

AP# 060007015

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>050589 | (X2) MULTIPLE CONSTRUCTION<br>A. BUILDING _____<br>B. WING _____ | (X3) DATE SURVEY COMPLETED<br><br>09/01/2009 |
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| NAME OF PROVIDER OR SUPPLIER<br><b>PLACENTIA LINDA HOSPITAL</b> | STREET ADDRESS, CITY, STATE, ZIP CODE<br><b>1301 ROSE DRIVE, PLACENTIA, CA 92870 ORANGE COUNTY</b> |
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|  | <p>The following reflects the findings of the Department of Public Health during a complaint/adverse investigation visit:</p> <p>Complaint Intake Number:<br/>CA00196614 - Substantiated</p> <p>Representing the Department of Public Health:<br/>██████████, HFEN</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>T22 DIV5 ART3-70223(b)(2) Surgical Service General Requirements<br/>(b) A committee of the medical staff shall be assigned responsibility for:<br/>(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>Based on observation, interview and record review, the hospital failed to have a policy and procedure in place for the introduction of devices into the OR</p> |  | <p>The plan of correction is prepared in compliance with federal regulations and is intended as Placentia-Linda Hospital's (the "hospital") credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.</p> <p><u>Organization Minutes:</u><br/>The confidential and privileged minutes are being retained at the facility for agency review and verification if required.</p> <p><u>Exhibits:</u><br/>All exhibits including revisions to Medical staff Bylaws, reviewed/revise or promulgated policies and procedures, documentation of staff and medical staff training/education are retained at the facility for agency review and verification upon request.</p> <p><u>Tag:</u></p> <p><u>Policy &amp; Procedures:</u><br/>The Director of Surgical Services developed and implemented a Management of Orthopedic Implants Policy in September 2009. This policy outlines the process for setting up and checking for correct orthopedic sided components prior to the start of surgery during the time out process. In addition, this policy outlines the process for a second timeout during surgery but prior to the insertion of an orthopedic component to verify that the correct orthopedic sided components were removed from its box. Both timeouts require active involvement by all members of the OR team and require documentation of such actions</p> | September 2009 |
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| Event ID: CHY311  | 3/3/2010     | 9:01:01AM            |
| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE<br><i>Karl Chapin</i> | TITLE<br>CEO | (X6) DATE<br>3/18/10 |

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|  | <p><b>Continued From page 1</b></p> <p>(Operating Room). This resulted in an incorrect implant device placed into a patient which then required a second surgery to remove the incorrect device and replace it with a correct device.</p> <p>Findings:</p> <p>The medical record for Patient H was reviewed on 8/20/09. Review of the record showed that on 2/5/08, the patient had a left total knee replacement. The patient was in the hospital for four days and received treatments that included pain medications and ice packing for pain control and physical therapy. On 8/21/09, additional review of Patient H's medical record showed in the implant tracking log for the 2/5/08 surgery an implant sticker from the implant device used, showed "Size 7, Right Posterior Femoral Component."</p> <p>On 7/16/09, Patient H was readmitted to the hospital for persistent left sided knee pain. An X-ray of the left knee showed the femoral (thigh bone) component of the knee replacement used on 2/5/08 was for a right knee. The patient subsequently underwent another surgery on 7/16/09. According to the physician's operative report, the surgery included removal of the existing femoral component, cementing in a new femoral component and debridement of extensive scar tissue in the left knee.</p> <p>Further review of the medical record showed that after the surgery the patient was on continuous pain medication of an epidural (a catheter placed in a spinal space) analgesia from 7/16/09 through</p> |   | <p>in the medical record.</p> <p>The Director of Surgical Services reviewed and revised the Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy in September 2009 to specify that correct orthopedic sided components will be checked during the first and second time out processes as outlined in the Management of Orthopedic Implants Policy.</p> <p><u>Training:</u> The Director of Surgical Services and the Educator inserviced 100% of the OR staff and 100% of the orthopedic vendors on both the new Management of Orthopedic Implants Policy and the revised Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy.</p> <p>This information has been incorporated into new OR staff orientation and existing staff annual reorientation. This information is documented in the employees Human Resource file.</p> <p>The Director of Surgical Services implemented a process for any new orthopedic vendor to be inserviced on both the new Management of Orthopedic Implants Policy and the revised Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy. This information is kept in a web based software program that tracks vendor education.</p> | <p>September 2009</p> <p>September 2009</p> <p>September 2009</p> |

