The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number: CA00292560 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 28183, 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.

70223 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 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.

The facility failed to ensure that Operating Room (OR) staff implemented their policy and procedure related to surgical site marking and verification,

Plan of Correction following Exit Conference conducted 8/7/12:

1. Mandatory education re: Sharp Healthcare Policy #46849.99 "Universal Protocol for Surgical and Invasive Procedures" was conducted for all OPP perioperative staff. Staff not present were required to complete the mandatory education prior to providing patient care.
   • Direct observational audits were conducted in the pre-op area to ensure site-marking visualization occurred before the patient was moved to the OR.
   • The OPP Surgical Passport form (i.e. hand-off tool) was revised to highlight verification that site-marking has occurred prior to movement of the patient from the pre-op to OR area. In addition, the patient hand-off between the pre-op and OR RNs will allow for review of the Passport status.
   • All Pre-op and OR RN staff were inserviced on the updated Surgical Passport form.

2. During the Time Out, the surgical team will assure the visibility of site-marking after prepping and draping.
   • All members of the surgical team have been inserviced on the requirement to verify site-marking visibility during time out.

Event ID: ZGPR11 8/8/2012 11:26:04AM

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

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 patient. 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.
**Laboratory Director's or Provider/Supplier/CLIA Identification Number:**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<td>050100</td>
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<td>08/08/2012</td>
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**Name of Provider or Supplier:**

SHARP MEMORIAL HOSPITAL

**Street Address, City, State, Zip Code:**

7901 Frost St, San Diego, CA 92123-2701 SAN DIEGO COUNTY

**Event ID:** ZGPR11

**Date:** 8/8/2012 11:26:04 AM

**Laboratory Director's or Provider/Supplier/CLIA Representative's Signature**

**Title**

**(X6) Date**

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**Summary Statement of Deficiencies**

- **Prefix:**
- **Tag:**

**Provider's Plan of Correction**

- **Prefix:**
- **Tag:**

4. Team STEPPS training was initiated in the OPP OR.
5. Departmental orientation for all newly hired perioperative staff will include review of the “Universal Protocol for Surgical and Invasive Procedures.”

Monitoring:
- 70 observational audits of randomly selected cases/month X 4 meeting criteria for site-marking were conducted to ensure:
  1. Verification of site-marking completion in the pre-op area prior to patient transfer to the OR.
  2. A verbal patient hand-off, utilizing the Surgical Passport, occurred prior to patient transfer to the OR.
  3. Visibility of site-marking at the time of time out.
  - Audit results indicate 100% compliance.
  4. The plan of action and audit results were reported to the Quality Department on a monthly basis.
  5. Audit results were report to the Quality and Patient Safety Committee.

**Responsible Parties:**

- Director, Outpatient Pavilion Manager, Outpatient Surgery

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Continued From page 2

LN 1 further stated she did not check off, "Site Initiated," on Patient A’s Surgical Passport (a red-lined section on the Outpatient Hand Off form of required items before a patient can be transferred to the OR).

The OR Circulating Nurse (LN 2) stated during an interview on 1/9/12 at 10:15 A.M. that after Patient A was transferred to the OR, she verbally verified the surgical site and procedure with Patient A, but did not ask the patient if the surgeon had marked the surgical site. According to LN 2, once the surgeon shaved the surgical site, she prepped and draped the site, but did not realize it was the incorrect side. LN 2 stated she did not see any markings, but did not think it was "unusual" at the time.

According to documentation in the Operative Report, dated 11/11, "The patient's left side had not been marked." Per the report, a Time-Out was performed, the patient's right side was prepped, and a small crease incision was made on the right side before the surgical team realized that the procedure was for a left orchectomy. An addendum to the Operative Report, by the surgeon, indicated that he informed the wife and patient of the incision error immediately after surgery.

The Surgeon stated during an interview on 1/12/12 at 11:00 A.M. that on the morning of Patient A’s surgery, he went to see the patient in Pre-Op holding, but the Anesthesiologist was with the patient at the time. The Surgeon stated he did not return to mark the surgical site of Patient A prior to the event.

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8/8/2012 11:26:04AM

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Continued From page 3

surgery. Once in the OR, the Surgeon stated he was standing on the patient's right side, showing the ORT how to shave prep the groin area. The Surgeon said he was in, "Educational mode," and it did not occur to him that he was shaving/prepping the incorrect surgical site. According to the Surgeon, the surgical team all said, "Left," during the Time Out, even though the Surgeon was standing on the patient's right side. The Surgeon then proceeded to make an incision on Patient A's right groin when LN 2 said, "Wait, its left side." The Surgeon stated the incision was superficial, about a couple inches in length, so he closed it with a surgical adhesive bond. The Surgeon acknowledged that, "It was our job to concentrate at that moment and we didn't. Everybody heard, but didn't listen."

The Anesthesiologist stated during an interview on 1/17/12 at 12:40 P.M. that once Patient A was in the OR, he verbally verified the surgical procedure and correct side with LN 2 and the ORT. He stated he was not sure if the surgical site was actually marked because he did not visually verify that it was.

During a phone interview on 1/18/12 at 4:15 P.M., Patient A stated he had some discomfort in PACU (post anesthesia care unit), because there were two incisions.

According to the facility's policy and procedure (P&P), Universal Protocol for Surgical and Invasive Procedures, dated 5/11, "The patient may not be transferred to an operating room or given anesthesia until the planned site/side has been
**Continued From page 4**

verified and initialed by the surgeon." Additionally, "The Circulating Nurse prior to transport to the operating room will verbally and physically verify the surgical site with the patient."

Upon admission to the operating room, "The anesthesiologist, scrub person and circulating RN will verbally and visually confirm patient identity, correct procedure, correct surgical site and review consent."

The P&P also required that: "After induction of anesthesia and immediately prior to the start of the surgical procedure, a Time Out will be performed." During the Time Out, "The entire team must pause and focus their attention to verify the correct patient, the correct procedure and the correct side/site is initialed."

The facility's failure to follow their policy and procedure resulted in physical discomfort from an unnecessary surgical incision to the groin area on Patient A.

This deficiency 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).

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).