The following reflects the findings of the California Department of Public Health during an Entity Reported Incident investigation.

Complaint No: CA 146060
Category: State Monitoring, Other Services

Representing the California Department of Public Health was [REDACTED], HFEN.

1280 1(a) HSC Section 1280
If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand ($25,000) per violation.

1280 1 (c) HSC Section 1280
For purposes of the 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

70527. Outpatient Service General Requirements.
(a) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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<tr>
<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</th>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050424</th>
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<tr>
<td>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</td>
<td>(X2) MULTIPLE CONSTRUCTION A. BUILDING</td>
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NAME OF PROVIDER OR SUPPLIER SCRIPPS GREEN HOSPITAL

STREET ADDRESS, CITY, STATE, ZIP CODE 10666 NORTH TORREY PINES ROAD, LA JOLLA, CA 92037 SAN DIEGO COUNTY

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<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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Continued From page 1

appropriate health professional and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

Based on interview and record review, the facility failed to have policies and procedures in place to meet the safety needs of all the patients in the outpatient surgery center. As a result on 3/26/08, during a surgery under a general anesthetic, Patient A slid off the operating room table onto the floor resulting in the termination of the surgical procedure before completion, admission to the hospital for IV antibiotic therapy and physical therapy for 5 days.

On 4/8/08 at 4:00 P.M., the Performance Improvement Director was notified that Immediate Jeopardy was determined to exist as the facility had no clear policy and procedures in place to ensure the safety of patients related to falls from the operating table during surgery.

Findings:

Patient A was admitted to the hospital’s outpatient surgery area on 3/26/08 for bilateral removal of skin expanders, insertion of permanent breast implants, and bilateral capsulectomies following a previous bilateral mastectomy (removal of the breast) for cancer per the medical record.
On 4/8/08, the medical record was reviewed. Patient A weighed 233.2 pounds according to the anesthesia record. Anesthesia was started at 10:34 A.M. and an LMA (Laryngeal Mask Airway—a tube with an inflatable cuff that is inserted into the pharynx) was inserted for airway and oxygen management. Patient A was placed on a tilt table allowing the surgeon to view and access the surgical site. Surgical restraining straps were placed across the patient’s forehead, upper legs and extended arms. The pelvic restraining strap was not connected across the patient’s lower abdomen because the physician had performed the surgical prep (cleaning of skin) prior to the start of surgery.

At 12:40 P.M. the anesthesiologist documented the following: “pt (patient) was tilted to (right) side-slipped torso off bed despite strap-head supported by me-pt all the way on floor-LMA out …”

Patient A had slid from the operating table onto the un-sterile floor of the OR (operating room) with open surgical incisions. According to the physician progress notes an ID (infectious disease) consult was obtained. The recommendation was not to insert the implants at that time, but rather to close the wounds and start IV (intravenous) antibiotics. The surgeon followed the ID physician’s recommendations and closed the wounds after inserting drains, and started IV antibiotics. The surgery ended at 2:08 P.M. according to the operating room record.
The orthopedic consultation report dated 3/26/08 indicated that Patient A sustained "Lumbo-sacral and thoracic spine contusions ...left shoulder and occipital contusions," as a result of the fall.

Patient A was originally scheduled for a one-day surgery according to the medical record. Patient A was admitted to the hospital following the fall from the OR table and discharged 5 days later on 3/31/08.

The outpatient surgery area, OR Suite # 1, where Patient A had surgery, was toured on 4/8/08 at 4:00 P.M. with Employees 1 and 2. According to the two employees, Patient A was secured to the OR table with a Velcro straps around her upper thighs. Her arms were both extended outward on arm extenders with Velcro straps. The employees stated they had used a plastic covering between the bottom sheet and the sheet Patient A was laying on, in order to make moving/ sliding the patient from the OR table to a gurney easier. When asked about the plastic covering, the employees showed a red biohazard trash bag that was placed between the sheets on the OR table.

According to Employees 1 and 2, Patient A had been heavier than their usual patient mix. She carried most of her weight through the middle of her torso. They stated the surgeon frequently tilted the table during surgery to view and access the operative site. Both employees' stated that "sleds" (side protectors placed under the mattress) or a bariatric bed may have been an appropriate intervention for Patient A. Neither of these
Employee 3 was interviewed and stated the only policy and procedure the ambulatory surgery center had with regard to securing patients in the OR was the one entitled “Positioning of Patients in Surgery.” The policy was reviewed with Employee 3 and the only reference to safety straps was, “Place safety straps as appropriate.” The hospital did not have a policy or procedure regarding placing a plastic, red biohazard bag between the sheets on the OR table in order to reduce friction/resistance to facilitate moving of obese patients after surgery. The application of the red plastic trash bag between the sheets on the surgical table and the limited application of restraints coupled with the tilted OR table facilitated Patient A’s fall to the floor.

Patient A will require a second surgery in order to complete the bilateral reconstructive breast surgery. A second surgery would subject Patient A to the inherent risks associated with general anesthesia and all the potential complications encountered with surgery including pain, the risk for surgical wound infection, blood loss and increased scarring.

On 4/8/08 at 5:40 P.M., the Department abated the Immediate Jeopardy after the facility provided a plan of correction which was acceptable. The plan of correction included the elimination of the plastic transfer sheets as standard OR table dressing.

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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.