POC acceptable 9/9/13 RR

PRINTED: 08/13/2013
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000008	A. BUILDING: _____ B. WING _____	C 01/05/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ANTELOPE VALLEY HOSPITAL MED CENTER	1600 W AVE J LANCASTER, CA 93534

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E 000	Initial Comments The following reflects the findings of the Department of Public Health during an entity reported incident investigation. Intake Number: CA00235788 - Substantiated Representing the Department of Public Health: State ID# 1224, RN, HFEN 1280.1(c) Health and Safety Code Section For purposes to 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.	E 000	RECEIVED 2013 SEP 10 AM 10:39 HEALTH FACILITIES INSPECTION DIVISION ADMINISTRATION	
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		
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 implementation of written policies and procedures in consultation with other appropriate health	E347	Corrective Action: At the time of the incident cited in this report, the policy and procedure addressing counting of sponges, sharps, and instruments (*OR PC.9 Accountability for Sponges, Sharps, and Instruments)* was current, having last been reviewed and revised 3/21/2007. Policy *OR.PC.9,* Continued on pg 2	

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Rina Abenoza TITLE: ACNO (X6) DATE: 9/9/13

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E 347	Continued From page 1 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 interview, record review, and observation, the facility failed to implement its policy and procedure on "Accountability for Sponges, Sharps and Instruments." On [redacted] 2010, the facility's staff failed to account for miscellaneous items, including a Glassman viscera retainer ("Fish" shaped device is made of soft flexible, sterile, latex-free material folds into a soft narrow roll for easy removal and disposal. It shields tissue/organ to reduce nicks and punctures.) used during Patient 1's surgical procedure which resulted in retention of a foreign object. On [redacted] 2010, Patient 1 was admitted to the facility and underwent a second surgical procedure to remove the retained "fish" surgical device, under general anesthesia. The facility's failure placed the patient at risk for possible complications including infection, bleeding, pain and possible injury to the bowel. Findings: An unannounced visit was conducted on September 21, 2011, to investigate an entity reported incident regarding retention of a foreign object in Patient 1. A review of the medical record revealed Patient 1 was admitted to the facility on [redacted] 2010, with diagnosis of a large bowel obstruction. An exploratory laparotomy with partial colectomy with end to end reanastomosis (incision through the abdominal wall for access/exploration of abdominal cavity and removal of the diseased	E 347	- Continued from page 1 - approved in 2007, lacked a signature block to reflect review by the Surgery Committee. However, the review and approval process for policies and procedures that was in place at the time of the cited incident included a review and verbal approval rather than signature from the Medical Staff. Since June 2009, the policy and procedure process has become more rigorous, includes greater standardization, and Medical Staff Committee review dates when applicable. For policies and procedures requiring medical director, medical staff, and/or governing body approval, signature approval blocks are included in the document. Patient Care Policy *SS.PC.9 (Accountability for Sponges, Sharps and Instruments)* was reviewed by surgical services management staff immediately after the incident cited in this report and found to provide adequate guidance. No changes or additions were made at that time. Following the incident, refresher education was provided to the surgical services staff regarding process and accountability for counting sponges, sharps, and instruments (video), including proper use of the count boards present in the OR suites. Safety practices involving radiopaque devices were also discussed at the Department of Surgery Committee and event was referred to Medical Staff Peer Review.	6/3/10 7/7/2010 7/20/2010

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E 347	Continued From page 2 portion of the colon then joining the remaining sections of the colon) was done on [redacted] 2010. A review of the "Report of Operation" Part B under "Count Status" dated [redacted] 2010, revealed there were three counts for sponges, needles, and instruments done by the circulating nurse and a scrub technician. The documentation indicated the counts were correct. However, there was no documentation to indicate that a "fish" device was added to the surgical field and counted. During an interview on September 20, 2011, at 1:26 p.m., RN 2 (operating room manager) stated the circulating nurse was supposed to document that the "fish" device was placed in the operating field to remind them that it needed to be removed later. He further stated the surgeon requested for the "fish" device to protect the bowels during closure of the surgical incision in the abdomen. The medical record revealed the patient was discharged on [redacted] 2010. On [redacted] 2010, Patient 1 presented to the facility's emergency room with the complaint of abdominal pain. He was sent home with pain relief medications. On [redacted] 2010, he again presented at the facility's emergency room with left groin pain. A left inguinal (groin) ultrasound was done and no inguinal hernia was identified. He again was sent home with pain relief medications. On [redacted] 2010, Patient 1 presented again in the emergency room complaining of abdominal pain and was admitted. The admission history, dated	E 347	-Continued from page 2 - The Surgical Services Nurse Manager conducted research of Association of Operating Room Nurses (AORN) tools/procedures and best practices. Surgical Services standard operating procedures addressing counting sponges/sharps/instruments were again reviewed. A process improvement (PI) team was formed to review current practice and determine if changes would improve patient safety. The PI team recommended changes in practice to enhance patient safety including expanding and standardizing the "count boards" in all operating rooms; adding verbal announcements by the scrub tech when a sponge/instrument is placed into or removed from a body cavity at which time the circulating nurse would update the count board; and codifying the process of conducting counts when circulating and scrub personnel enter/leave the room in relief status. Training in revised procedures was conducted in the usual method of shift briefings (announcements and educational sessions presented to all staff at the start of every shift for five days) with 1:1 and small group reinforcement. Preceptors training new employees cover this information during the orientation period. Managers monitored the revised processes. To further support the concept of a shared duty to protect patients, additional actions to enhance patient safety were introduced over the next five months. Surgical Services managers determined Continue on page 4	10/20/10 6/7/12 6/11/12 7/23/12 10/12/12

