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	(X3) DATE SURVEY COMPLETED
	050690	A. BUILDING _____ B. WING _____	04/08/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Santa Rosa	401 Bicentennial Way, Santa Rosa, CA 95403-2149 SONOMA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00247797 - Substantiated Representing the Department of Public Health: Surveyor ID # 27533, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. 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. Penalty number: 110009710 E 347 T22 DIV5 CH1 ART3 – 70223(B)(2)Surgical Services General Requirement Based on interview, and review of the clinical record and hospital policy, the hospital failed to update hospital policy and procedure to account for sponges used, when a wound vacuum system was changed in the operating room, resulting in the need for Patient 1 to return to surgery for removal of a retained wound vacuum sponge. THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ)			

RECEIVED
APR 20 2015
CDPH L&C
Santa Rosa D.O.

Event ID:5B0511 2/10/2015 12:50:01PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Judy Cooley TITLE SVP (X6) DATE 4/17/15

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 5

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.

4/22/15 - 10:20 am Received via E-mail
Revised POC Reviewed & accepted. Facility notified.
- Debbie HFEN

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050690	A. BUILDING _____ B. WING _____	04/08/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Santa Rosa	401 Bicentennial Way, Santa Rosa, CA 95403-2149 SONOMA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	WITHIN THE MEANING OF HEALTH AND SAFETY CODE SECTION 1280.1 IN THAT IT CAUSED OR WAS LIKELY TO CAUSE SERIOUS INJURY OR DEATH TO THE PATIENT, WHEN MEDICAL AND NURSING STAFF FAILED TO IDENTIFY THAT A FOREIGN OBJECT (WOUND VAC SPONGE) HAD BEEN RETAINED IN A PATIENT AFTER SURGERY. THIS VIOLATION PLACED THE PATIENT AT INCREASED RISK FOR COMPLICATIONS AND DEATH FROM THE RETAINED WOUND VAC SPONGE. Findings: A facility Adverse Event Report, dated 10/28/10, submitted to The Department, indicated that Patient 1 had a hospital stay from 09/17/10 to 10/18/10, with diagnoses including necrotizing fasciitis leg wounds with gangrene. Patient 1's clinical record was reviewed on 04/08/11 at 10:45 a.m. Physician's Progress Notes indicated that Patient 1 was admitted with a complaint of thigh pain and other signs of infection, on 09/17/10. Patient 1 was diagnosed with necrotizing fasciitis, a rapidly spreading infection which resulted in death of connective tissue in both legs. Surgical incision and drainage of three leg wounds was done on: 09/18/10, 09/19/10, 09/25/10, and 09/27/10. Patient 1 had open wounds on the left anterior (front) thigh, the right anterior thigh, and a larger, longer wound in the right medial (middle) thigh.		Immediate and Systemic Actions: 1. The Policy and Procedure entitled "Counts: Instrument, Sponge, Needle and Sharps" was revised and approved by the Medical Executive Committee. The policy includes a count of any dressings or sponges intentionally left in the wound at the time of the procedure. The policy was revised to state: "V.A.C foam dressings and sponges are not detectable on X-ray and are not absorbable. Hence, the number of foam pieces and sponges placed in a wound must be documented in the patient record. The number of foam pieces and sponges removed at the time of the dressing change must reconcile with the number of foam pieces placed during the previous dressing change." Education and training on the revised P/P was provided to: *Surgeons *Anesthesiologists and CRNAs *Registered Nurses working in hospital ORs and Labor and Delivery ORs via daily staff huddle messages Accountable Party: Director of Surgical Services and Maternal Child Services	December 21, 2010 November 14, 2010

