

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050567	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/28/2011
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NAME OF PROVIDER OR SUPPLIER MISSION HOSPITAL REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 27700 Medical Center Rd, Mission Viejo, CA 92691-6426 ORANGE COUNTY
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00253352 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 06793, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>The following reflects the findings of the California Department of Public Health during the investigation of COMPLAINT NO: CA00253352.</p> <p>Inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility.</p> <p>Representing the California Department of Public Health: 06793 HFEN</p> <p>Health and Safety Code Section 1280.1 (c): For the purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of</p>		<p>Immediate Jeopardy Response 2567</p> <p>a) HOW THE CORRECTION WILL BE ACCOMPLISHED, BOTH TEMPORARILY AND PERMANENTLY</p> <ul style="list-style-type: none"> • Proper marking of surgical sites with emphasis on spinal level marking was reviewed with all nursing staff including the nurse directly involved. • A customized Crew Resource Management program presented by Safer Healthcare Inc. was completed on both Mission Hospital Campus Locations. The Crew Resource Management program is an integrated training, process improvement and management system that uses all available resources including people, process and technology to enhance safety and operational efficiency. All levels of staff including Physicians and Anesthesiologists were required to attend. • Crew Resource Management (CRM) implementation entered Phase II where on site coaching of the CRM skill set and a train the trainer program was conducted the week of July 5-8, 2011. 	
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Event ID:NDLF11

6/13/2012

3:48:02PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Jan Brewer Wright QI July 2, 2012

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	<p>Continued From page 1</p> <p>licensure has caused, or is likely to cause, serious injury or death to the patient.</p> <p>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."</p> <p>The CDPH verified that the facility informed the patient or party responsible for the patient of the adverse event by the time the report was made.</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</p> <p>T22 DIV 5 CH1 ART3 - 70223 (b) (2) A committee of the medical staff shall be assigned responsibility for: 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.</p> <p>The above regulation was NOT met as evidenced by:</p> <p>Based on medical record review, staff interview, and review of the facility's policies and procedures (P&P), the facility failed to ensure implementation of the P&P for reducing the risk of wrong site surgery. This failure resulted in a second extensive surgery at the correct site for the patient.</p>		<ul style="list-style-type: none"> The PreAdmit Testing Department of Perioperative Services now works closely with our Physicians offices to ensure that the latest radiology studies are available for viewing and site confirmation in our Pre Operative Holding area and for display and viewing in the Operative Suite. The Pre Admit Registered Nurse is critically evaluating the body of Radiology reports to ensure that are in alignment with the diagnosis and consented procedure. All of our Operative Suites have been outfitted with a Picture Archiving Communications System (PACS). This system allows for the quality visualization of any historical radiology studies and used in conjunction with real time imaging to verify appropriate spinal level. Random audits are conducted daily to verify that the Surgical Time Out is being conducted according to our established policy. Any observed deviation is immediately corrected. The Surgical Services Department's Leadership Council has created Briefing Checklists for both the Circulating RN and Scrub personnel to be performed after the Surgical Time Out is conducted. 		

