

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050633	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/28/2015
NAME OF PROVIDER OR SUPPLIER TWIN CITIES COMMUNITY HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 1100 Las Tablas Rd, Templeton, CA 93465-9704 SAN LUIS OBISPO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00376465 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25092, 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 1280.3: 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>The following reflects the findings of the California Department of Public Health, Licensing and Certification, during the investigation of an Entity Reported Incident.</p> <p>Entity Reported Incident Number: CA00376465</p> <p>The investigation was limited to the specific Entity Reported Incident investigated and does not represent a full inspection of the facility.</p> <p>Representing the California Department of Public Health:</p> <p>Health Facilities Evaluator Nurse, 2041.</p>		<p>Action Item #1</p> <p>The facility Universal Protocol for preventing wrong site, wrong procedure, wrong person surgery, time out policy was revised to reflect the World Health Organization (WHO) standards.</p> <p>The policy was updated to add a documentation review in the pre-op area to assure all the essential documents clearly identify the specific site and procedure to be performed and that all the documents agree.</p> <p>The policy was updated to specifically indicate that procedures involving toes and fingers must have the specific toe or finger marked. The policy was approved by the Governing Board on June 5, 2014.</p> <p>Continued page 2</p>	6/5/2014

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

[Signature]

TITLE

PCOI

(X6) DATE

5/18/15

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 10

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>California Codes Health & Safety code, Section 1279.1 (a) (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the Department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.</p> <p>California Codes Health & Safety code, Section 1279.1 (b)(1)(A) (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.</p> <p>California Codes Health & Safety Code Section 1280.1 (c):</p>		<p>Action Item #2</p> <p>The facility moved from using a time out form in the electronic medical record to using a paper time out form that followed the World Health Organization (WHO) standards.</p> <p>With the new time out form, the pre-op nurse assures the documentation is correct and matches prior to the patient leaving the pre-op area. The pre-op nurse is also responsible for documenting that the correct specific surgical site was marked by the surgeon.</p> <p>The new time out form was implemented on December 2, 2013.</p> <p>Continued page 3</p>	12/2/2013

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	<p>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>California Code of Regulations, Title 22, §70223 (b)(2):</p> <p>Surgical Services General requirements.</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(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 interview, surgical record review, and facility documentation review, the facility failed to implement its policy and procedure for preventing wrong site surgery. The facility staff failed to ensure the site of a surgical procedure was correct during the preoperative period and again during the "time out" period (a short period of time before the procedure begins, when the surgical team verifies that the patient, informed consent, procedure, location on the body and surgery site all correspond). These</p>		<p>Action Item #3</p> <p>A failure mode and effects analysis was completed in October 2013 on Stop the Line processes within the facility. On November 8, 2013 the Governing Board approved a Stop the Line policy. Surgery staff education was completed by January 13, 2014.</p> <p>The purpose of this policy is foster a culture of patient safety and eliminate avoidable patient harm, all staff is empowered to "Speak Up" when potential sources of patient care errors are identified without fear of blame or retaliation. The goal is to create the safest possible environment in which to deliver care to patients. All employees, medical staff, students and volunteers have the responsibility and authority to immediately intervene to protect the safety of a patient, to prevent a patient safety event and subsequent patient harm.</p> <p>Continued page 4</p>	1/13/14

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	<p>failures' resulted in a wrong site surgical procedure of Patient A's left little finger rather than the intended left ring finger. Further, the patient will need a second anesthesia and surgery to correct the intended ring finger abnormality.</p> <p>Findings:</p> <p>Review of the facility's Policy and Procedure entitled, "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery, Time Out," dated 5/3/12 outlines the following processes and procedures to be implemented for the prevention of wrong site surgeries:</p> <p>"Section 1.0, 1.1: the purpose of this policy is to establish a standard procedure for identifying the correct patient, procedure and anatomical side/site prior to all operative and invasive procedures."</p> <p>"Section 3.0 Scope, 3.2: This policy applies to all procedures involving incision or percutaneous puncture or insertion, the intended procedure site is marked. The marking takes into consideration laterality, the surface, (flexor, extensor), the level (spine), or specific digit or lesion to be treated. The patient or legal representative shall participate in the procedure preparation, identification, and marking process. However, if the patient is unable to respond for any reason all steps in the protocol will be completed as they apply."</p>		<p>Action Item #4</p> <p>Appropriate corrective counseling provided to employees who failed to follow facility policy and procedures. Chief Human Resource Officer verified completion on December 20, 2013.</p> <p>Action Item #5</p> <p>The Director of Peri-Operative or designee will audit 5 patient charts each week to ensure the surgical consent, history and physical and orders indicate the specific location of the procedure that was performed and that the three documents agree. A review of the universal time out checklist will be included in this review to ensure the pre-op nurse is addressing these items prior to the patient going to surgery. The results of these audits will be presented to the performance improvement committee, medical executive committee and governing board on a quarterly basis. The audits will begin the week of May 11, 2015 and continue until 90% compliance is obtained for at least 6 months.</p>	<p>12/20/13</p> <p>5/11/15</p>

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	<p>"Section 3.3: These sites include but are not limited to the following examples: 3.3.2: Multiple structures (such as fingers and toes)..."</p> <p>"Section 4.0 Policy ...Facility shall identify the correct patient, procedure, and anatomical side/site prior to all operative and invasive procedures."</p> <p>"Section 7.0 Procedures: 7.1.2: The physician performing the procedure in conjunction with the patient shall clearly mark the procedure side/site with the word "Yes."</p> <p>"Section 7, 7.1.14: Prior to performing the procedure, the surgical/procedural team will take a moment (time-out)... The team shall verbally verify the following:</p> <p>7.1.14.1: Correct patient identity.</p> <p>7.1.14.2: Confirmation that the correct side and site are marked.</p> <p>7.1.14.3: An accurate procedure consent form.</p> <p>7.1.14.4: Agreement on the procedure to be done.</p> <p>"7.1.14.6: Relevant images and results are properly labeled and appropriately displayed."</p> <p>"7.2 Verification, 7.2.1: For scheduled operative/invasive procedures, the proposed</p>			

