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 COMPLETEO
	050726	A. BUILDING _____ B. WING _____	08/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
STANISLAUS SURGICAL HOSPITAL	1421 OAKDALE ROAD, MODESTO, CA 95355 STANISLAUS COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00240051 - Substantiated Representing the Department of Public Health: Surveyor ID # 27709, 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. Abbreviations: DON Chief Nursing Officer DQM Director of Quality Management MD Medical Doctor OR Operating Room ORT Operating Room Technologist RN Registered Nurse RNM Registered Nurse Manager Health and Safety Code Section 1279.1 (c), "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."		Linda Owen - Chief Nursing Officer 3:58 PM 3/14/11 - Noted Acceptable POC. - Shirley Campbell, HFEN APR 13 2011 LICENSING ... FRESNO	

Event ID: 2R0B11 4/5/2011 8:22:56AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
	CEO	4-11-11

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	Continued From page 1 The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. (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. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY Based on staff and physician interviews, clinical record and administrative document reviews, the facility failed to implement facility established policy and procedures titled "Marking and Verification of Surgical Procedure/Site Universal Protocol" revised 2/10/10. The facility staff failed to ensure the site of a surgical procedure was correct during the pre-operative (before surgery) time out (a brief period of time immediately before surgery, where the surgical team verified: the patient, signed informed consent, procedure, location on the patients body, and that the site of the surgery all corresponded). This resulted in the patient having a wrong site surgical procedure incision made, arthroscopic scope inserted and initial shaving of bone begun. Findings: Record review was conducted on 8/26/10 and had documentation that Patient 1 was admitted to the		Stanislaus Surgical Hospital initiated the following actions: 1. On 8/20/2010 Stanislaus Surgical Hospital voluntarily self reported the event to CDPH. 2. Revised the policy "Marking and Verification of Surgical Procedure/Site Universal Protocol". The revision identified the circulator as the team member to initiate the "time out". The surgical team must verbally agree the surgical site marked with initials of the surgeon or physician assistant actively involved and present in the procedure. The Nurse Executive, Director of Clinical Services, updated the policy. The policy was approved by the Governing Board on 10/30/2010. 3. "Time out" script posters were posted in two locations in each operating room. The circulator verbalizes the script during "time out". The script includes patient's name, verification of surgical site with consent, procedure and the statement "Can you see the site marking?" Poster developed by Operating Room Manager. 4. On 8/23/2010 a surgical staff meeting was conducted. The updated policy and procedure was reviewed. The "time out"	8/20/2010 10/30/2010 8/23/2010

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	Continued From page 2 hospital on [redacted]0. [redacted] was admitted for a surgical procedure to be done to [redacted] left ankle to give [redacted] more range of motion to the ankle. On 3/2/11, during review of the Administrative Policy and Procedure titled, "Marking and Verification of Surgical Procedure/Site Universal Protocol," dated 2/10/10, page 2 of 3 indicated, "Procedure for Verifying the Surgical Site Prior to Marking" "1. ...patient identifies the correct surgical site. 2. Review of the Medical Record, including...Physicians orders...informed consent form...3. Prior to incision, the Circulating Nurse will confirm:...b. 'Time Out' can be called by any member of the surgical team.... d. All members of the surgical team (Surgeon, Anesthesiologists, Circulating Nurse, Surgical Technician and Surgical Assistant) must verbally agree at a minimum on the following: i. identify...patient using two identifiers...ii. Correct surgical side (if applicable) iii. Correct surgical site.. and v. Surgical site marked with initials of the surgeon or Physician Assistant (PA) actively involved and present in the procedure." On 3/2/11 at 3:07 p.m., during a telephone interview, MD 1 indicated, that the left leg was marked preoperatively by MD 1. The patient's right leg was prepared for surgery while MD 1 was out of the room scrubbing (a preoperative washing of the skin). MD 2 had called the preoperative time out. Following the time out, MD 2 made a small incision (a cut into the skin for surgery) on the right ankle. Sterile NS (normal saline), (a special fluid without any bacteria that has the same salt content as the		script and the components of the time out process were reviewed including the requirement for all staff and physicians to pause and actively participate in the "time out". Operating room employees signed a copy of the policy and it was placed in their personnel files. The meeting was conducted by the OR Manager. 5. The action plan report was presented to the Performance Improvement/Risk and Medical Executive Committees during the month of October 2010. The Director of Quality of Care presented the action plan report. Monitoring process: a "time out" audit tool was developed and implemented on 8/24/2010. Random audits were conducted daily until 12/31/2010. On 1/3/2011 the random audits were converted to twice a week. The data will continue to be forwarded to Quality Dept. and a report provided to the Performance Improvement/Risk Committee and Medical Executive Committee (MEC). The OR manager was responsible for the audits. The Director of Quality of Care reported compliance to the committees.	8/30/2010 10/30/2010 8/24/2010 1/3/2011 10/5/2010

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hospital on [redacted]. [redacted] was admitted for a surgical procedure to be done t[redacted] ankle to give[redacted] more range of motion to the ankle.

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On 3/2/11 at 3:07 p.m., during a telephone interview, MD 1 indicated, that the left leg was marked preoperatively by MD 1. The patient's right leg was prepared for surgery while MD 1 was out of the room scrubbing (a preoperative washing of the skin). MD 2 had called the preoperative time out. Following the time out, MD 2 made a small incision (a cut into the skin for surgery) on the right ankle. Sterile NS (normal saline), (a special fluid without any bacteria that has the same salt content as the

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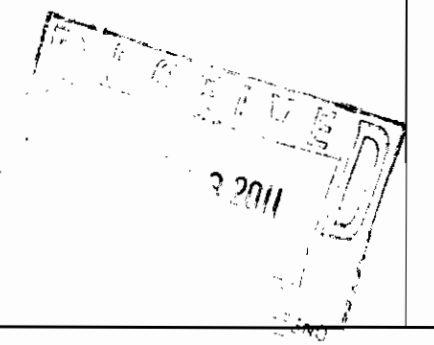
human body) had then been injected into the right ankle joint to help see it better. The Arthroscopic scope (medical equipment that can see into the body through very small incisions) had been inserted into the joint. A little more blood than desired had been seen. MD 1 had started to adjust the right leg tourniquet (a device used to decrease or stop bleeding) and at that time, MD 2 had asked if that was the leg that needed surgery. The arthroscope had then been removed, followed by the closure of the small incision. MD 1 indicated that the total time into the procedure had been about 10 to 15 minutes which included the suturing and dressing of the wrong site (right ankle).

On [redacted]11 at 12:54 p.m., during a telephone interview, RN 2 stated, "it happened really fast...after the time out, MD 1 made...incision...put in a port and some fluid...then realized it was the wrong leg,...stopped...and started surgery on the other leg."

On [redacted]11 at 3:20 p.m., the clinical record Progress Note had been reviewed. It indicated, the right leg had been prepared for surgery, the time out had been done, and surgery on the right ankle was then begun. After the right leg was identified at 8:10 a.m. by MD 2 as the wrong site, the incision was closed and covered by 8:15 a.m. The left ankle was prepped and draped and surgery continued by 8:28 a.m.

The left surgical site was marked in pre-op and the patient verbally confirmed the left ankle procedure. In the operating room the right ankle was positioned



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	Continued From page 4 and prepped without the operating room staff viewing the marked surgical "left" ankle. The consent was read out loud (for the left ankle). The staff failed to recognize the "wrong site" had been readied for surgery. The failure to follow the facility policy and procedure and 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. The above facility failure may result in an Administrative Penalty. 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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