

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

*Revised 7/26/12 PHS/mj*

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050515</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>05/05/2011</b>
NAME OF PROVIDER OR SUPPLIER <b>KAISER FOUNDATION HOSPITAL - SAN DIEGO</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY</b>		
(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
	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number CA00253183 - Substantiated</p> <p>Representing the Department of Public Health Surveyor ID # 12766, Health Facilities Eval. Nurse</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p><i>PHS 70223</i> <del>70225</del> 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.</p> <p>Patient L, an 85 year old male, presented to the hospital's surgical services for the removal of the right kidney on [redacted] 10. The right kidney was surgically removed on the same date, only to be</p>		<p><b>RECEIVED</b> CA DEPT OF PUBLIC HEALTH</p> <p><b>MAY 27 2011</b></p> <p>LICENSING &amp; CERTIFICATION SAN DIEGO COUNTY DISTRICT OFFICE</p> <p><b>T22: DIV 5 CH1 ART3 70233 Surgical Services General Requirements</b></p> <p><b>Plan of Correction</b> 1. Updated and implemented policy and procedure titled "Patient Procedure Site Verification Policy" which includes mandatory review of all relevant images for any surgical or invasive procedure for which an image was obtained. This review will validate the surgical procedure and/or the site/site of the procedure. The image will be available and reviewed during the Time Out process. • Policy approved by the Surgical Services Committee and Medical Executive Committee.</p>	1/1/2011

Event ID: NDLD11      5/6/2011      10:11:29AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Barbara A. Stevens Ph.D., RN*      TITLE: *Chief Nurse Executive*      (X6) DATE: *5-25-11*

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*Marian Yerna, Assistant Administrator  
QUALITY & SAFETY*

*7/26/2012*      1 of 6

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	<p>Continued From page 1</p> <p>discovered that the incorrect kidney (right) had been removed. The medical records of Patient L provided that the left kidney was the organ that had been previously identified, over a four year period, to have a suspected cancerous tumor mass. Patient L had been seen over a four year period of time by various physicians in the healthcare system, with each physician ordering computed axial tomography (CT) exams. The results of the CT exams were documented in the medical record of Patient L as follows:</p> <ol style="list-style-type: none"> <li>1. [REDACTED] 2006 - left renal mass</li> <li>2. [REDACTED] 2007 - left renal mass.</li> <li>3. [REDACTED] 2010 - enlarged from 2007 study, referring to the left kidney.</li> <li>4. [REDACTED] 2010 - left renal mass increased in size since [REDACTED] 10.</li> <li>5. [REDACTED] 10- mass in upper pole of the left kidney.</li> </ol> <p>Surgeon S was interviewed related to the case on 1/19/11 at 8:30 AM, and stated that he did see Patient L once in an office visit in [REDACTED] 2010 " for the surgical evaluation of a left kidney mass, and did not see Patient L again until the [REDACTED] 10 surgery date. Surgeon S documented the [REDACTED] 10 office visit with, "Pertinent imaging: as in left renal mass enlarged from 2.15 to 3.5 cms (centimeters) over a year "</p> <p>Surgeon S stated that he met with Patient L in the pre-operative area of surgery, reviewed the procedure with the patient, and then marked the surgical site of the right kidney area. Surgeon S stated that the CT images would have been easily available on a screen in the operating room suite. Surgeon S stated in the interview that he did not feel the radiology images were relevant to this</p>		<p>2. All Perioperative Staff were in-serviced on the updated "Patient Procedure Site Verification Policy" to prevent the reoccurrence of a surgical procedure being performed on a wrong body part.</p> <p>3. During the Time Out, the Operating Room Circulator Nurse and Surgeon will assure all relevant imaging studies are available, displayed and verified.</p> <ul style="list-style-type: none"> <li>• All Operating Room Circulator Nurses were: <ol style="list-style-type: none"> <li>a. Trained and given access to our Online, electronic imaging system.</li> <li>b. Instructed and required to access, display, and verify relevant images with the surgeon, prior to surgical incision.</li> </ol> </li> <li>• All members of the Surgical Team have been trained and given access to the online imaging system and trained on the requirement to verify laterality by review of relevant images.</li> </ul> <p>4. All Surgeons were in-serviced on the updated "Patient Procedure Site Verification Policy".</p> <ol style="list-style-type: none"> <li>a. Any surgical or invasive procedure for which an image was obtained will be available and reviewed during the Time Out process. This review will validate the surgical procedure and/or the site/side of the procedure.</li> <li>b. In the event that diagnostic films or online images are not available, then a transcribed report must be present in the medical record and used for verification of the surgical site / side.</li> </ol> <p>5. As part of the Department's orientation all newly hired Perioperative Staff will review the, "Patient Procedure Site Verification Policy".</p>	<p>2. All Staff in-serviced by 3/5/2011</p> <p>3. All Staff trained by 3/5/2011</p> <p>4. All Surgeons in-serviced by 3/5/2011</p> <p>5. On-going</p>