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|                    | <p><b>Continued From page 2</b></p> <p>7/18/09 at 1100 hours. Additionally, the patient received an oral pain medication, hydrocodone with acetaminophen (a combination narcotic and non-narcotic pain reliever). The patient received 11 doses of this medication from 7/17/09 through 7/19/09 for severe pain. The patient was discharged on 7/19/09.</p> <p>On 8/20/09 at 1500 hours, MD A, the surgeon performing both the 2/5/08 and the 7/16/09 surgeries, was interviewed. MD A stated that the company representative for the implant device brought the knee implant components into the OR after the size needed was determined. The representative showed the boxes to the MD, the circulating nurse and the OR technician. MD A stated that the size written on the box was in large letters but the side the device was to be used on was in smaller letters. According to MD A, the top of the femoral implant was higher on one side and the high side goes to the outside of the knee. MD A went on to add that the implant was a dark color making it harder to see in the knee during surgery.</p> <p>On 8/21/09, at 0830 hours, ORT B (OR technician) present at the 2/5/08 surgery was interviewed. ORT B was unable to remember this specific surgery, however, described the usual course of events during a surgery of this type at this hospital. According to ORT B, the implant company representative started placing the implants in the OR. The implant company representative obtained these implants from a larger container located in a hallway outside the OR. After the incision was made the representative would bring a box</p> |               | <p>The Director of Surgical Services inserviced all current orthopedic surgeons on both the new Management of Orthopedic Implants Policy and the revised Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy. This information will be provided for any new orthopedic surgeon on both the Management of Orthopedic Implants Policy and the Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy. The Director of Surgical Services will maintain sign in sheets for each orthopedic surgeon inserviced.</p> <p><u>Monitoring:</u><br/>The Director of Surgical Services and/or qualified designee reviewed a 100% of all orthopedic implant cases through either direct observation or medical record review for four consecutive months (September 2009 – December 2009) to determine whether both the first time out to confirm that the correct orthopedic sided components were present and whether the second time out to confirm that the correct orthopedic sided components were rechecked again were done according to the new Management of Orthopedic Implants Policy and the revised Operative/Invasive Procedural Site/Side Identification (Universal Protocol) Policy. Results indicate that 100% of all orthopedic implant cases had the correct orthopedic sided components checked during the first timeout and 100% of all the orthopedic implant cases had the correct orthopedic sided components rechecked again during the second timeout.</p> | <p>September 2009</p> <p>September 2009</p> |

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|  | <p><b>Continued From page 3</b></p> <p>containing the implant for the surgeon, OR technician and circulating RN to see. The circulating nurse would put the implant identifier in the implant tracking record. When asked if anyone in the team said the site and size of the implant device out loud, ORT B said it was not a usual practice.</p> <p>On 8/21/09, at 0900 hours, the circulating RN (RN C) was interviewed. RN C also did not remember the specific surgery. RN C stated that during the time out process (a time when all staff are to be focused on ensuring the correct procedure is being done on the correct side of the correct patient), the only reference to the implant would be that it was present. RN C also stated that usually after the surgeon removed the head of the femur, the bone was measured to determine the size of the implant. The surgeon then said the size needed out loud. The implant representative then would hold the implant box up prior to opening and placing it in the operating field so the team could see it but it would be the surgeon that confirmed it was correct. RN C went on to state that left or right side does not usually get verbalized.</p> <p>A telephone interview was conducted with the implant company representative (CR 1) present in the OR on 2/5/08. CR 1 was unable to recall events of the surgery on 2/5/08. According to CR 1, the usual procedure was that implants are outside the OR. When the implant size and type are decided upon, CR 1 would walk outside and get the implants. When the implants were brought back into the OR they would be shown to the surgeon,</p> |   | <p>This information was reported to the Performance Improvement Committee, the Medical Executive Committee and the Governing Board at their regularly scheduled meetings and no further review or action was required.</p> <p><u>Responsible Person(s):</u><br/>Director of Surgical Services<br/>Director of Clinical Quality Improvement</p> <p><u>Disciplinary Action:</u><br/>Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.</p> <p>Medical Staff members demonstrating non-compliance with corrective action will be referred for peer review in accordance with Medical Staff bylaws, as appropriate.</p> |                    |

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|   | <p><b>Continued From page 4</b></p> <p>the OR tech and the circulating RN, then the circulation RN would be given the implant box. When asked if this was always the process used, CR 1 stated no. Sometimes, the nurse would tell me, the CR, to open the box and hand it to the OR technician. CR 1 was unable to remember what system was used for this case. CR 1 went on to add that the surgeon would usually read out loud the size and site when the implant box was shown to him or her.</p> <p>On 8/21/09, review of the hospital's policy and procedure "Operative/Invasive Procedural Site/Side Identification" showed that implants were to be available but failed to show a procedure for how the implants were to be introduced into the OR during the surgical procedure. On 8/21/09, at 1000 hours, the Director of Clinical Quality Improvement confirmed that there were no policies or procedures for introduction of devices/implants during surgery.</p> <p>The facility's failure to develop policies and procedures to prevent the wrong replacement components being inserted during surgery 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(c).</p> |  |   |  |

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