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
	050100	A. BUILDING _____ B. WING _____	08/08/2012

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SHARP MEMORIAL HOSPITAL	7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00296958 - Substantiated Representing the Department of Public Health: Surveyor ID # 12766, 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. 70223 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 interviews and record review, the surgical team at Hospital B, under the direction of Physician V, failed to implement all aspects of existing hospital policies and procedures (P&P) related to		Plan of Correction following Exit Conference conducted 8/8/12: Sharp Healthcare Policy #46849.99 "Universal Protocol for Surgical and Invasive Procedures" was reviewed with perioperative staff. Processes supporting the policy regarding relevant diagnostics were implemented as outlined below: 1. Education conducted with perioperative staff highlighted the need for diagnostic images for those procedures involving lateralized organ removal, joint replacement, and/or any procedure performed on the brain or spine. This education was also incorporated into ongoing departmental orientation. • Guidelines were provided to the OR RN staff to STOP the procedures noted above from proceeding if diagnostic imaging was not available, and to notify the Surgery Charge RN. 2. The Surgery Scheduling booking process was modified to include screening for available diagnostic images for procedures involving laterality, level, and/or multiple structures when the operative site is an organ, bone, spine, and/or head. 3. The Imaging Procedure Report was enhanced to provide image location information to surgery and radiology departments in order to locate and upload images when necessary to allow for retrieval on the date of surgery by surgical staff and surgeons.	1/23/12 1/26/12 2/9/12 4/6/12 4/6/12

Event ID:94UE11 8/17/2012 12:48:28PM

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Joan M. Eng	Director, Regulatory Affairs	8/29/12

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.

Ahs 9/11/12

TAWS

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	Continued From page 1 the identification of the correct surgical site/side. This resulted in the removal of the left kidney of Patient K, when the suspected cancerous mass was actually located in the right kidney. The surgical team failed to have any of the relevant images of the kidney(s) available and displayed during any part of the surgical procedure. Patient K, a 53 year old male, presented to the Emergency Department of Hospital A on [redacted]12 with blood in the urine. Imaging exams (computed axial tomography/CT) were completed at Hospital A, and indicated that Patient K had a suspected cancerous mass in the right kidney. The original documentation related to the suspected mass was provided in two reports authored by Physician L (radiologist) at Hospital A. Patient K was subsequently referred to Hospital B's surgical services for the removal of the LEFT kidney on [redacted]12. The left kidney was surgically removed on the same date, only to be discovered that the incorrect kidney (left) had been removed. The CT images of Patient K, completed at Hospital A on [redacted]12, were not available to the surgeon or surgical team at Hospital B on the day of surgery on [redacted]12. Two reports related to the CT exams were authored by Physician L at Hospital A. Report #1 was dated [redacted]/12 at 12:21 PM, and documented, "Suggestion of 3 cm soft tissue mass, left renal mid to lower pole lateral surface. Recommend further evaluation with contrast enhanced CT."		4. The Pre-Operative Safety Checklist was revised to include Diagnostic Image Availability Verification. The checklist also outlines the actions the OR RN must take if the diagnostic imaging is not available for those procedures involving lateralized organ removal, joint replacement, and/or any procedure performed on the brain or spine. Monitoring: 1. Audits have been conducted on 100% of all surgical procedures involving lateralized organ removal, joint replacement, and/or any procedure performed on the brain or spine X 4 months to ensure Pre-operative Safety Checklist Diagnostic Image Availability Verification occurred. • Data reflect 100% compliance. 2. Audit results were reported to the Regulatory Affairs department. 3. The data will be incorporated into the Quality Assurance program. Responsible Party: Director, SMH Surgical Services	4/16/12 8/11/12 8/24/12

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	Continued From page 2 An addendum was added to the report on the same date which stated the wrong kidney (left) had been incorrectly identified with the mass and the mass, "Is actually located within the **RIGHT** kidney." Report #2 was completed using the recommended contrast on [redacted]12 and timed at 4:48 PM. The findings aspect of the imaging exam documented, "There is a 5.2 x 5.0 x 5.0 cm (centimeter) soft tissue mass within the right renal pole." The final impression, documented by Physician L, again referred to, "Mildly enhancing left renal mid to lower pole 5 cm mass." The two reports did offer conflicting information related to right and left, however both reports generated by Physician L carried an addendum stating the left kidney was incorrectly identified in the reports and the renal mass was located in the right kidney. During the investigation, the electronic medical record from Hospital A provided evidence of Physician V (surgeon) accessing the images and laboratory reports of Patient K on [redacted]12 at 5:21 PM, 33 minutes after the addendum related to the correct (right) kidney had been posted by Physician L. There was no evidence to support Physician V had read the two reports created by Physician L. Physician V was interviewed on 2/3/12 at 11:30 AM, and stated he had accessed the Hospital A medical records (images) of Patient K remotely, and confirmed he did review the images (CT) in his office on [redacted]12, upon notification from a colleague			

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regarding Patient K. Physician V stated he had no recollection of reviewing the written CT reports generated by Physician L from Hospital A.

