California Department of Public Health

POC accepted N. Williams 7/5/12

HEALTH FACILITIES INSPECTION DIVISION ADMINISTRATION
2012 JUL -3 PM 3:49
RECEIVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000096	A. BUILDING _____ B. WING _____	C 08/24/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
METHODIST HOSPITAL OF SOUTHERN CA	300 W HUNTINGTON DR ARCADIA, CA 91006

(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
E 000	Initial Comments The following reflects the findings of the Department of Public Health during an entity reported incident investigation. Intake Number: CA00240013 - Substantiated The inspection was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: [redacted] RN, HFEN 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 likely to cause, serious injury or death to the patient.	E 000	Preparation and submission of this plan of Correction does not constitute an admission or agreement by Methodist Hospital of Southern California (the "Hospital") of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies. The Hospital is submitting this Plan of Correction as required by state and/or federal regulations. This Plan of Correction documents the actions by the Hospital to address the alleged deficiencies. This Plan of Correction constitutes credible evidence of compliance with the cited regulations. E264 – 22 Cal Code Regs § 70213(a) Nursing Service Policies and Procedures & E347 – 22 Cal Code Regs § 70223(b)(2) Surgical Service General Requirements	
E 264	T22 DIV5 CH1 ART3-70213(a) Nursing Service Policies and Procedures. (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. This Statute is not met as evidenced by:	E 264	Immediate Actions taken upon discovery of the retained surgical sponge included: • Patient notified . • Surgical sponge removed using a minimally invasive procedure. • CDPH Report submitted. • Root cause analysis ("RCA") conducted. Findings indicate: (1) The sponge was retained during the second, emergent, procedure, which was performed on March 24, 2010;	[redacted]/10 [redacted]/10 08/12/10 08/12/10
E 347	T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be	E 347		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: COO — (X6) DATE: 6/29/12

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E 347	Continued From page 1 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. This Statute is not met as evidenced by: Based on interviews and record reviews, the facility failed to implement its written policy and procedure on "surgical counts". The facility staff failed to correctly count the surgical sponges used during Patient 1's surgical procedure, which resulted in the retention of a foreign object (RFO). On [redacted] 2010, Patient 1 underwent a cholecystectomy (the removal of the gallbladder) and on [redacted] 2010, the patient returned to the operating room for another surgical procedure due to bleeding. Subsequently, on [redacted] 2010, the patient underwent another surgery for the removal of a retained surgical sponge which adhered to the jejunal wall (small bowel). The repeated surgical procedure placed Patient 1 at risk for possible additional complications, including sepsis (invasion of the body by pathogenic microorganisms and their toxins), small bowel obstruction, and visceral perforation (damage or puncture wounds to the organs), and subjected the patient to general anesthesia. Findings: On August 23, 2011, an unannounced visit was made to the facility to investigate an entity reported incident regarding retention of a foreign object in Patient 1. A review of the face sheet indicated Patient 1 was	E 347	(2) The patient fully recovered from that procedure and was discharged home without symptoms; and (3) Follow-up admissions and ED visits were unrelated to the retained foreign object. • The involved scrub tech and RN demonstrated competency in following the Surgical Count Policy and Procedure. More permanent measures taken included: • Computerized documentation revised to allow for additional counts required in complex cases. Responsible Parties: Director of Surgical Services, Chief Nursing Officer, Manager of Clinical Informatics. • Multidisciplinary group of OR staff members convened to assess and resolve areas of patient safety and vulnerability in the OR. Responsible Parties: Director of Surgical Services and Chief Nursing Officer.	08/12/10 08/30/10 09/08/10 (convened) Ongoing Assessment

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E 347	Continued From page 2 admitted to the facility on [redacted] 2010, with diagnosis of abdominal pain. A review of the Operative Report dated [redacted] 2010, indicated Patient 1 was diagnosed with acute acalculous cholecystitis (inflammation of the gallbladder - muscular sac attached to liver, which stores bile). The operative report indicated Patient 1 underwent the surgical procedure of laparoscopic cholecystectomy (surgical removal of gall bladder). The surgery involved the dissection of a specific portion of the gallbladder that caused significant amount of bleeding, therefore, for better operative results, the surgeon performed an open cholecystectomy (a major, more invasive surgery). The operative report further indicated the findings of a gangrenous cholecystitis (infection, inflammation and edema which lead to the death of tissue in the gallbladder). A review of the Perioperative Chart form dated [redacted], 2010, indicated Patient 1 arrived in the operating room at 5:39 p.m., and departed the operating room at 7:27 p.m.(approximately 2 hours in length for the surgery). The perioperative form under the "staff section" identified a surgeon, an anesthesiologist, scrub tech (ST 1), circulator nurse (RN 1) and the first relief circulator nurse (RN 2). A review of the perioperative form indicated RN 1 prepped the patient and at 6:45 p.m., RN 2 signed into the surgery room. Further review of the "count section" of the perioperative form indicated there were three (3) different circulating nurses (RN 1, RN 2, and RN 3) who performed the counts of the sponges, needles and instruments, not two as previously documented. The counts were documented as correct, however the perioperative form indicated no documentation of	E 347	• Surgical Count Policy and Procedure was revised to better conform to AORN Perioperative Standards. Responsible Party: OR Director • OR inventory of clear plastic bags for sponge counts increased. Responsible Party: Director of Surgical Services and Materials Management • Mandatory in-service of all OR staff on Surgical Count Policy and Procedure • All OR staff read and signed an acknowledgement of the AORN Perioperative Standards and recommended practices and the Surgical County Policy and Procedure. • All staff members demonstrated competence. Responsible Parties: Perioperative Director and OR Manager Monitoring of these measures includes: • Real-time monitoring of sponge counts conducted by the charge nurse or the OR Nurse Manager. Monitoring conducted for 15 cases per month for three months. Monitoring criteria included:	09/08/10 (revised) 01/30/11 (approved) 10/1/10 01/05/11 12/31/10