Event ID: NDL11

5/6/2011

10:11:29AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

*Debra A. Stevens Ph.D. RN*

*Chief Nurse Executive*

*5-25-2011*

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	<p><b>Continued From page 2</b></p> <p>case, because "the procedure did not require a review of the anatomy or vasculature "</p> <p>A document, submitted by the hospital administration, provided evidence that the surgical procedure was scheduled on [REDACTED] 10 at 5:35 PM for [REDACTED] 10, and that the surgery was to be done on the right kidney. During the 1/19/11 interview Surgeon S stated that he had no recollection of scheduling the surgery for Patient L.</p> <p>Surgeon S stated the error was discovered when a pathologist notified him there was no mass in the kidney that had been submitted to the pathology department. The pathology report was dated [REDACTED] 10.</p> <p>Prior to the surgical procedure date, Patient L was seen by Nurse Practitioner T (NPT) on [REDACTED] 10, at which time a history and physical (H&amp;P) was conducted. NPT documented in the H&amp;P, "Computerized Tomography initially in 4/06 was found to have 3 centimeter renal mass. States that it had been stable until last year where it had started to increase in size and would like to have it removed. States that he has been having right flank pain." The note by NPT makes no reference to site/side (left or right) related to the mass, but only that Patient L referred to pain on the right side.</p> <p>NPT was interviewed on 1/26/11 at 1:30 PM. NPT stated he examined and conducted a history and physical on Patient L on [REDACTED] 10. Patient L indicated to him that the surgical site was to be at the right kidney and Patient L "pointed to it."</p> <p>NPT stated that he failed to review any of the relevant CT images from the past four years that indicated the tumor was located on the left kidney, when conducting the history and physical on</p>		<p><b>Monitoring</b></p> <p>Time Out Imaging Review Audit:</p> <ol style="list-style-type: none"> <li>1. Beginning January 24, 2011, weekly audits of 100% of the surgical procedures involving laterality to verify pertinent images are reviewed as part of Time Out. <ul style="list-style-type: none"> <li>• Audit results indicate 100% compliance since implementation.</li> </ul> </li> <li>2. Audit results reported to the Quality Department on a weekly basis.</li> <li>3. Audit results reported to the Patient Safety Committee and Medical Staff Quality Oversight Committee.</li> </ol> <p><b>Responsible Parties</b></p> <ul style="list-style-type: none"> <li>• Director of Perioperative Services</li> <li>• Chief Nurse Executive</li> <li>• Physician Director of Surgical Services</li> </ul>	<p><b>Monitoring</b></p> <p>1 On-going</p> <p>2 On-going</p> <p>3 May 2011 and ongoing quarterly</p>

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Barbara Astrows PhD, RN</i>	TITLE <i>Chief Nurse Executive</i>	(X6) DATE <i>5-25-2011</i>

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	<p><b>Continued From page 3</b></p> <p>Patient L [REDACTED] 10. NPT relied on Patient L's verbal statement that the surgical side/site was to be the right kidney.</p> <p>NPT finalized the process on [REDACTED] 10, and had Patient L sign a surgical consent for the removal of the right kidney.</p> <p>The hospital adopted the Joint Commission Universal Protocols standard of care related to performing surgery on the correct site/side and was reflected in the policy and procedure (P&amp;P) titled Procedure and Site Verification (#2020 October 2008 )</p> <p>As documented in the P&amp;P (Policy section #2), "If relevant, the imaging films will be properly displayed labeled and displayed on nearby view boxes."</p> <p>Section 3.E. #1 further explained and reiterated the process for "Time Out" prior to performing surgery. The Time Out as defined in the P&amp;P was for the purpose of providing the "opportunity for the team members to share pertinent information regarding the patient's care and conduct a final verification process."</p> <p>Documentation in Section 3. E. #11 of the P&amp;P, provided that the "availability of relevant images, properly labeled and displayed."</p> <p>During the surgical procedure on 12/18/10 the relevant images related to Patient L were not utilized.</p> <p>RN C was assigned to the surgical case involving Patient L on [REDACTED] 10 and was interviewed on 1/26/11 at 1:45 PM. RN C was responsible for providing additional corroboration with Patient L related to the procedure to be performed. RN C stated that Patient L identified to her that the</p>			
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	<p><b>Continued From page 4</b></p> <p>surgery was to be performed on the right kidney. Per the interviews with Surgeon S and RN C, the relevant CT images of Patient L from the past four years were not reviewed by Surgeon S, nor displayed on the view boxes in the surgical suite prior to surgery or during the procedure. Patient L was then taken to the surgical suite where the right kidney (incorrect kidney) was surgically removed.</p> <p>The hospital administration did not provide any investigation or report related to the error, which resulted in the incorrect kidney being removed from Patient L. The Department was provided with the medical records related to Patient L's procedure dated [REDACTED] 10 through discharge from the hospital on [REDACTED] 10.</p> <p>The wife of Patient L was interviewed on 1/27/11 at 1:30 PM. She stated she had no prior knowledge of which kidney contained the mass and trusted that Surgeon S was aware of the affected kidney. Patient L's wife went onto state that she was present in the pre-operative area when Surgeon S came into discuss the procedure on [REDACTED] 10, and then went onto mark the right kidney (incorrect area) for surgery. Patient L's wife stated that Patient L had been having pain on the right side of his body and that caused him to associate the right sided pain with the right kidney. Patient L's wife went onto state that the medical error has impacted Patient L physically with fatigue and dietary restrictions, and emotionally with depression.</p> <p>An additional interview was conducted with Patient L on 4/20/11 at 1:10 PM. Patient L reflected upon the surgical error and how the error altered his lifestyle. During the interview process Patient L</p>			
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