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(X6) DATE

Jan Brewer, Director of I *July 2, 2012*

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	<p>Continued From page 2</p> <p>Findings:</p> <p>Review of the facility's P&P "Reducing wrong site, wrong procedure, or wrong person surgery" revealed the directive that the procedural/operative site/side should be marked in all cases involving right/left side distinction, multiple structures (for example, fingers, toes), or multiple levels (for example, the spine), whether the surgery/procedure was performed in the OR (Operating Room) or the non-OR setting. The P&P stated the mark must be positioned so that it was visible after the patient was prepped and draped. In spinal surgery, the general level of the procedure (cervical, thoracic, or lumbar vertebrae) must be marked preoperatively. Intra-operatively, prior to incision, the surgeon performing the procedure should mark the exact inter space to be operated on using the standard intraoperative radiographic (x-ray) marking techniques.</p> <p>The P&P also cited responsibilities of the physician performing the surgery/procedure included "marking the site preoperatively" and "Read and interpret the radiographic films to be used during the procedure and confirm that the films have been placed correctly for the correct patient." The P&P stated the Preoperative nurse would chart in the patient's record that the site was marked by the surgeon and that, if applicable, staff would verify that x-ray films were in the procedure suite, correctly labeled, and displayed.</p> <p>On █10, Patient 1 was seen by the surgeon in the surgeon's office. The surgeon documented</p>		<ul style="list-style-type: none">• Efforts were focused on three domains: individual behavior, institutional culture, and technology to put in place the process, framework, and technology to prevent a wrong site, wrong spinal level or wrong patient event from occurring within our Operating Rooms.b) TITLE/POSITION PERSON RESPONSIBLE FOR THE CORRECTION Director of Surgical Servicesc) MONITORING Audits (all surgeries) were conducted related to availability of x-rays, proper site marking, and adherence to universal protocol guidelines. Audits were continued until three consecutive months of 90+% compliance was completed. (Dec 30, 2011).d) CORRECTIVE ACTION COMPLETION Corrective actions were completed by July 27, 2011 with monitoring continuing as described.	<p>July 27, 2011</p>
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE <i>Director PI</i>	(X8) DATE <i>July 2, 2012</i>
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	<p>Continued From page 3</p> <p>Patient 1 had a severe degenerative scoliosis (curvature of the spine) with stenosis (an abnormal narrowing of the spinal canal) most marked at lumbar (lower back) vertebrae L2-3 and L3-4. Patient 1 was no longer responding to epidural injections (pain medication injected into the epidural space along the spinal column) and, despite her age of 85, was going to require surgical intervention.</p> <p>Medical record review showed Patient 1 was admitted to the hospital on [REDACTED] 10. The physician's admission history and physical examination report dated [REDACTED] 10, showed Patient 1 had severe spinal stenosis at L2-3 and L3-4 and to a lesser degree at L1-2.</p> <p>Medical record review showed that on [REDACTED]/10, Patient 1 signed consent for surgery for interbody fusion (surgery to prevent the spine from bending) at L2-3 and L3-4. The anesthesia record, the PACU (Post Anesthesia Care Unit) record, the original operative report, and the physician's postoperative progress notes, each referenced surgery at the L2-3 and L3-4 levels. A lumbar spine x-ray taken while the patient was in the PACU showed interbody bone blocks (implants that are filled with bone and placed between and around certain segments of the adjacent vertebrae) placed at the L1 and L2 interspaces.</p> <p>During an interview with the facility's Risk Analyst on 6/15/11, and review of the facility's investigatory documentation showed there was an x-ray available to mark the site of the site for the surgery; however,</p>			
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>[Signature]</i>	TITLE QI	(X6) DATE July 2, 2012

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	<p>Continued From page 4</p> <p>there were no films in the operating room during the surgery. Staff stated the C-arm (fluoroscopy, a type of x-ray used during the surgery) image is very small and would show only spaces between two vertebrae; the view would not allow for the inclusion of any anatomical landmarks that would help define the correct spinal level. Staff also stated during the facility's investigation, it was determined the surgeon had not marked the skin at the surgical site preoperatively and had not read the radiologist's report of the post operative x-ray of the spine. The surgeon reviewed the post-op x-ray himself, instead. Based on the information, the physician and surgical staff failed to ensure Patient 1's surgical site was marked and that x-rays were available in the operating room according to the facility's P&P to prevent wrong site surgeries.</p> <p>Patient 1 was transferred to a skilled nursing facility on [REDACTED] 10. On Patient 1's discharge, there was no documented evidence the surgeon was aware he had performed the surgery at a level not consistent with Patient 1's consent.</p> <p>Patient 1 had to return to the hospital on [REDACTED] 10 because of increasing pain in her back and lower extremities. Medical record review for the [REDACTED] 10 admission showed a second opinion neurology consult, dated [REDACTED] 10, stating that on [REDACTED] 10, Patient 1 had been scheduled for an extreme lumbar interbody fusion at L2-3, L3-4; however, it appeared the surgery was actually performed at L1-3 and Patient 1 continued to have L3-4 stenosis and spondylolithesis (when a bone in the back (vertebra) slides forward over the bone below it). The</p>			

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Jan Brewer *Wheat* *PI* *July 2, 2012*

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	<p>Continued From page 5</p> <p>neurologist recommended L3-L4 posterior decompression interbody fusion.</p> <p>During an interview on 6/15/11, the Risk Analyst stated the surgeon was not aware he had performed surgery at the wrong site until the neurologist provided the consultation on [REDACTED] 10. On [REDACTED] 10, Patient 1 had to undergo a decompression laminectomy (a surgical procedure requiring cutting into the back to remove bone from the vertebrae and/or thickened tissue that is narrowing the spinal canal and squeezing the spinal cord and nerve roots) of L3-4 and possibly L2-3, and fusion of the lumbar spine at L1-L5 under general anesthesia.</p> <p>The facility's failure to ensure implementation of their P&P to reduce the risk of wrong site surgery 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 Section 1280.1(c).</p> <p>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).</p>				

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