

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER <b>Sharp Memorial Hospital</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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
	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00424919 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 28183, 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 1280.3(g): 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 &amp; Safety Code Section 1279.1 (a)</p> <p>(a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.</p> <p>Health &amp; Safety Code Section 1279.1 (b)(1)(D)</p>		<p style="text-align: center;"><b>RECEIVED</b> <b>CA DEPT OF PUBLIC HEALTH</b></p> <p style="text-align: center;"><b>FEB 13 2017</b></p> <p style="text-align: center;"><b>LICENSING &amp; CERTIFICATION</b> <b>SAN DIEGO NORTH DISTRICT OFFICE</b></p>	

Event ID: OIGF11

2/1/2017

11:44:01AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Jan M. Eng* TITLE: *Director, Regulatory Affairs* (X6) DATE: *2/8/17*

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s) 1 thru 7*

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.

*Acceptable POC*  
*Juan HFEN 2/14/17*

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  060100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER Sharp Memorial Hospital			STREET ADDRESS, CITY, STATE, ZIP CODE 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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	
	<p>(b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.</p> <p>Health and Safety Code Section 1279.1 (c)</p> <p>(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>Health and Safety Code Section 1280.3 (g)</p> <p>(g) 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 General Acute Care Hospitals - 70223(b)(2) Surgical Service General Requirements</p> <p>(b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation</p>				

Event ID:OIGF11

2/1/2017

11:44:01AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  060100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER  Sharp Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSG IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	<p>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 interview and record review, the hospital failed to ensure that Operating Room staff implemented the hospital's policy and procedure (P&amp;Ps) for accounting for a complete count of lap sponges (gauze material used to absorb body fluid during surgery) used on Patient A during surgery on 10/8/14. This failure resulted in an 18 inch by 18 inch lap sponge being left undetected in Patient A's abdominal cavity for a period of eleven weeks, requiring an additional surgery, which included the removal of scar tissue, right fallopian tube, and part of colon.</p> <p>Findings:</p> <p>Patient A was admitted to the hospital on 10/8/14 for pre-term labor at 32 weeks gestation. The patient underwent a repeat C-section (Caesarean section - surgery to deliver a baby through incisions in the mother's abdomen and uterus after past delivery by C-section) by MD 1 with uneventful delivery of infant. Patient A was then discharged home on 10/12/14 with instructions to schedule postpartum follow up at 6 weeks.</p> <p>The clinical record was initially reviewed on</p>		<p>A1. Immediate corrective steps included the following:</p> <p>a) Communication of the event, and review of SHC Intraoperative Count policy and expectations to SMBHWN OR staff members commenced via daily huddles, morning and afternoon reports.</p> <p>b) Count audits commenced for all cesarean section cases to ensure compliance with policy.</p> <p>c) Count audits commenced for all cases to ensure compliance with policy.</p> <p>d) Mandatory education and competency training for all surgical personnel involved with counts was completed.</p> <p>A2. Practice changes were evaluated and implemented based on review of the literature and evidence based practice included:</p> <p>a) Loading of the Sponge Accounting System from the bottom up and horizontally with radiopaque tape showing,</p> <p>b) Use of visual reminders (signage),</p> <p>c) Lining the kick bucket with a clear plastic bag vs. red biohazardous bag to allow for easier visualization of contents, and</p> <p>d) Confirmation prior to the start and at end of case that the kick bucket is empty.</p> <p>e) Staff were provided access to view a video on the Sponge Accounting System as well.</p> <p>A3. Continued refinement of the sponge count safety process included:</p> <p>a) Purchase of new adjustable IV poles with improved layout for Sponge Accounting System visualization, and</p> <p>b) Continued refinement and implementation of specific OR whiteboard standardized documentation.</p> <p>A4. Radiofrequency (RF) technology was trialed, purchased and fully implemented at SMBHWN.</p>	<p>12/26/14</p> <p>12/26/14</p> <p>12/30/14</p> <p>1/19/15</p> <p>2/1/15</p> <p>1/12/15</p> <p>4/15/15</p> <p>7/21/15</p>

