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
	050073	A. BUILDING _____ B. WING _____	[redacted]2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUND. HOSPITAL & REHAB. CENTER - VALLEJO	975 SERENO DR, VALLEJO, CA 94589 SOLANO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00187028 - Substantiated Representing the Department of Public Health. [redacted], 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: 110007711 E 211 T22 DIV5 CH1 ART3-70213(d) Nursing Services Policies & Procedures (d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. Based on interview and record review, the facility failed to implement their policy and procedure which ensured pre-surgical		Our medical center takes seriously all issues related to patient safety. We have thoroughly investigated this unfortunate event in order to identify opportunities to improve patient care and safety. It was determined that the preparation of the preoperative packets by the Vision Service Assistant was an individual practice issue whereby more than one packet was being completed at one time. Staff was educated to focus on assembly of only one packet at a time. **Responsible party:** Ophthalmology Manager An analysis of the event indicated that Patient 2, the wife of Patient 1, was scheduled for a cataract surgery with the same surgeon for the following month, [redacted] 2009. Patient 2's A-Scan (ultrasound biometry), was incorrectly labeled with Patient 1's name/identifiers and placed in Patient 1's preoperative packet. Patient 1's A-Scan (ultrasound biometry) had both Patient 1 and Patient 2 labels on it.	5-15-09

Event ID: 59SC11 12/21/2010 4:22:17PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Mary Bonnie	Area Quality Leader	1-17-11

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1/24/2011 POC accepted. Sec. Verbal Notified at 5:22pm via VM.

JAN 18 2011

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Continued From page 1

verification of an intraocular lens to be matched and then implanted using Patient 1's identifiers. Patient 1 underwent cataract surgery and when his lens was removed, the lens was replaced with one which had the correct measurements for another patient. A second surgery was required to remove the wrong lens. This resulted in the increased risk for complications related to surgery, including infection, prolonged time for healing of the eye, and patient discomfort.

THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) 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 ENSURE PRE-SURGICAL VERIFICATION THAT THE CORRECT LENS INPLANT WAS TO BE USED. THIS VIOLATION PLACED THE PATIENT AT RISK FROM HAVING TO HAVE A SECOND SURGERY TO INPLANT THE CORRECT INTRAOCULAR LENS.

Findings: See Tag E294

E 294 T22 DIV5 CH1 ART3-70215(b) Planning and Implementing Patient Care

(b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis,

An additional label with the patient identifiers had been adhered to the A-Scan prior to placing it in Patient 1's Pre-Operative Packet. In preparing Patient 1's history and physical, the surgeon referenced the A-scan in Patient 1's packet, which actually belonged to Patient 2. During the time-out (per Universal Precautions policy) in preparation for Patient 1's procedure, the circulating nurse immediately communicated her concerns about conflicting identifiers on the A-scan and attempted to verify the scan accuracy. The lens implant calculations were verified against the H&P. The calculations from the H&P matched the scan. The calculations documented on the H&P were incorrect because they were calculated using the wrong a-Scan.

Actions

It was determined that labels are not needed, as the patient identifiers are electronically documented on the diagnostic test results at the time the test is performed.

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	Continued From page 2 planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission. Based on interview and record review, the facility failed to implement their policy and procedure which ensured pre-surgical verification of an intraocular lens to be matched and then implanted using Patient 1's identifiers. Patient 1 underwent cataract surgery and when his lens was removed, the lens was replaced with one which had the correct measurements for another patient. A second surgery was required to remove the wrong lens. This resulted in the increased risk for complications related to surgery, including infection, prolonged time for healing of the eye, and patient discomfort. THE VIOLATION OF LICENSING REQUIREMENTS CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) 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 ENSURE PRE-SURGICAL VERIFICATION THAT THE CORRECT LENS INPLANT WAS TO BE USED. THIS VIOLATION PLACED THE PATIENT AT RISK FROM HAVING TO HAVE A SECOND SURGERY TO INPLANT THE CORRECT INTRAOCULAR LENS. Findings:		1. The use of the label was discontinued. This change in procedure will reduce the opportunity to misidentify the scan. 2. Assure all A-Scans are uploaded into the Ophthalmologic Imaging Server (OIS) so they will be available digitally at the time of the procedure, and the paper version will no longer be needed. - Time-out should be performed with verification using the original source of calculation. - The A-Scan verification will be documented by the circulating nurse on the cataract safety check-list, by checking off the appropriate boxes in the designated section. The outpatient Ophthalmology Staff (as appropriate) was educated by the department manager's email notification of the new process. It was also discussed during a staff meeting.	5-12-09 5-12-09

