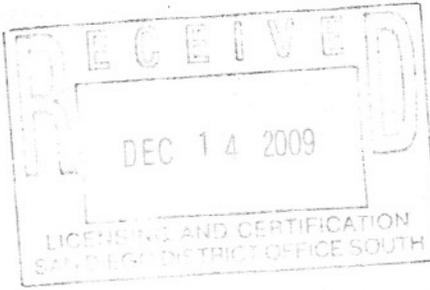


CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  060077	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED
NAME OF PROVIDER OR SUPPLIER <b>SCRIPPS MERCY HOSPITAL</b>		STREET ADDRESS, CITY, STATE, ZIP CODE 4077 FIFTH AVENUE, SAN DIEGO, CA 92103 SAN DIEGO COUNTY		
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	<p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident # 190528.</p> <p>Representing the California Department of Public Health: [REDACTED] HFEN</p> <p>1280.1(c) Health and Safety Code Section, 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>Title 22 Surgical Service General Requirements</p> <p>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>Based on observation, interview, and record review the facility failed to ensure that it's policy and procedure pertaining to surgical counts was implemented when a surgical sponge was retained in the abdomen of Patient 1 following a radical abdominal hysterectomy procedure (surgical removal of female reproductive organs and lymph nodes). As a result, approximately one and a half (1 1/2) years following her radical abdominal</p>		 <p><b>PLAN OF CORRECTION:</b> The hospital will ensure that it's policy and procedure pertaining to surgical counts will be implemented.</p>	

Event ID: 12/1/2009 1:49:06PM

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

*Kathy Seneff*

TITLE

*Director Risk*

(X6) DATE

*12-14-09*

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NAME OF PROVIDER OR SUPPLIER <b>SCRIPPS MERCY HOSPITAL</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>4077 FIFTH AVENUE, SAN DIEGO, CA 92103 SAN DIEGO COUNTY</b>
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	<p><b>Continued From page 1</b></p> <p>hysterectomy surgery, Patient 1 required a second surgical operation to remove a retained 4 inch by 4 inch surgical sponge from her abdominal/pelvic cavity.</p> <p>Findings:</p> <p>A clinical record review was initiated at Facility A on 6/4/09 at 2:30 P.M. Patient 1 was admitted to Facility A on 12/10/07 with a diagnosis of cervical cancer per the face sheet. Per a History and Physical dated 12/10/07, the patient had not undergone any previous abdominal surgeries. On 12/10/07, Patient 1 underwent a radical abdominal hysterectomy, bilateral salpingo-oophorectomy (removal of both ovaries and tubes), and pelvic lymph node dissection, according to an Operating Room (OR) Memoranda dated 12/10/07. Per that same document, the surgeon who performed the procedure was Medical Doctor (MD) 1. Per the OR Memoranda, three separate surgical counts of sponges, which included a baseline count prior to the procedure, a count at the beginning of wound closure, and a final count at skin closure, were performed by Scrub Technician 1 (ST, a technician who participates in a sterile surgical operation, prepares sterile supplies and passes them to the surgeon, assisting the surgeon during the procedure, accounting for needles, sharps, sponges and other supplies used during the operation) and LN 1. LN 1 documented that all 3 sponge counts were correct.</p> <p>Per an Operative Report dated 12/10/07, MD 1 documented that "sponge and laparotomy (larger</p>		<p>All O.R. nurses and scrub technicians have been educated on the policy requirements related to counts.</p> <p>All employees involved in this case have been individually counseled.</p> <p>1:1 education for all nurses and scrub technicians has occurred related to separating the sponges as they are counted.</p> <p>Housekeeping staff have been educated to remove all red bags in operating suites between cases.</p> <p><u>Responsible person:</u> Administrative Director, Surgical Services <u>Timeline:</u> 6/15/09 – 7/17/09</p> <p><u>Audit/Monitor:</u> following education, the O.R. Safety Officer from Scripps La Jolla independently audited several Mercy San Diego cases to ensure compliance with the Plan of Correction <u>Timeline:</u> 7/20/09 – 7/24/09</p> <p>An audit of all surgical cases related to complete and accurate Counts and</p>	
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Event ID:	12/1/2009	1:49:06PM	Recording of actions taken, if the count is not correct is occurring.	(X6) DATE
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			Timeline: 11/3/09 – 12/31/09	