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E 347	Continued From page 3 [redacted]2010, indicated the patient "has been suffering of abdominal pain for a while now, and has come to the emergency room, having multiple tests, but without any particular diagnosis." A computed tomography (CT scan is a medical imaging procedure that uses computer-processed X-rays to produce tomographic images or 'slices' of specific areas of the body) of the pelvis, without contrast, was done which showed a retained foreign body in the pelvis characteristic of a retained "fish" surgical device. The patient was informed of the retained surgical device. According to the operative report dated [redacted] 2010, the patient underwent an exploratory laparotomy and a removal of intraperitoneal foreign body (incision through the abdominal wall for access/exploration of the abdominal cavity and removal of the foreign body) under general anesthesia. The documentation indicated the foreign body was localized and identified almost immediately after the peritoneum (membrane that lines the cavity of abdomen) was opened. The foreign body was removed without problem. The record indicated on [redacted]2010, Patient 1 was discharged from the facility. A review of the hospital's internal investigative report revealed the surgeon assistant left the operating room right after the surgery, and the scrub technician did the final count while assisting the surgeon. The scrub technician was not aware that the string which attached to the fish device had been cut off. The string was an indication that the "fish" device was still inside the abdominal cavity. On September 20, 2011, at 11:26 a.m., a sample of the Glassman viscera retainer ("fish" device)	E 347	-Continued from page 3 - that a six (6) month trial period with monitoring was appropriate due to the number of enhanced safety practices. At the end of the trial and monitoring period, the policy and procedure *SS.PC.9 (Accountability for Sponges, Sharps, Instruments)* was revised and renamed to *SS.PC.9 (Prevention of Retained Surgical Items [RSIs])* to provide additional focus on the importance of the counting process to eliminate the risk of retained objects. Initial Draft of Policy/procedure *SS.PC.9 (SS.PC.9 (Prevention of Retained Surgical Items [RSIs])* was reviewed and approved by the Department of Surgery Committee. The statement "Radiopaque surgical soft goods shall be left in their original configuration and shall not be cut or altered in any way" was added to the policy. The policy will return to Department of Surgery Committee for approval and distribution to all active surgeons with return attestation. Once approved, review of the revised policy will be part of new employee orientation. B. Responsible person: For Policy and Procedure Process: Director, Quality Management/Infection Control/Clinical Safety/Risk Management For Surgical Services implementation and monitoring: Executive Director, Surgical Services Continued on page 5	3/6/13 9/30/13 9/3/13 10/2/13

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E 347	Continued From page 4 was presented to the evaluator. The retainer was observed to be shaped like a fish and measured 9 inches long and 6 inches at the widest point. There was a 9 inches long string attached at the narrow end with a ring measuring 2 inches in diameter. During an interview on September 21, 2011, at 9:30 a.m., RN 1 (interim operating director at the time of the incident) stated the surgeon cut off the string from the "fish" device, and the scrub technician did not stop the surgeon. A review of the facility's policy and procedure on Accountability for Sponges, Sharps and Instruments revealed the scrub technician and circulating nurse perform mandatory counts visually and audibly. Sponges, sharps and miscellaneous items are counted as follows: a. Initial Count - prior to the start of the procedure. b. First Count - prior to the closure of the body cavity. c.Final Count - skin closure. d. Additional Counts- 1. Anytime there is a permanent relief of the scrub or circulating staff in the room (although direct visualization of all items may not be possible). 2. Before any part of a cavity or a cavity within a cavity is closed (e.g. exploratory laparotomy). 3. Instruments will be counted: a. Initial Count - prior to the start of procedure. b. Final Count - when cavity closure. The policy and procedure further indicated that,	E 347	- Continued from page 4 - C. Monitoring: For Surgical Services: Weekly random observations of performance of required sponge/sharps/instrument counts to verify compliance with standard operating practices and weekly verification of proper documentation in the Report of Operation. Monitoring to be conducted by Surgical Services Nurse Manager and charge nurses and reported to QM Department. Monitoring will include a minimum of 20 observations per week for four months (September 2013 – December 2013) with compliance to remain greater than 95%. D: Completion Date: Policy/Procedure Process Standardization Initial consolidation and conversion to the electronic data base format was completed June 2011. Inclusion of all departmental policies and procedures to an electronic data base and ongoing periodic review is ongoing. Surgical Services Completion of immediate correction Date of completion of monitoring	6/2011 Ongoing 7/23/12 12/31/13

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E 347	Continued From page 5 "The Circulating Nurse opening additional item(s) must count at the time audibly and viewed concurrently with the scrub person and record on the board to keep the count current and accurate." The policy and procedure did not specifically address the counting of the "fish" device. During a telephone interview on January 5, 2012 at 10:30 a.m., Employee C (scrub technician) stated he was involved with the sponge/instrument count on [redacted] 2010 during the procedure involving Patient 1. He stated the first three counts were done. An additional count for miscellaneous items was not done in this case. The "fish" device was not part of the surgical tray and it came in its own packaging. He further stated, the "fish" device could be written on the count board. He stated he could not recall if that was done. During a telephone interview on January 5, 2012 at 10:47 a.m., RN 3 (circulating nurse) stated the "fish" device was in a separate packaging. She stated during the closure of the abdomen, the "fish" device was placed on top of the intestines to avoid nicking the bowels, and the "fish" device had a string with a ring at the end. This ring was used to pull out the "fish" device before closing the skin. She further stated for Patient 1's case, she could not recall if the "fish" device was used. She further stated that she did three counts for sponges/instruments with the scrub technician, and in this case, an additional count was not needed. The facility's failure to implement its policies and procedures to prevent retention of a surgical device used during a surgical procedure was a deficiency that caused, or likely to cause, serious	E 347		

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E 347	Continued From page 6 injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1.	E 347		