P.O.C. accepted
S.C. 3/18/16

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
	050696	A. BUILDING _____ B. WING _____	10/17/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Keck Hospital of USC	1500 San Pablo St, Los Angeles, CA 90033-5313 LOS ANGELES COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00340877 - Substantiated Representing the Department of Public Health: Surveyor ID # 17030, 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 1280.3: 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. Title 22 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 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. Based on record review and interview, the facility surgical staff failed to implement its "Counts:		**INTRODUCTION:** Keck Hospital of USC prides itself on providing excellent patient care and is continually striving to implement measures to ensure the safety of our patients. As part of these efforts, Keck Hospital maintains policies and monitors processes to prevent the inadvertent retention of foreign objects, several of which have been adjusted or enhanced since the time of this event and subsequent survey. Since the date of this event in January 2013, no further incidents of retained percutaneous pin cannulas have occurred. In order to identify factors contributing to this incident and to identify an action plan for prevention, a multidisciplinary meeting occurred on 2/27/2013. The review identified the following opportunities:	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE [signature] TITLE Manager (X6) DATE March 2 2016

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 6

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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	Sharps and Sponges/Instruments" policy and procedure when surgical instruments counts were not done during Patient A's surgical procedure and an x-ray was not done when instrument counts were not performed. This failure resulted in a retention of a metallic sheath [used to direct a path into the lumbar (lower back), 5-S sacral (between lower back and hip) 1 disk space through the bone spur] in the left posterior (rear in space) superior (higher in space) iliac spine [a projection at posterior end of the iliac crest (the thick curved upper border of the ilium, the most prominent bone on the pelvis)]. Subsequently, Patient A was subjected to an additional surgical procedure under MAC (monitored anesthesia care) anesthesia for the removal of the retained metallic sheath and was at risk for additional complications such as bleeding, blood clots, build-up of blood or fluid in one area, damage to nerves, incomplete relief of pain and coma (state of unresponsiveness in which the person shows no voluntary movement or behavior). Findings: On September 23, 2013, an unannounced visit was conducted at the facility to investigate an entity-reported incident of a retained foreign object after a surgical procedure on Patient A. A review of the facility's Adverse Event Report Form, forwarded to the Department by fax and dated January 22, 2013, indicated Patient A was admitted to the facility on January 11, 2013, for "lumbar spondylolisthesis" (a condition that one		**ACTIONS TAKEN:** 1. Developed a standardized, systemic verbal handoff process and implemented a communication white board that tracks items that require counting per policy (sharps, instruments, sponges, etc.) for OR staff to use with each other when being relieved or taking breaks. **Responsible person:** Executive Administrator, Perioperative Services 2. The OR Committee updated the Perioperative Services Policy, "Counts: sharps and Sponges/Instruments" to reflect that instead of an x-ray, percutaneous pin cannulas will become part of the formal instrument count process. **Responsible person:** Executive Administrator, Perioperative Services	**Compliance date: 5/22/2013** **Policy approved & online: 8/29/2013**

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	vertebral body becomes progressively out of alignment). On January 11, 2013, Patient A underwent a surgical procedure, L 4 (Lumbar 4th level) to S 1(Sacral 1st level) minimally invasive laminectomy with transformational lumbar interbody fusion (a type of spine surgery that involves approaching the spine from the back of the body to place bone graft between two vertebrae). On January 15, 2013, a tube-like structure was noted on a lumbosacral spine x-ray. On September 23, 2013, a review of the clinical record of Patient A disclosed the pa tient w as admitted to the facility on January 11, 2013, with a diagnosis of lumbar spondylolisthesis. The patient was discharged on January 17, 2013. According to the Operative Record transcribed on January 13, 2013, Patient A underwent a L4-S1 minimally invasive laminectomy with transformational lumbar interbody fusion on January 11, 2013. The patient tolerated the procedure and was transferred to the post anesthesia recovery unit. At the end of the surgical procedure, all sponge and needle counts were correct. A review of the Intraoperative Nursing Record dated January 11, 2013, disclosed the three counts of sponge and needles were correct. However, the three counts of "Instrument" were not conducted before the procedure, before any part of a cavity was closed and prior to skin closure. A review of the Operative Report dictated on January 17, 2013, indicated in doing a predischarge		3. Educate OR staff on the following topics: • Action Item #1 • Action Item #2 • OR technicians develop "situational awareness" and "own" the Mayo stand (a removable instrument tray set on a movable stand positioned over or adjacent to a surgical site), to enhance awareness of what instruments go in and out of the patient and assist with keeping track of these instruments. **Responsible person:** Executive Administrator, Perioperative Services 4. Educate physicians on the following topic: • Action Item #2 via memo sent to all physician faculty and discussion in Orthopedic, Neurosurgery, and Radiology faculty meetings	**Compliance date: 10/23/2013 & 10/25/2013** **Compliance date: October 22, 2013 for memo, November 2013 for discussion in faculty meetings**