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	<p><b>Continued From page 2</b></p> <p>type of sponge used in surgical procedures) count were noted to be correct."</p> <p>On 6/12/09 at 9:00 A.M., a clinical record review was initiated at Facility B, where Patient 1 was admitted on 6/8/09.</p> <p>Per a Preoperative History and Physical (H&amp;P) dated 6/8/09, MD 2 documented that Patient 1 had undergone a radical hysterectomy by MD 1 at Facility A on 12/10/07. MD 2 documented, "at the time of a follow-up Magnetic Resonance Imaging (MRI) scan (specialized X-Ray) on 12/22/08 (more than 1 year after Patient 1's hysterectomy procedure), the radiologist reported a "mass" that was possibly a "foreign body." That finding was reported to the patient's oncologist (cancer doctor). The only abdominal operation Patient 1 had undergone up to that date was the radical hysterectomy at Facility A, on 12/10/07. Per the H&amp;P, Patient 1 continued to have hip and back pain, and a second abdominal operation was performed in February of 2009 to search for the foreign body, but no foreign body was found at that time. A subsequent abdominal X-ray report, dated 5/5/09, and surgical procedure report, dated 5/12/09, at Facility B, continued to document the presence of a foreign body in Patient 1's pelvis.</p> <p>Per the Preoperative H&amp;P dated 6/8/09, Patient 1 had what appeared to be a retained sponge in her abdomen, and prior to receiving further chemotherapy, her oncologist recommended removal of the sponge.</p>			
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Event ID: 12/1/2009 1:49:06PM

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

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	<p><b>Continued From page 3</b></p> <p>Per an Operative Report dated 6/8/09, Patient 1 underwent a third abdominal operation by MD 2 at Facility B, on 6/8/09, for the removal of a retained 4 inch by 4 inch sponge from the left side of the patient's pelvis. The sponge was found and successfully removed.</p> <p>On 6/25/09 at 8:30 A.M., an interview was conducted with MD 1. MD 1 confirmed that he did not have an assistant surgeon for Patient 1's radical hysterectomy performed on 12/10/07 at Facility A. MD 1 stated that he remembered the case well. Per MD 1, he was informed by the nurse circulator that all of the surgical counts were correct, and he relied on that information to be accurate.</p> <p>On 7/1/09 at 1:30 P.M., an interview was conducted with LN 1, the nurse circulator. Per LN 1, she did not recall anything about Patient 1's radical hysterectomy procedure on 12/10/07, or the surgeon, because so much time had elapsed. LN 1 was unable to offer any explanation as to how the sponge was left in the patient, when all of the counts had been documented as "correct," per the OR Memoranda.</p> <p>On 7/1/09 at 2:30 P.M., an interview was conducted with ST 1. ST 1 also did not remember Patient 1's surgical procedure on 12/10/07. ST 1 was unable to verbalize how a sponge could have been left in Patient 1 when all of the surgical counts had been documented as correct. ST 1 stated that perhaps a sponge was left over in a receptacle bucket from a previous case. According to ST 1, if staff unknowingly started Patient 1's procedure with</p>			

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	<p><b>Continued From page 4</b></p> <p>an extra sponge in the room, then a sponge could be retained in the patient, and the count would still come out as "correct" at the end of the case. When asked who was responsible for ensuring that all sponge buckets were appropriately cleaned and emptied prior to beginning another surgical procedure, ST 1 replied that housekeeping staff was responsible.</p> <p>Facility A's policy and procedure, dated 5/06, and entitled "Counts: Intraoperative Sponge, Sharps, Instruments, and Accessories" was reviewed. The purpose of the policy was to ensure safe practice and surgical team accountability for items placed on the sterile field, for use during a surgical procedure when the depth and location of the surgical wound was such that an item could be retained in the patient. Section III of the policy documented that the policy applied to "scrub personnel." Per the policy, all counts were to be audible and visualized by both the scrub personnel and the nurse circulator (the nurse circulator is responsible for managing the nursing care of the patient within the OR and coordinating the needs of the surgical team with other care providers necessary for completion of surgery). The scrub personnel/scrub technician was responsible for maintaining an accurate count of items on the sterile field. Per the policy, sponges were to be separated as they were counted. In addition, the policy documented that the operating room suite would be cleaned and inspected for any remaining counted items from the previous case before another patient could enter the room. The policy did not document that housekeeping staff was</p>			

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	<p><b>Continued From page 5</b></p> <p>responsible for ensuring that all counted items from the previous case were removed before another patient entered the room.</p> <p>On 7/1/09 at 3:15 P.M., an interview was conducted with the Administrative Director of the OR (ADOR). Per the ADOR, because so much time had elapsed since Patient 1's surgery, it was difficult to determine what may have contributed to the sponge being retained. However, as a result of the facility's own investigation, it was determined that the involved OR staff was not consistent in sponge counting practices and techniques, which was not in accordance with the facility's policy and procedure.</p> <p>The facility failed to implement its policy and procedure pertaining to surgical counts when a licensed nurse circulator and a scrub technician failed to maintain accountability for all counted items on the sterile field or in the OR suite in general. In addition, the facility failed to ensure that OR staff implemented consistent counting practices of surgical sponges.</p> <p>These violations resulted in injury and harm to Patient 1 when she required a third surgical operation to remove a retained 4 inch by 4 inch surgical sponge from her abdominal/pelvic cavity, approximately one and a half (1 1/2) years following her radical hysterectomy procedure.</p> <p>On 7/2/09 at 3:30 P.M., the Director of Risk Management was informed that the violation of the retention of a foreign object in a patient may result</p>			

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	<p><b>Continued From page 6</b> in an Adverse Penalty.</p> <p>The facility's failure to implement its policy and procedure pertaining to surgical counts and failed to ensure that OR staff implemented consistent counting practices of surgical sponges, 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>			

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