

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/06/2008	
NAME OF PROVIDER OR SUPPLIER VENTURA COUNTY MEDICAL CENTER-SANTA PAULA HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 825 N TENTH ST, SANTA PAULA, CA 93060 VENTURA COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during a Complaint Investigation visit.</p> <p>The following reflects the findings of the Department of Public Health during the investigation of Complaint No. CA00133347</p> <p>Inspection was limited to the specific complaint investigated and does not reflect the findings of a full inspection of the facility.</p> <p>Representing the Department of Public Health:</p> <p>[REDACTED]</p> <p>HSC Section 1280.1(a)(c)</p> <p>(a) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of a deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation.</p> <p>(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 5 CH1-70223(b)(2) SURGICAL SERVICE GENERAL</p>			

CA DEPT OF PUBLIC HEALTH
 2008 MAY 15 PM 4:45
 LICENSING & CERTIFICATION
 VENTURA DISTRICT OFFICE

Event ID: RUW011 4/30/2008 8:45:47AM 05/09/08

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

Medical Record Ventura County Medical Center Administrator 5/14/08

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>Continued From page 1</p> <p>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>Based on staff interview, clinical record review and review of policies and procedures, the facility failed to implement its written policy and procedure to ensure that sponges, sharps and instruments used during surgical procedures are accurately accounted for. Patient A had abdominal surgery on 10/23/07. Radiological studies done five days later, on 10/28/07, revealed a retained surgical sponge in the patient's abdomen. The patient returned to surgery the same day for removal of the sponge.</p> <p>Findings:</p> <p>Clinical record review on 02/26/08 revealed that Patient A was admitted to the facility on 10/23/07 for abdominal surgery. The procedures performed included an exploratory laparotomy, total gastrectomy, esophagojejunostomy, splenectomy and jejunostomy feeding tube. According to the Operating Room Nursing Record dated 10/23/07,</p>		<p>Actions Taken:</p> <p>1. VCMC/SPH reviewed and revised its existing policy entitled "Accountability for sponges, sharps, and instruments (D.1)" to reflect additional measures to prevent retained sponges during surgical procedures. The Surgical and Medical Executive committees approved the policy changes on 1/4/08 and 1/8/08 respectively. As well, an e-mail reminder of policy change was sent to every surgeon who works at VCMC or SPH on May 14, 2008.</p> <p>2. The Surgical Services Nurse Manager inserviced the staff at VCMC and SPH on the existing and revised policy and procedure related to surgical sponge counts in January of 2008.</p> <p>3. The Medical Director for VCMC/SPH inserviced all surgeons on the existing and revised policy and procedures related to surgical sponge counts.</p> <p>4. The Clinical Nurse Manager for Surgical Services (CNMSS) spoke with the circulating RN and Operating Room Tech about this incident on October 30, 2007.</p> <p>(continued on page 3 of 6)</p>	

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	<p>Continued From page 2</p> <p>the scrub nurse and the circulating nurse signed that all sponge counts for the surgery were correct.</p> <p>Following surgery, the patient was tachycardic, had persistent hiccups, and developed nausea and vomiting. An x-ray series of the abdomen completed on 10/28/07, five days after the operation, demonstrated what appeared to be a retained laparotomy sponge. The patient returned to the operating room the same day, and the retained sponge was removed from the left side of the abdomen.</p> <p>According to the operative report, inspection of the peritoneal cavity revealed "murky" drainage which appeared to be leaking from the anastomosis. Due to the location and surrounding inflammation, no attempt was made to repair the leak. The patient remained intubated and sedated, and returned to the intensive care unit in stable, but critical, condition. Patient A was transferred to the main hospital campus later the same day and underwent further surgical intervention.</p> <p>The Surgery Department policy and procedure D.1 "Accountability For Sponges, Sharps, and Instruments" was reviewed on 03/06/08 at 9:40 a.m. The purpose of the policy is to provide guidelines to ensure that sponges, sharps and instruments used during surgical procedures are accounted for, and to provide safe practice for the surgical patient, prevent patient injury and adhere to legal standards.</p> <p>The policy stated in part: "All counts shall be</p>		<p>Compliance and Monitoring Process:</p> <ol style="list-style-type: none"> 1. The CNMSS will conduct random, weekly observational audits in the OR to monitor compliance with the sponge count policy, take corrective action if needed, and report on compliance monthly to the Director of Nursing (DON) and the Medical Director (MD). 2. The CNMSS will audit all patients who meet the criteria for a postoperative xray (as outlined in the policy) daily (Monday through Friday) for three months and then weekly on a random basis to monitor compliance, take corrective action, if needed, and report on compliance monthly to the DON and MD. 3. The DON and MD will report on compliance to the Medical Executive Committee, the Hospital Administrator and the Health Care Agency Director, who will report on compliance to the Governing Body. <p>Persons Responsible: Clinical Nurse Manager Surgical Services Director of Nursing Medical Director of VCMC/SPH Hospital Administrator</p>	06/09/08

