

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>CA040000254</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>C</b> <b>07/13/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>FRESNO SURGICAL HOSPITAL</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>6125 NORTH FRESNO ST FRESNO, CA 93710</b>		
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A 000	Initial Comments  The following reflects the findings of the Department of Public Health during a complaint/adverse event visit:  Complaint Intake number: CA00258732 - Substantiated  The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.  Representing the Department of Public Health: [Redacted] Rn, HFEN  Deficiencies were issued for the entity reported incident CA00258732	A 000	<p style="text-align: center;"><b>POC ACCEPTABLE</b> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p>Reviewed By: <u>Stanford</u> Name</p> <p style="text-align: center;"><b>Facility Notified</b></p> <p>Name: <u>Lori Ruffner</u> Date: <u>10/2/11</u> Time: <u>4:00 PM</u> Notified By: <u>Stanford</u> Name</p>	
A 001	Informed Adverse Event Notification  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."  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. <b>DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY</b>	A 001	Informed Adverse Event Notification  The facility informed the patient and the family of the adverse event prior to reporting the incident to CDPH per Health and Safety Code Section 1279.1(c).	
E 347	T22 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	E 347	T22 DIV 5 CH1 ART3-70223 (b)(2) Surgical Services General Requirements  The Document Management Committee which is chaired by the Chief Nursing Officer is responsible for the development, maintenance and implementation of the written policies and procedures in consultation with administration and other appropriate healthcare professionals. All of the policies and procedures are approved at the Medical Executive Committee and the Board of Managers meeting prior to being implemented.	

Licensing and Certification Division

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

STATE FORM

6099

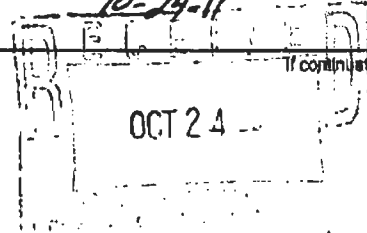
NZ0L11

CEO

TITLE

10-24-11

(X8) DATE



If continuation sheet 1 of 5

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E 347	<p>Continued From page 1</p> <p>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>This Statute is not met as evidenced by: Based on staff interview, clinical record, and administrative document review, the facility failed to implement the " Universal Protocol for Preventing Wrong Site ...Surgery " policy and procedures. The facility failed to ensure time outs were implemented when staff failed to identify the correct surgical site for Patient 1. This failure caused Patient 1 to undergo additional surgical time and necessitated an admission to the facility instead of going home the same day as the surgery.</p> <p>On [REDACTED] 11 at 1:40 p.m., the Operating Room (OR) Registered Nurse (RN)1 entered the Pre-op area to retrieve the patient for surgery and identified that the surgical site was not marked. RN1 was unable to locate the surgeon, but did locate Physician Assistant 1 and requested to have Patient 1 ' s surgical site marked. The Pre-Anesthetic Evaluation form dated [REDACTED] 11 at 1:44 p.m., was completed and signed by Anesthesiologist 1. Anesthesiologist 1 documented the surgical site as " Right (should have been left) Knee Arthroscopy. " At 1:51 p.m., according to the " Anesthetic Record, " Patient 1 was brought into the OR 6 by RN1 without rechecking to ensure the correct site (left knee) had been marked. Upon arrival to OR 6, no other team members were present except RN 1. Members of the team were paged by RN 1. As the team arrived, a time-out (a confirmation to ensure the OR team had the correct patient, side/site of surgery...) should have been announced, but this was not done at the</p>	E 347	<p>The Universal Protocol policy and procedure has been revised by the CNO on February 23, 2011 to emphasize that a site mark is to be made at or adjacent to the incision site, and must be visible after the patient is prepped and draped. Verbiage was added to the policy that states during a time out, activities are suspended to the extent possible, so that team members can focus on active confirmation of the patient, site and procedure. The <u>entire</u> surgical team is to actively participate in the "time out" process which includes active communication among all members of the procedure team. The Time Out procedure was revised to include that an oral verification of the correct side and site be performed by each member of the OR team which acknowledges that they are engaged and focused on the process of "Time Out". The time out procedure was revised to include verification of the correct patient, correct side/site and correct procedure to be performed. All other components previously included in the time out such as antibiotics, correct implants and equipment, were removed and included in the pre-procedure verification checklist in order to allow the team to focus on only the mandatory elements of the time out procedure. Documentation of the time out on the Operating Room Record was also revised to reflect these changes in practice.</p> <p>The pre-procedure Verification Checklist was also revised By the CNO on 3/1/11 to include a double check off by the pre-op RN and the OR RN, to assure the site has been marked at or adjacent to the site by the Licensed Independent Practitioner who is privileged to perform the procedure or is involved in the procedure. OR staff and Pre-op staff were educated on the newly revised form by the OR Coordinator and the Pre-op/PACU manager .</p>	