Physician V stated he examined Patient K in his office on [redacted]/12, and the examination failed to provide any evidence related to laterality (left or right) of the kidney tumor. Physician V recalled on the morning of the surgery ([redacted]12) he intended to access the images related to the case, but forgot the necessary log in information needed to access the images remotely from Hospital B.

The documents listed below constitute the medical records from Physician V and Hospital B. The specific documents illustrate the incorrect surgical site/side preceding the surgical procedure. The correct surgical side should have been the right kidney.

1. Physician V's office history and physical, dated [redacted]12, identified, "Left renal mass."

2. Booking document for the scheduling of the procedure, dated [redacted]/1, identified, "LEFT radical nephrectomy."

3. Surgical department preoperative planning document [redacted]/1, identified, "LEFT radical nephrectomy."

4. Physician V's history and physical at Hospital B, dated [redacted]12, identified "Mass in LEFT kidney."

5. Pre-anesthesia evaluation, dated [redacted]12,

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	Continued From page 4 identified, "LEFT radical nephrectomy." 6. Pre-surgical verification worksheet, dated [redacted]/12, identified, "LEFT radical nephrectomy." 7. Registration information, dated [redacted]/12, identified, "Diagnosis LEFT kidney mass." 8. Surgical consent signed by Patient K and dated [redacted]/11, identified, "LEFT laparoscopic radical nephrectomy." 9. Surgical nursing documentation, dated [redacted]12, identified, "Procedure to be done LEFT radical nephrectomy. 10. Pre-operative safety checklist, identified, "Surgical site verified with patient - LEFT kidney." Missing from the surgical team's operating room suite were the images (x-rays/scans) of the kidney, which had been completed on [redacted]/12, prior to the surgery. Hospital B's policy and procedure (P&P) titled Universal Protocol For Surgical and Invasive Procedures (#46849.99) was reviewed in conjunction with the investigation. The P&P directed the surgical team related to the methodology of ascertaining the correct site/side for surgery. Hospital B's P&P related to verification of the correct site/side included, "Relevant images and results are properly labeled and displayed."			

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The images of Patient K, done at Hospital A, were not available to the surgical team at Hospital B. There were no x-rays, CT images, or CD disc to view in the operating room suite on [redacted]/12, to confirm the correct side /site of the kidney tumor.

Members of the surgical team were interviewed on 1/27/12, including Physician K (anesthesiologist) at 6:30 AM, the Registered Nurse at 7:30 AM, and a Surgical Technician at 7:50 AM. All three attested to the thoroughness of the pre-procedure verification process related to establishing the correct side/site for the surgery on Patient K, and all the preoperative documentation indicated surgery was to be performed on the left kidney. In addition, Patient K corroborated during the preoperative verification process the left kidney was the correct surgical side/site. The request to view any images was brought into question by Physician K. The RN stated she was asked to bring up the radiological images on the computer screen, but none were available. The surgical technician again reiterated this aspect in a separate interview.

The members of the surgical team were asked if the missing radiological images constituted enough lack of information to stop the surgical procedure from moving forward. The surgical team members stated the absence of the images was brought to the attention of Physician V, and Physician V made a decision to proceed with the scheduled surgery.

The surgical error was driven by the fact that the

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documents all had the incorrect information, and the images related to the right kidney were not available any time during the surgical procedure.

On 2/29/12 at 8:00 AM, a visit was made to view the images of Patient K, done at Hospital A on [redacted]/12. The CT images displayed provided a marking of R on the viewing screen to indicate laterality (right versus left). Additionally, the Emergency Department physician notes from Hospital A were reviewed from the [redacted]/12 visit and clearly document the presence of a "Mass right kidney."

A critical checkpoint, required by the hospital's policy and procedure, was bypassed by the surgical team when the surgery went forward on [redacted]2 without the required availability of the kidney radiology (CT) images for review immediately before the procedure.

On [redacted]/12, Patient K underwent another surgical procedure to remove the remaining cancerous right kidney, at a third hospital. The hospital's pathology report dated [redacted]/12, documented the intake of a right kidney from the procedure (right radical nephrectomy), and indicated the presence of renal cell carcinoma (kidney cancer).

In addition, Patient K's sister reported on [redacted]/12 via email, "They had to take [Patient K's] kidney. No clear margins. They were unable to save it. Which means he is on dialysis. Very sad. He should be discharged hopefully tomorrow."

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	Continued From page 7 As of [redacted]/12, both of Patient K's kidneys had been removed. Patient K, a 53 year old man, will need continuous on-going kidney dialysis to survive. The facility's failure to ensure the surgical team implemented all aspects of existing hospital policies and procedures related to the identification of the correct surgical site/site and the images of the kidney(s) available and displayed during the surgical procedure, resulted in the removal of the left kidney of Patient K, when the suspected cancerous mass was located in the right kidney. 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).			

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