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	<p>Continued From page 3</p> <p>audibly and visually performed according to the procedure by the circulating nurse and scrub nurse...The circulating nurse and scrub nurse shall document and sign the Peri-Operative Record with the results of the counts...".</p> <p>The procedures stated in part: "Sponges shall be counted on all procedures involving a major body cavity...Sponges shall be counted in the Operating Room prior to; and at the closure of the fascia, at the closure of the skin and at the request of the surgeon by the scrub nurse and the circulating nurse together...".</p> <p>Staff 1 was the circulating nurse during Patient A's surgery on 10/23/07, and was interviewed on 03/06/08 at 10:00 a.m. Staff 1 confirmed that she was responsible for ensuring that the sponge count was correct. According to Staff 1, the surgery was long, started at 9:12 a.m. and ended at 1:35 p.m. Staff 1 stated that the procedure initially scheduled was a partial gastrectomy, but ended as a total gastrectomy. She indicated that there was a lot of bleeding and added that the sponge count is usually below 25, but was over 60 in this case. Staff 1 concluded that she miscounted a sponge.</p> <p>Following its investigation of the adverse event, the hospital revised the policy and procedure, and it was approved by the Surgical and Medical Executive Committees on 01/04/08 and 01/08/08, respectively. The sponge count procedure was revised to require a post operative x-ray under the following circumstances:</p>			
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	<p>Continued From page 4</p> <p>1. Greater than forty sponges used; 2. Size of Patient BMI (body mass index) > 40 (obesity = BMI of 30 or >) in an Open Chest or Open Abdomen procedure; 3. Greater than four (4) hours duration in an Open Chest or Open Abdomen procedure; 4. Significant change from intended procedure; 5. At the surgeon's discretion.</p> <p>Patients in whom a sponge is left after abdominal surgery are at high risk for serious complications including pain, infection, abscess and/or fistula formation, and intestinal obstruction. The facility's failure to ensure that the sponge count was correct and that no sponges were retained in Patient A following his surgery on 10/23/07, created a situation that was likely to cause serious injury or death to the patient.</p> <p>HSC 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>Actions Taken:</p> <p>1. VCMC and SPH reviewed its policy and procedures for reporting adverse events pursuant to Health and Safety Code section 1279.1. (Administrative policy 107.023)</p> <p>2. VCMC and SPH will adhere to the timely reporting of adverse events set forth in Health and Safety Code section 1279.1</p> <p>(Continued on page 6 of 6)</p>	

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	<p>Continued From page 5</p> <p>(b) For purposes of this section "adverse event" includes any of the following:</p> <p>(D) Retention of a foreign object in a patient after surgery or other procedures, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.</p> <p>Based on review of an adverse event reported by the facility and review of a patient's clinical record, the facility failed to report the retention of a foreign object in a patient after surgery within five days after the adverse event was detected.</p> <p>Findings:</p> <p>Clinical record review on 02/26/08 revealed that Patient A was admitted to the facility on 10/23/07 for abdominal surgery. Radiological studies done on 10/28/07 to check the patency of the surgical anastomosis revealed a retained surgical sponge. The patient returned to surgery the same day for removal of the sponge</p> <p>The retention of a foreign object in a patient after surgery is an adverse event that must be reported to the Department no later than five days after the adverse event has been detected. Although the facility was aware of the retained surgical sponge on 10/28/07, it did not report the adverse event to the Department until 11/28/07, twenty-six days after the initial five day reporting requirement.</p>		<p>(Continuation from page 5)</p> <p>3. The Medical Director, inserviced all physicians who work at VCMC and SPH and the DON, inserviced nursing managers, who inturn, inserviced their staff on the policy for reporting adverse events during the months of January and February. Will be concluding education with a follow-up memo of reminder.</p> <p>4. The Hospital Administrator reviewed policy and procedure for timely reporting of adverse events with the Medical Director.</p> <p>Compliance and Monitoring:</p> <p>1. The Hospital Administrator and Medical Director will assure compliance with this policy by monitoring incidents as they are reported.</p> <p>2. Reporting to CDPH will occur as soon as an incident is identified, with compliance at 100%.</p> <p>Persons Responsible: Hospital Administrator Medical Director</p>	6/09/08
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E 000	<p>Initial Comments</p> <p>The following reflects the findings of the Department of Public Health during the investigation of Complaint No. CA00133347</p> <p>Inspection was limited to the specific complaint investigated and does not reflect the findings of a full inspection of the facility.</p> <p>Representing the Department: MaryBeth Liggett, Health Facilities Evaluator Nurse</p>	E 000		
A 009	<p>1279.1(a) HSC Section 1279</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>This RULE: is not met as evidenced by: Based on review of an adverse event reported by the facility and review of a patient's clinical record, the facility failed to report the retention of a foreign object in a patient after surgery within five days after the adverse event was detected.</p> <p>Findings:</p> <p>Clinical record review on 2/26/08 revealed that Patient A was admitted to the facility on 10/23/07</p>	A 009		