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E 347	<p>Continued From page 2</p> <p>time.</p> <p>At 1:54 p.m., according to the anesthetic record, the anesthesiologist started induction, during this time the Physician Assistant (PA) came into the OR and placed the tourniquet on the upper thigh of the wrong extremity (right knee), and placed the wrong extremity (right knee) into the leg holder (positional device), without checking the surgical site marking verifying the correct surgical site.</p> <p>At approximately 2:00 p.m., the RN1 finished assisting the anesthesiologist and started to prep the wrong extremity where the tourniquet was, not verifying the surgical site marking. Once the prep was completed RN1 handed the wrong prepped extremity to Operating Room Technician 2 (a fill in ORT) who started draping the extremity without visually verifying the surgical site marking.</p> <p>At 2:00 p.m., ORT1 arrived back from break and proceeded to complete the set up of the instruments on the back table. ORT 2 left OR 6 when ORT 1 returned.</p> <p>At 2:05 p.m., a time out was performed with all team members present. The incorrect site was documented in the OR record as the correct site as no one visually verified the marking of the site to be operated on.</p> <p>Anesthetic OR Record dated [redacted] 11 indicated a tourniquet was applied to the right leg (wrong site) and inflated at 2:08p.m., to 350 pounds of pressure to minimize bleeding and deflated at 2:25p.m.</p> <p>At 2:25 p.m., the surgery was completed to the wrong site.</p>	E 347	<p>All operating room staff were educated on the Universal policy and procedure changes by the OR manager on February 23, 2011. This education also included the pre-procedure verification Checklist. The Universal Protocol policy and procedure (TX 04.011) and OR Verification checklist will be in effect for all patients having a surgical procedure performed at FSH. This process will be monitored going forward to assure strict compliance</p> <p>30 surgical procedures per month will be monitored concurrently by the OR Coordinator to assure that the time out is completed according to the new policy and that the site is marked appropriately. Monitoring criteria will include: The licensed Independent Practitioner's initials will be made at or adjacent to the incision site; the marking is visible after the patient is prepped and draped; activities are suspended during the timeout procedure; time out includes correct patient identification; correct side/site and correct procedure; an oral verification from each team member occurs acknowledging the correct side/site and procedure and that the time out is documented on the OR record. The results to the audits will be reported by the OR representative to the Hospital Wide Quality Committee on a quarterly basis. Ongoing concurrent monitoring will continue for a minimum of 6 months, until the quality committee has seen satisfactory compliance with all components of the Universal Protocol policy and procedure.</p>	2/23/11 S. [redacted] Kori Ruffman CNO

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E 347	<p>Continued From page 3</p> <p>At 2:28 p.m., according to the RN operative record and the physician operative report, Patient 1 was placed on a gurney and RN 1 began to roll Patient 1 out of OR 6. Surgeon 1 reentered OR 6 and questioned the OR team as to which knee he had operated on. The team responded, " Right Knee " Surgeon 1 stated " I operated on the wrong knee. "</p> <p>At 2:46 p.m. on [REDACTED] 11, Patient 1 was placed back on the OR 6 surgical table and a left knee arthroscopy was completed.</p> <p>On 7/21/11 at 11:30 a.m. during an interview Patient 1 stated he had a lot of trouble just trying to walk to the bathroom. He stated he does not have a leg to bear weight on. Patient 1 stated he could not use crutches until one of his knees healed to be able to support weight bearing. He stated he still wore a brace on his left knee.</p> <p>The clinical record was reviewed on 2/25/11 and showed Patient 1 arrived at Surgical Pre-Op holding area on [REDACTED] 11 at approximately 12:20 for an elective Left Knee Arthroscopy. The " Consent for Surgery " was signed and dated [REDACTED] 11 at 12:20 p.m., which indicated the procedure was to be performed as a " Left Knee Arthroscopy, Debridement, and Micro-fracture Medial Femoral Condyle. "</p> <p>The facility policy and procedure titled " Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery " Revised 12/01/08 indicated ... (D) " A site mark will be made at or adjacent to the incision site, and must be visible after the patient is prepped and draped " ... " a verbal time out must be done immediately before the start of the case, after the patient is</p>	E 347		

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E 347	<p>Continued From page 4</p> <p>draped, and before the first instrument is passed " ... " Confirmation of the following will be made: correct patient, correct side/site, correct procedure, correct patient position ... "</p> <p>The facility ' s failure to ensure staff followed the " Universal Protocol for Preventing Wrong Site ... " resulted in Patient 1 sustaining a wrong site surgery when the marking for the surgery was not visually verified by staff when the first " time out " prior to the start of surgery was not conducted. On 7/21/11 at 11:30 a.m., Patient 1 stated he continued to have a lot of trouble walking and he was unable to bear weight since the surgery done on █/11 - █ months earlier.</p> <p>This 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.</p>	E 347			