

OK 5/5/14

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
 DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050557	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/16/2013
NAME OF PROVIDER OR SUPPLIER Memorial Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 1700 Coffee Rd, Modesto, CA 95355-2803 STANISLAUS 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>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00180867, CA00180956 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25738, 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 1279.1 Retention of a Foreign Object in a Patient (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>The hospital detected the adverse event on [redacted] 2009, when reported by a family member. The facility reported the adverse event to the Department on [redacted] 2009.</p>		<p><u>Corrective actions accomplished for the patient affected:</u> CA00180867, CA00180956</p> <p>The plan of correction is prepared in compliance with California Law and is not an admission of liability or wrongdoing.</p> <p>A. How the correction will be accomplished, both temporarily and permanently?</p> <p>1. Sponge count practices were reviewed March 13, 2009 with the following corrective actions initiated during March 18-31, 2009:</p> <ul style="list-style-type: none"> • Counts are required and performed in accordance with AORN guidelines and "Management of The Environment of Care- Sponge Count" policy 	3/31/09

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4/3/2014

12:24 50PM

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

TITLE

(X6) DATE

X: Darvn J. Kumar

Chief Executive Officer

May 2, 2014

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

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.

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	<p>Adverse Event Notification - Informed 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>Health and Safety Code 1279.1 (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>The CDPH verified that the facility reported the adverse event to the Department no later than five days after the adverse event was detected.</p> <p>Title 22 DIV 5 CH1 ART 3 70223 Surgical Services General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and</p>		<ul style="list-style-type: none"> Standardization of sponge count practices that includes case conversion from closed to open status and transition of scrub and circulating nurse during a procedure Verbal announcement of sponge count results to OR Team at each count stage Role delineation for circulator and scrub during sponge count reconciliation and at time of staff transition Alert system implementation for case conversion from closed to open Standardized receptacle for lap sponge management off sterile field 	<p>5/29/09</p> <p>3/31/09</p> <p>5/29/09</p> <p>3/31/09</p> <p>5/29/09</p>	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050657	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/16/2013
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	<p>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>These regulations were not met as evidenced by:</p> <p>Based on patient and staff interviews and facility document review the facility failed to fully implement the policy & procedure for accurate sponge counts. As a result of this failure, Patient A had to undergo a second surgery approximately two months later to remove the surgical sponge. During the second surgery, the surgeon found that the sponge had eroded into her small bowel and had caused extensive damage and inflammation, resulting in a portion of the small bowel being surgically removed.</p> <p>Findings:</p> <p>A review of Hospital 1's perioperative documents dated [REDACTED] 09, indicated Patient A underwent a surgical procedure for a right ovarian cyst at this hospital. A review of the surgeon's operative report identified that initially the surgery called for the use of a laparoscope (a tube inserted in to the abdomen to view and work in the surgical area). Due to the condition of the patient's lower abdominal organs, the surgeon decided</p>		<p>2. Policy review was conducted on March 16, 2009. Revisions were initiated on March 18, 2009, to incorporate corrective actions and AORN Perioperative guidelines.</p> <p>3. Operating Room staff and physician inservices were conducted during March 18-31, 2009 regarding practice changes and policy requirements.</p> <p>4. Foreign Body task force was established in July, 2009 to continue refinement of the "Management of The Environment of Care- Sponge Counts" policy and explore other tools to eliminate retained foreign bodies.</p>	<p>3/18/09</p> <p>3/31/09</p> <p>7/28/09</p>

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	<p>an incision was needed to open the area to complete the surgery.</p> <p>At the end of the surgery the surgeon's report notes identified that "the pelvis was irrigated with normal saline and the lap tapes (sponges) were extracted and accounted for by the circulating nurse. The incision was then closed and Patient A was transferred to the recovery room."</p> <p>On 2/6/14 at 10:30 a.m., a phone interview was conducted with this surgeon. The surgeon noted that Patient A had "lots of adhesions and required lots of lap tapes." The surgeon stated that his usual procedure at that time "would be to do a visual and manual exploration of the cavity to check for any objects." He stated that, "the circulating nurse and scrub person do a count of the sponges/tapes, and other equipment when I start to close the innermost cavity. After the first count is correct I will continue closing and after a second count is verified I would complete the closure of the skin. I don't recall how the nurses monitored the count because I am concentrating on the patient. I was told the count was correct two times. I felt confident that the count was correct at the end of the surgery based on the input from the staff."</p> <p>A review of a facility document titled Nursing Peri-Operative Record, in a section titled "Counts" directed that three counts were performed by the staff: a pre-operative count,</p>		<p>B. The title or position of the person responsible for the correction: Operating Room Manager</p> <p>C. A description of the monitoring process to prevent recurrence of the deficiency:</p> <p>The following monitoring system was put into place to reduce reoccurrence:</p> <ul style="list-style-type: none"> Sponge count reconciliation is verified and documented before incision, during each stage of closing of an incision, during case conversion from closed to open, and during any transition of scrub and circulating nurse during a procedure. Immediate investigation of count discrepancies by the surgical team both on and off the sterile field. If 	<p>3/31/09- 5/29/09</p> <p>3/31/09</p>	

