

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 060236	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/16/2011
NAME OF PROVIDER OR SUPPLIER SIMI VALLEY HOSPITAL & HEALTH CARE SERVICES		STREET ADDRESS, CITY, STATE, ZIP CODE 2975 Sycamore Dr, Simi Valley, CA 93065-1201, VENTURA 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: CA00289861 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 13034, 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>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY: T22 DIV CH1-7023(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(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.</p>	<p>Accepted plan of correction 12/18/12 Caroline Sp... Caroline Sp...</p>	<p>Simi Valley Hospital is committed to providing quality care. Preparation and/or implementation of this plan of correction does not constitute admissions or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared and/or executed solely because it is required by law.</p> <p>The following actions and/or changes have been initiated in response to events cited for Patient A, and applies to all current and future patients admitted to the facility regarding the process to ensure accurate surgical instrument counts during surgical procedures.</p> <p>Sponge, Sharps, and Instrument handling policy and processes were reviewed, re-evaluated, and revised as follows:</p> <p>Existing policy "Care of Surgical Instruments" was amended and approved to include the identification of missing surgical instruments during the sterile processing tray reassembly period, with notification of the O.R. charge nurse of the discrepancy.</p> <p>Sterile Processing staff were educated on the policy and department's process changes by the Sterile Processing Supervisor. The Sterile Processing Supervisor or lead sterile processing technician will audit 100% of all reassembled surgical trays for both missing instruments and notification of the Surgery charge nurse for cases where an instrument cannot be located. Audits will be conducted</p>	<p>10/27/11</p> <p>11/14/11</p>

Event ID: DYY611

5/24/2012

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

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Caroline Sp... Sr. Rep. at Case Inc

6/1/12

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	<p>Continued From page 1</p> <p>Based on staff interview, clinical record and facility policy and procedure review, the facility failed to implement its policy and procedures to ensure that sponges used during surgical procedures are accurately accounted for. Patient A had abdominal surgery on [REDACTED] 11 performed by Surgeon 1 and Surgeon 2. During the surgery a small bowel mass measuring 4-5 cm (centimeters) in size was discovered. An intraoperative consult with a Surgeon 3 recommended that Patient A return at a later date for surgical removal of the bowel mass.</p> <p>Patient A returned on [REDACTED] 11 for removal of the small bowel mass. Following the resection of the mass and a portion of the small bowel that the mass was attached to, the specimen was sent to pathology. According to the pathology report the "subserosal (below a serous membrane) nodule (mass) is seen to contain white gauzy material with occasional broad light blue fibers. The tissue associated with the gauze is soft yellow and partially liquefied. The gauze is fully encapsulated (the process of the formation of a capsule or a sheath around a structure) and confined to subserosal tissue only without involvement of bowel wall."</p> <p>Investigation including interview with the patient and medical history review revealed Patient A did not have any abdominal surgeries prior to the procedure in [REDACTED] 2011 when the mass was discovered. However, records indicated that in [REDACTED] 2007 Patient A had a vaginal hysterectomy and repairs</p>		<p>daily until 100% compliance is achieved for six consecutive months followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board. All cases that fallout will be investigated by the Sterile Processing manager for investigation, process review, corrective actions and remedial 1:1 staff education as appropriate, in order to prevent future occurrence.</p> <p>All Operating Room staff were educated on the policy changes by the Director of Surgery. The Director of Surgery or Surgery Charge nurse will audit 100% of all surgical cases that require instrument trays for the presence of an inventory count sheet and for discrepancies in the documented inventory count versus the number of instruments in the actual tray. Any fallouts will be immediately reported to the Sterile Processing Manager for investigation and corrective action. Audits will be conducted daily until 100% compliance is achieved for six consecutive months followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board.</p>	<p>06/30/13</p> <p>12/14/11</p> <p>06/30/13</p>