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	<p>side/site must be clearly identified on the scheduling form..."</p> <p>"7.2.5: All relevant documentation including the consent form, history and physical (H&P), and diagnostic data shall be verified by the pre-procedural nurse/procedural team. If there are any discrepancies or uncertainties, the pre-procedural nurse/procedural team shall call the surgeon/physician for clarification prior to the start of the procedure."</p> <p>A review of Patient A's medical record was conducted on 2/19/14. Patient A was seen by Physician 1 on 8/21/13, 9/4/13, and 10/3/13 with the assessment of mallet finger deformity of the "left ring finger" (deformity of a finger when the extensor tendon is damaged, the finger or thumb is not able to be straightened). Physician 1's assessments and notes all indicated the left ring finger had the deformity, however, a history and physical (H&P) completed on 10/28/13, indicated the left "little" finger had the deformity.</p> <p>Patient A arrived at the facility on 11/5/13 with a surgical diagnosis of left ring mallet finger per the appointment notification form faxed from Physician 1's office. The hospital's surgery schedule, dated 11/5/13, also indicated Patient A was scheduled for repair of the left ring mallet finger.</p> <p>The perioperative documentation, dated 11/4/13, indicated a telephone pre-surgical</p>			
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	<p>interview between the pre and post procedural nurse (PPON) and Patient A occurred and the documentation confirmed the procedure/surgery to be done was repair of the "left ring finger" tendon.</p> <p>A review of the initial nursing assessment dated 11/5/13 was conducted on 2/20/14. The PPON indicated in the nursing assessment that the operable location was the left finger. During an interview on 4/30/14 at 9:15 a.m., the PPON recalled speaking with Patient A and requested Patient A show the PPON the finger the facility was operating on. According to the PPON, Patient A showed PPON the ring finger on her left hand. The PPON recalled the left ring finger was deformed, and that the rest of the fingers didn't appear abnormal.</p> <p>An order dated 11/5/2013, was received from Physician 1 for surgery which indicated the surgery to be performed as follows: "Repair extensor tendon central slip left." The physician order did not indicate which finger on the left hand was to be operated on. Another order dated 11/5/2013, instructed staff to have Patient A sign a surgical consent for "left hand mallet finger repair" but did not specify which finger. Another order also dated 11/5/2013 instructed staff to "verify surgical site."</p> <p>The PPON/procedural team failed to clarify the surgical site with the physician, as to the specific finger to be operated on, prior to completing the consent form per hospital policy</p>			

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	<p>(7.2.5). A review of Patient A's signed consent form dated 11/5/2013 indicated the following: "Left hand mallet finger repair."</p> <p>During an interview on 2/24/14 at 11:35 a.m., Physician 1 explained seeing the patient in the pre-op area prior to surgery (11/5/13). Physician 1 indicated marking the left hand of Patient A rather than the actual finger to be operated on. This was not consistent with policy (3.0.3.2,3.3.4.0.).</p> <p>According to the Operating Room (OR) report (viewed on 2/14/14), Patient A was sedated and taken to the OR where the facility did a time out, per facility policy, for the purpose of identifying the correct patient, procedure and anatomical side/site prior to all operative and invasive procedures. In the case of Patient A, the consent was incomplete per policy and the markings were not accurate as to the particular finger (digit) per policy. The intraoperative report indicated surgery was performed on the "Finger left little."</p> <p>During an interview with Physician 1 on 4/29/13 at 11:35 a.m., he confirmed the H&P was not correct. Physician 1 stated retrospectively, "No one looked at the surgery schedule," which identified the "Left ring mallet finger."</p> <p>During an interview with a circulating nurse (CN 1) on 4/29/13 at 1:30 p.m., CN 1 indicated she prepared Patient A for surgery but was not in the surgery room very long for the actual</p>				

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	<p>procedure. CN 1 recalled a marking on the left hand, but stated the marking did not point to "the finger" that was to be operated on.</p> <p>During an interview with the Chief Nursing Executive and the Director of Clinical Quality on 4/30/14 at 2 p.m., they agreed the facility's policy and procedure, quoted above, were not followed for Patient A's surgery conducted on 11/5/2013.</p> <p>The information contained in the H&P did not correlate with the information faxed from the physician's office regarding the surgery site for patient A. In addition, the physician's order for the surgery and the patient's consent form were both incomplete and were not clarified prior to the surgery.</p> <p>These failures led up to an inaccurate time out in the O.R. This time out process is used to ensure the surgical consent, markings, and proposed surgery are all the same and all staff is in agreement.</p> <p>While the facility policies and procedures provided multiple opportunities to identify the correct operable site, the facility staff failed to follow these policies and procedures which resulted in the wrong site surgery and the need for a second surgery and anesthesia to correct the ring finger deformity for Patient A.</p> <p>The facility's failure to ensure staff followed their policy and procedure is a deficient practice that has caused, or is likely to cause</p>			

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	<p>serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the Health and Safety Code Section 1280.1 (c)</p> <p>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 continues an immediate jeopardy within the meaning of Health and Safety Section Code 1280.1 (c).</p> <p>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).</p>			

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