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A 009	Continued From Page 1 for abdominal surgery. Radiological studies done on 10/28/07 to check the patency of the surgical anastomosis revealed a retained surgical sponge. The patient returned to surgery the same day for removal of the sponge The retention of a foreign object in a patient after surgery is an adverse event that must be reported to the Department no later than five days after the adverse event has been detected. Although the facility was aware of the retained surgical sponge on 10/28/07, it did not report the adverse event to the Department until 11/28/07, twenty-six days after the initial five day reporting requirement.	A 009		
A 012	1280.1(a) HSC Section 1280 If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation. This RULE: is not met as evidenced by: DEFIENCY CONSTITUTING IMMEDIATE JEOPARDY: T22 DIV 5 CH1-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS	A 012		
E 347	T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and	E 347		

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E 347	<p>Continued From Page 2</p> <p>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>This RULE: is not met as evidenced by: Based on staff interview, clinical record review and review of policies and procedures, the facility failed to implement its written policy and procedure to ensure that sponges, sharps and instruments used during surgical procedures are accurately accounted for. Patient A had abdominal surgery on 10/23/07. Radiological studies done five days later, on 10/28/07, revealed a retained surgical sponge in the patient's abdomen. The patient returned to surgery the same day for removal of the sponge.</p> <p>Findings:</p> <p>Clinical record review on 2/26/08 revealed that Patient A was admitted to the facility on 10/23/07 for abdominal surgery. According to the Operating Room Nursing Record dated 10/23/07, the scrub nurse and the circulating nurse signed that all sponge counts for the surgery were correct. However, radiological studies done on 10/28/07 to check the patency of the surgical anastomosis revealed a retained surgical sponge. The patient returned to surgery the same day for removal of the sponge.</p> <p>The Surgery Department policy and procedure D.1 "Accountability For Sponges, Sharps, and Instruments" was reviewed on 3/06/08 at 9:40 a.m. The purpose of the policy is to provide guidelines to ensure that sponges, sharps and instruments used during surgical procedures are</p>	E 347		

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E 347	<p>Continued From Page 3</p> <p>accounted for, and to provide safe practice for the surgical patient, prevent patient injury and adhere to legal standards.</p> <p>The policy stated in part: " All counts shall be audibly and visually performed according to the procedure by the circulating nurse and scrub nurse ...The circulating nurse and scrub nurse shall document and sign the Peri-Operative Record with the results of the counts ... ".</p> <p>The procedures stated in part: " Sponges shall be counted on all procedures involving a major body cavity ...Sponges shall be counted in the Operating Room prior to; and at the closure of the fascia, at the closure of the skin and at the request of the surgeon by the scrub nurse and the circulating nurse together ... ".</p> <p>Staff 1 was the circulating nurse during Patient A's surgery on 10/23/07, and was interviewed on 3/06/08 at 10:00 a.m. Staff 1 confirmed that she was responsible for ensuring that the sponge count was correct. According to Staff 1, the surgery was long, started at 9:12 a.m. and ended at 1:35 p.m. Staff 1 stated that the procedure initially scheduled was a partial gastrectomy, but ended as a total gastrectomy. She indicated that there was a lot of bleeding and added that the sponge count is usually below 25, but was over 60 in this case. Staff 1 concluded that she miscounted a sponge.</p> <p>Following its investigation of the adverse event, the policy and procedure was revised and was approved by the Surgical and Medical Executive Committees on 1/04/08 and 1/08/08 respectively. The sponge count procedure was revised to require a post operative x-ray under the following circumstances:</p> <ol style="list-style-type: none"> Greater than forty sponges used; 	E 347		

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 630010957	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/06/2008
NAME OF PROVIDER OR SUPPLIER VENTURA COUNTY MEDICAL CENTER-SANTA PA		STREET ADDRESS, CITY, STATE, ZIP CODE 825 N TENTH ST SANTA PAULA, CA 93060		
(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 347	Continued From Page 4 2. Size of Patient BMI (body mass index)> 40 (obesity = BMI of 30 or >) in an Open Chest or Open Abdomen procedure; 3. Greater than four (4) hours duration in an Open Chest or Open Abdomen procedure; 4. Significant change from intended procedure; 5. At the surgeon ' s discretion. Patients in whom a sponge or instrument is left after surgery are at high risk for serious complications including pain, infection, abscess and/or fistula formation, and intestinal obstruction. The facility's failure to ensure that the sponge count was correct, that no sponges were retained in Patient A following his surgery on 10/23/07, and its failure to identify the retained surgical sponge until five days later, created a situation that was likely to cause serious injury or death to the patient.	E 347		