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	X-ray assessment, it was noted that a "metallic sheath from the percutaneous pin placement for the navigational guidance system" was retained in the patient's back from a surgical procedure performed on January 11, 2013. The Authorization and Informed Consent to Surgery or Special Diagnostic or Therapeutic Procedures dated January 16, 2013, revealed an informed consent was obtained from the patient for removal of "retained hardware in sacral spine." The informed consent addressed the risks of the procedure that included bleeding, blood clots, build-up of blood or other fluid in one area, damage to nerves, incomplete relief of pain and coma. A review of the Operative Record dictated on January 17, 2013, disclosed that on January 16, 2013, Patient A had returned to surgery for a retained metallic sheath from the percutaneous pin placement for the navigational guidance system. The patient had undergone removal of the metallic sheath that was along the area over the subcutaneous pocket in the left posterior superior iliac spine under MAC anesthesia. According to the facility's policy and procedure titled, "Counts: Sharps and Sponges/Instruments" dated on July 29, 2010, all sharps/sponges and instruments opened on the sterile tables are counted prior to the beginning of a procedure, before any part of a cavity is closed, and prior to skin closure. The procedure stipulated that if instrument counts were not performed on spine procedures, then an x-ray would be taken in lieu of		**Responsible person:** Medical Staff Director for memo to all faculty physicians and Service Chiefs for discussion in faculty meetings 5. All new hire RNs and operating room technicians will receive orientation on the Perioperative Services policy, "Counts: Sharps and Sponges/Instruments". All employees will receive annual competency validation testing on "Counts: Sharps and Sponges/Instruments" policy. **Responsible person:** Executive Administrator, Perioperative Services	Compliance date: August 2013 & Ongoing

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	a instrument count. Also, immediately prior to leaving the operating room, on spine, total joint cases and hemi arthroplasty cases, a n A/P (Anterior/Posterior) x-ray will be taken in lieu of an instrument count. The primary surgeon views the x-ray and notes in the progress note "no intentional metallic objects noted." A radiologist will provide a stat read at the request of the surgeon. There was no documentation that Patient A had an x-ray taken prior to leaving the operative room in lieu of an instrument count. A telephone interview was conducted with Employee 2 (circulating nurse) on October 3, 2013 at 3:28 p.m. Employee 2 stated the metallic sheath was considered as an instrument but should not be counted. According to Employee 2, there was no x-ray taken for the patient in lieu of an instrument count. An interview was conducted with Employee 1 (perioperative director) on October 17, 2013 at 10:05 a.m. She stated Employee 2 failed to count the instruments (metallic sheath) during Patient A's surgical procedure. According to Employee 1, Employee 2 failed to follow the facility's policy and procedure on counting instruments used in the patient's surgical procedure and to take the x-ray prior to leaving the operative room when instrument counts were not performed. The facility's failure to implement its policy and procedure to prevent retention of a surgical instrument during a surgical procedure is a deficiency that has caused, o r is likely to cause			

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	serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the Health and Safety Code Section 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 1280.3(g).			