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050690	A. BUILDING _____ B. WING _____	04/08/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Santa Rosa	401 Bicentennial Way, Santa Rosa, CA 95403-2149 SONOMA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	Patient 1 returned to the operating room on 09/28/10. A, "Long Operative Report," dated 09/29/10, indicated that all three wounds were inspected and no sign of residual infection was found. All wounds were irrigated, and sponge dressings for Vacuum-Assisted Wound Closure Therapy (VAC) were placed in the wounds and secured with skin staples. The vacuum tubing and occlusive dressings were applied and vacuum was confirmed. The OR (Operating Room) Record documented the initial and final sponge counts were correct. The counts were verified by an OR Tech and an R.N. (Registered Nurse); however, the number of wound vac sponges (therapeutic packing) left intentionally in the wound, to facilitate the wound vac therapy, was not documented. Vacuum-Assisted Wound Closure Therapy provided controlled negative pressure to wounds in an effort to expedite wound closure. The use of negative pressure stretched the cells and pulled them closer together. VAC therapy is also thought to stimulate the growth of new blood vessels which assisted with new cell growth. Patient 1 returned to the operating room on 10/2/10, for the last incision and drainage of the leg wounds. A, "Long Operative Report," dated 10/02/10, indicated no signs of residual infection had been seen, however a pocket of fluid was found in the right medial thigh wound. The fluid was evacuated, the space irrigated, and a new vacuum sponge was placed in the area. Sponge dressings for the VAC system were placed in all the wounds and secured with adhesive dressings. The vacuum		2. Mosby's "Nursing Skills Checklist entitled "Negative-Pressure Wound Therapy" was reviewed with all registered nurses working on inpatient nursing units. Accountable Party: Director of Adult Services 3. The Policy and Procedure entitled "Vacuum-Assisted Wound Therapy Closure" was revised and approved by the Medical Executive Committee. The Policy includes a sponge count upon insertion and removal during dressing changes and documentation in the "Drain Integumentary Wound VAC" flowsheet. The policy was revised to state: "V.A.C. foam dressings and sponges used with negative pressure wound therapy or vacuum assisted wound closure (VAC * Therapy) are not detectable on X-ray and are not absorbable. Hence, the number of foam pieces and sponges placed in a wound must be documented in the patient record.	February 28, 2011 December 27, 2010

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050690	A. BUILDING _____ B. WING _____	04/08/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Santa Rosa	401 Bicentennial Way, Santa Rosa, CA 95403-2149 SONOMA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	tubing and occlusive dressings were placed and vacuum was confirmed. The OR Record documented the initial and final sponge counts as correct. The counts were verified by an OR Tech and an R.N., however, the number of wound vac sponges (therapeutic packing) left intentionally in the wound, to facilitate the wound vac therapy, was not documented. By 10/07/10, Patient 1's wounds were small enough to be closed with plastic surgery; the number of wound vac sponges removed prior to closure was not documented. Patient 1 was discharged home on 10/21/10. Patient 1 returned to the Emergency Department on 10/23/10, with a fever and pain in her right thigh. A CT scan indicated a very large abscess cavity in the right thigh muscles. An attempt was made to drain the abscess in the Emergency Department but was unsuccessful. Patient 1 was taken to the operating room on 10/24/10, where needle aspiration of the right thigh revealed pus. Further surgical exploration revealed what the surgeon described as a, "wound vacuum sponge," retained in the deep soft tissue of the right thigh. The sponge was partially incorporated into the surrounding tissue and extensive dissection was needed to remove it. A final pathology report, dated 11/22/10, indicated the retained foreign body removed from Patient 1's right thigh was a piece of synthetic material that measured 27.0 x 7.0 x 3.7 centimeters. During an		The number of foam pieces and sponges removed at the time of the dressing change must reconcile with the number of foam pieces placed during the previous dressing change." Education and training on the revised P/P was provided to all registered nurses working on inpatient nursing units Accountable Party: Director of Adult Services	February 28, 2011

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050690	A. BUILDING _____ B. WING _____	04/08/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - Santa Rosa	401 Bicentennial Way, Santa Rosa, CA 95403-2149 SONOMA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	interview, and concurrent review, on 04/08/11 at noon, of the Perioperative Services' policy and procedure, titled, "Counts: Instrument, Sponge, Needles and Sharps," dated 5/07, Administrative Staff A stated that the policy had not been updated to include counting VAC sponges and foam dressings i.e., therapeutic packing. The hospital's failure to develop, maintain, and implement written policies and procedures, to prevent the retention of a wound vacuum sponge used during a surgical procedure, in violation of Section 70223(b) (2) of the California Code of Regulations, was a deficiency that caused, or was likely to cause, serious injury and death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1. 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).		Monitoring: The Director of Surgical Services or her designee conducted audits for four months on all surgical patients where wound vac systems were utilized to ensure compliance with the policies and procedures. The results of the audits demonstrated 100% compliance with the policies. The results of the auditing were reported to the Medical Executive Committee.	July 31, 2011 February 28, 2013 May 22, 2013