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E 347	Continued From page 3 a relief nurse between the three nurses. This indicated a discrepancy in the actual staff who were in the operating room during Patient 1's surgery. A review of the nurse's notes dated [redacted] 2010 at 7 a.m., indicated Patient 1's blood pressure was low at 93/62 (normal range 120/80), and had remained low for most of the night (low blood pressure results from reduced blood volume possibly from heavy bleeding). The nurses notes indicated Patient 1 had decreased urine output, was diaphoretic (sweating), the Jackson Pratt (JP) drain (a suction drainage device used to pull excess fluid from the body) had minimal output and the abdominal dressing was re-enforced due to blood drainage leaked to a gown. At 11 a.m., the nurses notes indicated Patient 1 remained hypotensive (low blood pressure), complained of severe abdominal pain, the JP drain did not have any drainage and the abdominal dressing and the pad under the patient were soaked with bloody drainage. A review of the "Operative Report" dated [redacted] 2010 indicated Patient 1 returned to the operating room in an emergent condition for hemostasis (a stoppage of bleeding in part of the body). The preoperative diagnosis was hemorrhagic shock (a life threatening condition where insufficient blood flow reaches the body tissues), status post open cholecystectomy. The operative report indicated Patient 1 received a blood transfusion and that there were some bleeders found against the liver and gallbladder bed. Patient 1 was then placed on a ventilator and transferred to the intensive care unit after the surgery. A review of the intraoperative report dated [redacted]	E 347	(1) Sponges are separated for counting; (2) Sponges are counted audibly; (3) All counts are viewed by two people, one of whom is an RN; (4) The number of counts performed is accurate for the procedure; (5) Counts are performed in a timely manner; (6) Discrepancies are handled according to the Surgical Count Policy and Procedure; and (7) Documentation accurately reflects counts performed. Responsible Parties: OR Manager • Annual Monitoring reported through Surgery Department. To date = 100%. Ongoing compliance. • Responsible Parties: OR Manager	

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E 347	Continued From page 4 [redacted]2010 indicated there was one scrub technician and one circulating nurse that performed the counts of the sponges, needles, and instruments for Patient 1's emergent surgery. The Discharge Summary dated [redacted] 2010, indicated Patient 1 was discharged home in stable condition. A review of the facility's "ChartMaxx" Basic Chart Selections between [redacted] 2010 and [redacted] 2010, indicated Patient 1 returned to the facility five different times after his discharge home with the complaint of chest pain, headache, and not unable to urinate. On [redacted] 2010, Patient 1 was re-admitted to the facility with diagnoses of chest pain and hematuria (blood in the urine). The radiology report dated [redacted] 2010, showed a ribbon-like density in Patient 1's right upper quadrant of the abdomen which looked like a lap sponge or some drainage material. The radiology report indicated a foreign body reaction or abscess. A review of the Operative Report dated [redacted] 2010, indicated Patient 1 underwent supracervical procedure "laparotomy" for the removal of the retained foreign body. The findings indicated a surgical sponge retained entirely removed with segment of the sponge adhered (sticking) to the jejunal wall, which required the removing in pieces. During an interview on August 23, 2011 at 9:40 a.m., the Director of Performance Improvement and Clinical Management (RN 4) stated Patient 1's surgery on March 23, 2010, had three different circulating nurses because it was during	E 347		

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E 347	Continued From page 5 change of shift. However, Patient 1's surgery was approximately two hours in length, which did not validate the need to use three different nurses. During further interview with RN 4 on August 23, 2011 at 11:10 a.m., she stated the surgical staff may have counted one sponge when it was actually two, and the staff should separate each sponge. RN 4 stated the facility concluded the sponges were not counted correctly, or maybe double counted the sponges. A review of the facility's policy and procedure titled "Surgical Sponges" dated March 2009 indicated counting sponges, sharps and instruments during the course of surgical procedures were performed to account for items and ensure that the patient was not injured as a result of a retained foreign object. The policy and procedure indicated sponges were separated, counted audibly and concurrently viewed during the count procedure by two individuals, one of whom was a registered nurse. The policy stipulated the count documentation was the responsibility of the circulating registered nurse, it was documented on the intraoperative record and that a baseline pre-operative sponge count must be performed on all cases except cystoscopy. The facility's failure to implement its policy and procedure to prevent the retention of the surgical sponge used during a surgical procedure was a deficiency that caused, or was 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).	E 347		