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Continued From page 3

During an onsite investigation on [redacted]/09, a review of Patient 1's record revealed the patient was admitted on [redacted]/09 for surgical removal of a cataract lens of the left eye and implantation of an intraocular lens. The admission information for Patient 1 revealed the next of kin was Patient 2

A review of the ophthalmology department intraocular lens worksheet, dated [redacted]/09, revealed that it included both Patient 1 and Patient 2's names for the exam. The worksheet was prepared preoperatively and recorded the measurements to ensure the correct lens was implanted in the eye. Patient 1's name was affixed to the upper right corner of the exam by a preprinted sticker. The sticker had Patient 1's name and the date of surgery, [redacted]/09. Patient 2's name was printed on the worksheet and included Patient 2's medical record number. The discovery of two different names on the document which included the size of lens to implant was discovered during Patient 1's surgery on [redacted]/09.

A review of the facility policy, titled Universal Protocol. Patient, Procedure and Site Marking, Briefings and Final Verification Policy, dated [redacted]/09, included the following:
III. Policy Statement

The pre-procedural verification was an ongoing process of information gathering and

Responsible Party:
Ophthalmology Manager, Special Procedures Manager, Chief of Special Procedures

Monitoring

1. Audit monthly a random sample of pre operative packets assembled in out patient Ophthalmology Clinic to ensure that the secondary label is not used and packets are error-free.
2. Audit monthly a random sample of A-Scans performed on the Ellex 3 to determine that all are uploaded into OIS.

The threshold of 95% was reached for audits completed in June, July, August, September, and October 2009. Reports were made monthly to Risk Management, and quarterly to Performance Improvement Committee. The measure of success was achieved and monitoring was discontinued.

Oct. 31, 2009

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	Continued From page 4 verification which began when the decision to perform a procedure was made, continuing through all settings and interventions involved in the pre-procedure preparation of the patient, up to and including the time-out just before the start of the procedure. The purpose of the pre-procedure verification process was to make sure that "all relevant documents, blood and related information, implants or special supplies/equipment are available prior to the start of the procedure, and matched to the patient's identifiers. ." During an interview on 5/12/09 at 10:15 a.m., the Vision Service Assistant stated patient records are prepared in the ophthalmology clinic before surgery. The preprinted stickers are put in the upper right corner of the page to more easily see the name of the patient. The Vision Service Assistant stated the record goes through many hands before getting to surgery. The assistant did not know how the error occurred. During an interview on 5/13/09 at 11:30 a.m., the Circulating Nurse stated the two names on the document were discovered during "time out", a mandatory period of time before surgery during which the surgical team reviewed the patient, procedure, site of operation and lens required. The presence of two names on the document was seen as a clerical error and the physician proceeded with the left eye lens implant on Patient 1			

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	Continued From page 5 On 5/12/09 at 9:15 a.m., Risk Management Staff stated that on [redacted]/09 when the event was investigated as a clerical error, it was then discovered that Patient 1 had received the wrong intraocular lens implant. Patient 1 received Patient 2's lens implant in error. During an interview on 5/12/09 at 5 p.m., Patient 1 stated that after surgery he was unable to see out of the left eye. Patient 1 stated he had to have a second surgery and it was taking longer for the eye to heal, it was more painful and it felt like sand in his eye. The facilities failure to implement policy and procedure to ensure pre-surgical verification of an intraocular lens matched the correct patient is a deficiency that has 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. 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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