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	<p>a first count, and a final count, each signed by two nurses. The next line on the document is "All counts correct unless otherwise noted," and there was no note on the document to indicate otherwise. Another area of the Nursing Peri-Operative Record identified "staff in the room" that indicated a change in personnel in which circulating RN #1 was replaced by circulating RN #2 for a period of 15 minutes. This time period was identified as a break time by the Operating Room Manager (ORM). In Hospital #1's policy titled, "Management of the Environment of Care Sponge Count" revised 4/07, indicated under item 6.2, "A sponge count will occur anytime there is closure of a cavity within a cavity, before wound closure begins, at the end of the procedure, AND at any time there is transition of care between scrub personnel and/or circulating nursing staff (anyone responsible for counts)." However the Nursing Peri-Operative Record did not document that a count occurred with the circulator changes.</p> <p>On 11/26/13 between 1:00 p.m. and 2:30 p.m., phone interviews were conducted with three members of the Operating Room staff that were involved in this case, the Operating Room Manager (ORM), the Assistant Operating Room Manager (AORM) and the Circulating Room Nurse (CN, manages the work of the OR during the surgery). These interviews were conducted individually. The ORM was questioned about how many counts were to be done during a surgical procedure. The ORM</p>		<p>sponge is not found, an x-ray will be performed and incision re-opened as needed to retrieve retained sponge.</p> <p>Practice and policy refinements continue into 2014 as a continuous improvement process.</p> <p>D. The date the immediate correction of the deficiency will be accomplished: March 31, 2009</p>	3/31/09	

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	<p>stated that 3 counts should occur, one before the patient is brought into the operating room, one prior to closing a cavity and the 3rd time would be prior to skin closure. The ORM added if a C-section or uterine procedure is involved a 4th count should occur. The interviews with the AORM and CN concurred with these statements. All three nurses identified, in a similar manner, how the "sponge counter bag" was to be used during a surgery to monitor the count and none noted any other use for the "sponge counter bag."</p> <p>Documents provided by Hospital #2, where Patient A had the second surgery, revealed a History & Physical (H&P) dated [REDACTED]09 noting that Patient A had the original surgery at Hospital #1 on [REDACTED]09. The H&P noted that Patient A had reported having bloody stools 1-2 weeks after the [REDACTED]09 surgery and a low grade fever prior to seeking care at Hospital #2. At Hospital #2 Patient A had a CT scan (an in-depth x-ray exam) to check for a retained foreign object, which was how the lap sponge was identified. Patient A underwent surgery on [REDACTED]09 for the retained foreign object that was a lap pad/sponge that had eroded into her small bowel and had caused extensive damage per the surgical report. The surgical report continued to describe that a portion of the small bowel needed to be removed because of the damage and inflammation caused by the retained lap sponge. The bowel was reconnected in this same surgery. Postoperatively, Patient A had an uneventful</p>				

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	<p>recovery and was discharged to home.</p> <p>On 11/4/13 at approximately 11:00 a.m., a phone interview was conducted with Patient A. Patient A confirmed that the two surgeries had occurred as noted and that she did not have any surgical procedures between Hospitals 1 & 2.</p> <p>According to Hospital #1's self-report of an adverse event, on approximately [REDACTED] 09 the surgeon was notified by Patient A's daughter that the patient underwent another procedure at another hospital (Hospital #2) to remove the foreign object.</p> <p>A review of Hospital #1's documents included the policies and procedures (P&Ps) in use at the time of the procedure in [REDACTED] 2009. The hospital surgical Policy & Procedure titled, ". . . Management of the Environment of Care - sponge count," revised 4/07, identified that the purpose was to provide guidance in an effective process for ensuring sponges are accounted for before, during and after a surgical procedure. The policy also noted under item 6.1 that a sponge count would be utilized "in any case were the depth and location of the operative site is such that a sponge could be retained..."</p> <p>Instructions in item 7.2 of this P&P were, prior to the start of a case "scrub personnel and circulating nurse count together in a manner easily visible to both parties by completely</p>				

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	<p>opening and separating each sponge. Perform count in interactive, audible manner." Instructions in item 7.2.6 of the procedure were that, "Circulator will record the number of each kind of sponge on the count board."</p> <p>In item 7.3.1 of the procedure instructions were that ". . . When lap sponges . . . are removed from the operating field, they are to be opened and dropped in the middle of the sponge receptacle [sponge counter bag]." Item 7.3.2 indicated that "Circulator is to remove lap sponge(s) from receptacle...and ensuring that there is only one sponge present." Item 7.3.3 indicated that "Circulator to place lap sponge into an empty pocket of the blue bag on rim of receptacle..." Instructions in item 7.3.4 indicated that "A total of five lap sponges are placed in the 5 separate pockets of the blue bag..."</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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