

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  06/15/2011
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 CA00245251 - 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>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 the 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</p>		<p>a. Corrective actions</p> <ul style="list-style-type: none"> <li>Education Department completed focused one on one reviews of Hospital's Policy to prevent retained foreign bodies with all Operating Room staff. A mock surgical field was set up and policy review and discussion, demonstration, and repeat demonstration performed. All staff signed an attestation that they understood and will follow the policy that was reviewed with them.</li> <li>Erasable white boards are used in each OR suite to document the presence of all sponges and miscellaneous items used in a surgical case that are present on the sterile surgical field.</li> </ul>	2012 AUG 17 AM 11 27

Event ID CEVI11

7/27/2012

12 13 43PM

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

TITLE

(X6) DATE

*[Signature]* DIRECTOR QI 8-15-2012

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*Reviewed  
8/15/12  
06793  
(SF)*

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	<p><b>Continued From page 1</b></p> <p>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, the facility failed to ensure implementation of established policies addressing sponge counts for surgical procedures. A retained surgical sponge after a major surgical procedure caused the patient to be subjected to the risks of a second major surgery and general anesthesia for the removal of the retained sponge.</p> <p>Findings.</p> <p>Review of the policy "Counts Sponges, Sharps, Instruments, and Miscellaneous" showed the directive that sponges, sharps, and miscellaneous items must be counted and documented prior to incision, before closure of a cavity within a cavity, before wound closure begins, and at skin closure or at the end of the procedure.</p> <p>Review of Patient 1's medical record showed an Intraoperative Nursing Record documenting Patient 1 had undergone a coronary artery bypass surgical procedure (a surgical procedure in which one or more blocked coronary arteries are bypassed by a blood vessel graft to restore normal blood flow to</p>		<ul style="list-style-type: none"> <li>• Clear plastic pocketed panels are used on all surgical cases to separate and hold sponges of any type or size to assist in the visual verification of items removed from the sterile surgical field and to aid in the performance of a surgical count.</li> <li>• All surgical cases of 3 hours in length or less are completed by the same Perioperative staff that started the case. This practice was put in place to minimize the number of Perioperative staff involved in a surgical procedure.</li> <li>• A customized Crew Resource Management program presented by Safer Healthcare Inc. was completed at both Mission Hospital Campus Locations. The Crew Resource Management program is an integrated training, process improvement and</li> </ul>	<p>2012 AUG 17 AM 11 27</p>

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*[Signature]* Director of QI *8-15-2012*

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	<p><b>Continued From page 2</b></p> <p>the heart) on █10 On the Intraoperative Nursing Record, the nurse documented the "initial," "additional," and "final" sponge counts as correct</p> <p>In the Discharge Summary, the physician documented that at the end of the coronary artery bypass surgical procedure the sponge, needle, and instrument counts were correct However, on █10, a chest x-ray performed on Patient 1 showed "opacities" (an area that the x-ray light cannot pass through) and a Computed Tomography (CT) scan (a medical imaging procedure that utilizes computer-processed x-rays) confirmed a foreign object</p> <p>Patient 1 and Patient 1's family member were informed of the retained foreign object on █10</p> <p>During interview on 6/15/11, the Clinical Coordinator of Cardiovascular Surgery disclosed that possibly after the last count the surgeon had taken a sponge off the instrument table and inadvertently left the sponge in the cavity The Clinical Coordinator stated the operating room staff had felt "pressured" because the next case was due and the final count was done prematurely before the cavity was closed</p> <p>On █10, Patient 1 was returned to the facility for the second surgery under general anesthesia A thoracotomy (a surgical incision made in the chest wall) was performed. A surgical sponge was found in the pericardial cavity (a hollow space between the outer lining of the heart and the heart) and was removed Patient 1 was discharged on █10, in stable condition to continue treatment at a</p>		<p>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.</p> <ul style="list-style-type: none"> <li>• Crew Resource Management (CRM) implementation then entered Phase II where on site coaching of the CRM skill set and a train the trainer program began the week of July 5-8, 2011.</li> <li>• All lap sponges and raytec (4 x 4) sponges used in the Operating Room have been replaced with radio frequency tagged sponges provided by RF Surgical Inc. All custom case packs have the RF product in place. A special mat is in place on all Operating Room tables that works in conjunction with a scanning "wand" to detect the presence of any RF tagged</li> </ul>	<p>2012 AUG 17 AM 11 27</p>	

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	<p><b>Continued From page 3</b></p> <p>Rehabilitation Unit</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>		<p>sponge. All staff were in-serviced on the use of the product and the scanning is done on all surgical cases where sponges of any type are used.</p> <ul style="list-style-type: none"> <li>• The Surgery Department and the Leadership, Education, and Practice councils worked together to develop and implement standard work practices surrounding surgical case set up, communication, hand-off and the performance of surgical counts.</li> <li>b. Director, Surgical Services</li> <li>c. Monitoring processes</li> <li>• Random audits of the counting practice are conducted daily along with the surgical time out and any observed deviation is corrected on the spot. The audits from July-October 2011 demonstrated</li> </ul>	

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*Carl Brewer* DIRECTOR QI 8-15-2012

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