciplinary Policy and Procedure Committee on 11/20/12. Black Box Warning (BBW) policy (See attached policy -- Attachment 5) was amended to include: • When the BBW medication is an anticoagulant intended for therapeutic anticoagulation, a poster stating patient on anticoagulation therapy is to be placed at the head of the bed to alert others of this therapy. • The revised policy was submitted to Nursing Professional Practice Committee on 12/3/12 and approved. Medications --Orders, Administration, Storage and Documentation policy (See attached policy --Attachment 6) was amended to include: • Revisions to Medications Policy to add language regarding appropriate action for nursing communication orders with medications. Added: Policy III 4c. Medication orders (or medication administration instructions) included in electronic Nursing Communication Orders are prohibited and must be clarified with the physician using the telephone/verbal order process. If able to access the Electronic Health Record (EHR), the physician shall enter the specific order directly. The original Nursing Communication Order should be completed/discontinued in the EHR once the specific order is entered. The revised policy was submitted to Nursing Professional Practice Committee on 12/3/12 and approved. Medical Staff Medication Orders Policy (See attached policy --Attachment 7) was revised to clarify use of nursing communication order. • The electronic "Nursing Communication Order" is used to communicate single instructions to the nurse/care team (e.g., Nasogastric (NG) tube okay to use; central line ok to use; bronchoscopy scheduled for 1300). Orders entered using a Nursing Communication Order for which there are specific electronic orders (e.g. titrating or ordering medications, labs, diets or other treatments) are prohibited and require use of the specific electronic order. • The revised policy was submitted to Nursing Professional Practice Committee on 12/3/12 and approved.	

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	followed Medical Staff Bylaws, rules and regulations. MD 1 directed PA 1 to perform the removal of the epidural catheter on Patient 1 for which neither was privileged to perform. The removal of the epidural catheter while Patient 1 was on Lovenox led to the patient developing an epidural hematoma, removal of the epidural hematoma and paraplegia. Subsequently this necessitated a surgical procedure to remove the hematoma. This resulted in the patient developing paraplegia (loss of sensation and ability to voluntarily move from the waist down). The failure to ensure medical staff followed and implemented Medical Staff Bylaws policies and procedures led to the licensee's noncompliance with one or more requirements of licensure and caused, or are likely to cause, serious injury or death to the patient. The above facility failures may result in an Administrative Penalty. 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. 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).		Staff received education on the policy changes through Patient Safety Alerts, practice change updates in each shift report, and unit postings. On 11/27/12 Nursing, Peer Review, Medical Staff Office, Quality and Risk Management began providing mandatory education to clinical staff members on their responsibility in verifying the privileges of physicians and AHPs as well as resident physician competencies for procedures performed. The education also included the chain of command and patient consent process. Education is mandatory for all Registered Nurses (RN) and Respiratory Care Practitioners (RCP) currently working. All RN's and RCP's on medical leave will receive the education prior to their first shift of work. As of 12/31/12, 1,722 staff have received education for a current compliance rate of 89%. Classes were completed by 1/21/13 with 100% compliance. (See attached curriculum) 12/3/12 A medical staff committee was formed which includes representatives from Medical Staff and Operational leadership. The committee will provide facility-based oversight, focusing on identification and resolution of clinical practice, quality, patient safety, and regulatory compliance issues. The Committee will report to the Quality Council, Facility Executive Advisory Committee and to Medical Executive Committee. In January 2013 the Medical Staff newsletter Physician Edition will implement a new informational series; "Are You Aware?" describing Community Medical Centers Bylaws, Rules and Regulations and other Medical Staff policies for ongoing physician education. **2. The title of position of the person responsible for correction** President of Medical Staff and Chief Quality Officer	

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	followed Medical Staff Bylaws, rules and regulations. MD 1 directed PA 1 to perform the removal of the epidural catheter on Patient 1 for which neither was privileged to perform. The removal of the epidural catheter while Patient 1 was on Lovenox led to the patient developing an epidural hematoma, removal of the epidural hematoma and paraplegia. Subsequently this necessitated a surgical procedure to remove the hematoma. This resulted in the patient developing paraplegia (loss of sensation and ability to voluntarily move from the waist down). The failure to ensure medical staff followed and implemented Medical Staff Bylaws policies and procedures led to the licensee's noncompliance with one or more requirements of licensure and caused, or are likely to cause, serious injury or death to the patient. The above facility failures may result in an Administrative Penalty. 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. 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).		Three-time-weekly audits were performed 12/22/12 through 1/4/13 achieving compliance results between 96% to 100%. Based on these results, once weekly audits will be performed January through March 2013 with an expected goal compliance of 100 % with a threshold of 95%. Findings of non-compliance with assessments have been addressed through education to all pharmacy staff. Continued non-compliance will result in individual counseling and disciplinary action. Results will be reported monthly by the Director of Pharmacy to QPSC with action plans for compliance rate less than expected at 100%. On 11/12/12 a random review of epidural catheter insertions and removals for 2009, 2010 and 2011 was completed by Peer Review staff and revealed no further outliers. On 11/12/12 1,475 patient records were reviewed by Quality and Patient Safety Staff for appropriate privileging for Central Line, Arterial Line, and Chest tube insertion and removal procedures performed in October 2012. One outlier was identified and reported to Peer Review and the Fresno office of CDPH. 11/12/12 Patient Safety Nurse identified 458 neurosurgery patient records for 2012. Ten percent were randomly selected for review of procedural privileges for AHP and/ or physicians with 100% compliance from 1/1/2012 through 11/12/12. Audit results will be reported to QPSC in January 2013. Starting 11/14/12 Nursing Managers performed observational reviews on all patients with epidural catheters to ensure orange stickers were in place on the dressings through 12/31/12 with 100% compliance. On 11/15/12 a thorough review and analysis of the Epidural Policy and computerized education was performed by Nursing and Peer Review. This review identified a practice gap for patients receiving anti-coagulant therapy during the insertion and/or removal of an Epidural Catheter.	

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 _____	11/26/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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