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	<p>Continued From page 3</p> <p>the mass was attached was removed. The specimen was sent to pathology.</p> <p>The surgical pathology report stated in part "...the subserosal nodule" (mass) "is seen to contain white gauzy material with occasional broad light blue fibers. The tissue associated with the gauze is soft yellow and partially liquefied. The gauze is fully encapsulated and confined to subserosal tissue only without involvement of bowel wall, mucosa or lumen." In a physician's progress record dated [REDACTED] 11, at 1 p.m. Surgeon 3 documented, "Patient's specimen was reviewed with the pathologist this morning. Patient's specimen revealed 4 X 4 surgical gauze encapsulated via fibrotic tissue. I informed and discussed with patient and her husband about the finding this morning. They fully understood."</p> <p>Investigation including interview with the patient, examination and medical record review, revealed Patient A did not have any abdominal surgery prior to the surgical procedure in [REDACTED] 2011 ([REDACTED] 11), when the mass was discovered. However, records indicated that in [REDACTED] 2007 ([REDACTED] 07) Patient A did have surgical procedure (s) at the facility performed by Surgeon 1 and Surgeon 2.</p> <p>A review of the nurses' operating room record dated [REDACTED] 07 revealed Patient A entered the OR at 7:32 a.m. and left at 11:35 a.m. Surgeon 1 was the primary surgeon and Surgeon 2 was the assistant. The surgical procedure(s) performed included a total vaginal hysterectomy. According to the documentation on the operative record all sponge,</p>		<p>All new Operating Room employees will receive this training during clinical orientation on sponge, sharps and instruments count facility policies and be evaluated and validated for competency through direct observation by their assigned surgery preceptor before they are released to work without supervision.</p> <p>Interventional & Operative committee physicians reviewed and approved Prevention of Retained Surgical Items B01163 policy and were educated to the event.</p> <p>Written education created by the Director of Surgery titled "Preventing Retained Surgical Items" was distributed via U.S. mail to surgeons who hold privileges at the facility.</p> <p>System wide corporate policy AD-14005-S, facility # B01135 "Sponge Sharps, and Instrument Counts" was revised by the Adventist Health Clinical Best Practices Committee with an advance copy provided to the facility on 11/10/11 for staff education. Final draft of policy received by facility, reviewed by medical Interventional & Operative committee, and was approved for use.</p>	<p>12/06/11</p> <p>01/11/12</p>

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	<p>Continued From page 4</p> <p>lap, and instrument (blades) counts were correct. There were two counts, initial and final, and no sponge/lap/instruments were added during the procedure. The final operative report dated [REDACTED] 07 stated in part "Sponge, lap, and needle counts were correct X 2The patient was taken to recovery area in stable condition."</p> <p>A review of facility's policy # 11005 - effective date 3/1/01 - titled "Policy & Procedure - Sponge, Needle, Sharps and Instrument Counts Procedure" (the policy that was in effect in November 2007) revealed the summary stated in part.. " to provide guidelines of accountability for sponges, sharps, instruments and miscellaneous items used during an invasive procedure when the depth and location of the wound is such that the item could be lost or left in the patient." "Definitions; 1 b. Sponges will include laps, baby laps, raytecs, packing (example: nasal, throat or vaginal)." " Procedure: A. Policy: 1. Counts - Sponge, Sharp, Miscellaneous counts are taken: a.. before the procedure to establish a baseline. c. prior to closure of a cavity within cavity (examples bladder, uterus). e. at skin closure or end of the procedure. 5. In the event of more than one incision invasive procedure is performed on the same patient, counts will be done for each. B. Counts: 1. Counts are done audibly and viewed concurrently as they are separated and counted by two individuals, one of whom is a registered nurse. D. Documentation: counts on the operative record as each is completed; noted as correct/incorrect, and signed by the individuals who completed them."</p>		<p>Amended policy:</p> <ol style="list-style-type: none"> 1. Defines the neutral zone, minimally invasive surgery, and waived counts. 2. Additional sharps items that have a potential for retention were added. 3. Only towels with radiopaque markers will be used in wounds, counted, and easily distinguishable from other towels. Special order towels with radiopaque markers added to O.R. supplies. 4. Situational awareness (heightened awareness of distractions) defined to address scenarios vulnerable to surgical item retention. <p>All Operating Room staff were educated to the policy changes by the Director of Surgery.</p> <p>Electronic clinical documentation system enhancements were proposed to Adventist Health corporate Clinical Information System team and were approved. Computer fields added so that staff can now document the surgical count type and time the count was performed.</p> <p>All Operating Room nursing staff were re-educated by the Director of Surgery on when to count and how to document count types and times using the existing electronic fields, as well as given education on the new electronic fields that were being created. Updated electronic fields were created by Adventist Health Clinical Information System team and were released for use by Adventist Health facilities. The Director of Surgery notified all nursing staff to begin using the</p>	<p>10/14/11</p> <p>12/14/11</p> <p>12/14/11</p> <p>01/25/12</p>