Event ID:0IGF11

2/1/2017

11:44:01AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER Sharp Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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)	(X6) COMPLETE DATE
	<p>12/29/14. According to the ED (Emergency Department) note, dated 12/21/14, Patient A was brought in by medics for fever, pain and foul-smelling discharge from abdominal incision site. The patient was admitted with postoperative wound infection and had the wound opened, irrigated and packed.</p> <p>On 12/24/14, the patient had an MRI (Magnetic Resonance Imaging) done to assess an abscess within the abdomen. According to the MRI report, "The right lower quadrant abscess contains a foreign body which likely represents a retained sponge." A CT (CAT scan - Computerized Axial Tomography - an x-ray image of the body) was done to further assess the area, and also identified "a foreign body likely representing retained surgical foreign body such as a surgical sponge."</p> <p>On 12/24/14 Patient A was taken to the OR later that evening for exploratory laparotomy and removal of retained foreign body. The surgery also included lysis of adhesions (removal of scar tissue), right hemicolectomy with ileocolonic anastomosis (removal of right side of colon with joining of small intestine and remaining colon), partial omentectomy (partial removal of thin fold of abdominal tissue that encases the stomach, large intestine and other abdominal organs), and right salpingectomy (removal of fallopian tube) and lasted 4 hours and 24 minutes. According to the operative report, "The foreign body comprised of a blue plastic-like strip attached to clot-like material drenched in purulent fluid and it appeared to be in the process of being degraded."</p>		<p>Monitoring:</p> <ol style="list-style-type: none"> <li>1. Observational audits of the count process were conducted weekly x 4 weeks to verify that the preop, intraoperative and final counts were conducted following SHC policy and SMBHWN standardized practice.</li> <li>2. Observational audits were conducted weekly x 4 weeks to verify modifications adopted related to the kick bucket (use of clear plastic bag and verification that bucket is empty prior to initial count).</li> <li>3. An audit survey (initial, 3-month and 9 month subsequently) was conducted of OR RN and scrub staff to verify intraop communication related to sponges occurred and was documented on the whiteboards.</li> </ol> <p>Any instances of noncompliance noted during audit activity were addressed via the just culture/corrective action process. Results were incorporated into the Quality Assurance Program.</p> <p>Responsible Party: OR Director</p>	<p>2/1/15</p> <p>2/1/15</p> <p>3/31/15, 6/30/15, 12/31/15</p>

Event ID:0IGF11

2/1/2017

11:44:01AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER Sharp Memorial Hospital			STREET ADDRESS, CITY, STATE, ZIP CODE 7001 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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)	(X6) COMPLETE DATE	
	<p>On 1/3/15 the patient was discharged from the hospital.</p> <p>On 3/5/15 at 2:30 P.M., during an interview with the Circulating Nurse (RN 1), she stated that the C-section pack includes 4 bundles of 5 lap sponges each, for a total of 20 lap sponges. RN 1 and the Scrub Tech (ST 1) count the individual sponges with Patient A in the OR. Per RN 1, documentation does not indicate if sponges were added to the case, but the patient would not have left the OR if counts were incorrect. RN 1 acknowledged that if all counts were done correctly, the patient would not have a RFO (retained foreign object).</p> <p>On 3/18/15 at 1 P.M., ST 1 stated during an interview that lap sponges were counted three separate times after the initial count. ST 1 stated if counts were incorrect, the RN circulator and scrub tech "would let MD know count is off and stop closure." MD 1 no longer works at the facility and was unavailable for interview.</p> <p>According to the facility's policy, Intraoperative Counts, dated 12/13, Section III, TEXT, A. Dual Responsibilities "1. Sponge, sharp, miscellaneous items and instrument counts are the dual responsibility of the scrub person and the RN Circulator with full accountability for the process. 2. The RN Circulator and scrub person will conduct a systematic and accurate accounting of all counted items. This is important to help prevent patient injury as a result of a foreign body." Then, Section</p>				

Event ID:0IGF11

2/1/2017

11:44:01AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER Sharp Memorial Hospital		STREET ADDRESS, CITY, STATE, ZIP CODE 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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
	<p>III. B. RN Circulator Responsibilities, "Maintain an accurate ongoing count tally sheet/board of added items to the sterile field."</p> <p>The policy further indicates under Section III, D. General Count Considerations, "4. An initial count shall be conducted prior to the incision or procedure to establish a baseline... 6. When additional counted items are added to the sterile field, those items will be counted and added to the running count tally on the white board... E. Subsequent/Additional Counts shall be taken: 1. Before closure of a hollow organ or cavity within a cavity...2. Before cavity or wound closure begins... 3. At skin closure of each incision or end of each procedure..."</p> <p>The policy further indicates, under I. Sponges and Other Miscellaneous Items, "5. Soiled sponges should be fully opened, counted and then placed in plastic counting/viewing bags with opaque backs designed for that purpose, and remain available for viewing until the final counts have been conducted."</p> <p>The facility failed to follow their policy and procedure as it related to counting the lap sponges in the OR. The lap sponge left in Patient A's abdominal cavity was not correctly accounted for pursuant to the facility's policy on Intraoperative Counts. The practice is to keep the running count tally on the white board in the OR. The white board is erased after surgery and is not part of the patient's medical record.</p>			

Event ID:0IGF11

2/1/2017

11:44:01AM

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  060100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  01/31/2017
NAME OF PROVIDER OR SUPPLIER  Sharp Memorial Hospital			STREET ADDRESS, CITY, STATE, ZIP CODE 7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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	
	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 1280.3(g).				

Event ID: OIGF11

2/1/2017

11:44:01AM