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	<p>Continued From page 5</p> <p>Further review of the nurses' operating room records for the surgery of [REDACTED] 07 revealed staff failed to conduct sponge counts per established policies and procedures. Procedure directs the staff to conduct three counts, before procedure (baseline), prior to closure of a cavity within cavity (bladder), and at the end of the procedure. Staff conducted two counts (initial/final). Patient A had two invasive procedures performed by two surgeons, per policy there should have been two separate sets of sponge counts and documented as such. In addition, there was no system in place to verify that two staff members, one of whom should be a registered nurse, verified and signed the counts as correct, per established policies.</p> <p>Patients in whom a surgical sponge is left after a surgical procedure are at high risk for serious complications including pain and infection. The facility's failure to ensure that the sponge count was correct and that no sponges were retained in Patient A following surgery on [REDACTED] 07, created a situation that 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).</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>SurgiCount Safety-Sponge® System was reviewed and approved for use at the facility on 08/05/12. This software system and soft goods products is a data-matrix-coded sponge counting system that eliminates retention of surgical sponges when used in conjunction with a facility's existing policies and processes. Each sponge is imbedded with a serial number which is recorded by the software to indicate time in the patient and time out of the patient to ensure the final sponge count is correct. Expected training and implementation within 90 days. Training of all O.R. scrub techs and nursing staff will be performed by the SurgiCount Medical staff and the Director of Surgery as a product to be used in conjunction with and to supplement existing manual counting procedures.</p> <p>In order to monitor performance and ensure corrective actions have been achieved and sustained the Director of Surgery or the Surgery Charge nurse will audit 100% of surgical cases per month to include:</p> <ol style="list-style-type: none"> 1. Direct observation of the surgical case to assess compliance with the Sponges, Sharps, and Instrument Count policy elements to include proper counting techniques performed by the circulating nurse and scrub tech, staff performed the correct number of counts at the 	09/06/12

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			<p>correct times during the procedure, the surgeon(s) allowed time for all required counts, the surgeon(s) performed visual checks and wound sweeps of open cavity/organ cases, and the surgeon(s) verified that the final counts were correct</p> <p>2. Compliance with using surgical tray tracking forms to include signature of staff who assembled the tray, tray number, if applicable, signature of O.R. staff who performed the count, documentation of the item inventory, report of any discrepancies in the inventory count with the number of instruments actually received.</p> <p>Medical record review for compliance that the correct number of counts and the correct type and frequency of counts were performed and documented. Audits will be conducted by the Director of Surgery or the Surgery Charge nurse daily until 100% compliance with each audit element is achieved for six consecutive months followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board. All cases that fallout will be presented to the involved employee(s) by the Director of Surgery for investigation, process review, corrective actions, and remedial 1:1 education and competency reassessment in order to prevent future occurrence. The Director of Surgery will report physician fallouts to the Director of</p>	06/30/13

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Medical Staff Office and the Chief of Surgery for peer review, intervention and corrective actions.

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