

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>050424</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/27/2007</b>
NAME OF PROVIDER OR SUPPLIER <b>SCRIPPS GREEN HOSPITAL</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>10666 NORTH TORREY PINES ROAD, LA JOLLA, CA 92037 SAN DIEGO COUNTY</b>		
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	<p>The following reflects the findings of the California Department of Public Health during an Entity Reported Incident investigation conducted 11/27/07.</p> <p>Complaint No: CA 00133037 Category: Surgical Services</p> <p>Inspection does not represent the findings of a full inspection of the facility.</p> <p>Representing the California Department of Public Health was [REDACTED], RN HFEN.</p> <p>1280.1(a) HSC Section 1280</p> <p>If a licensee of a health facility licensed under subdivision (a), (b), of (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.</p> <p>1280.1(c) HSC Section 1280</p> <p>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.</p> <p><b>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY</b></p>			

Event ID:ZSKG11

5/8/2008

12:50:19PM

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	<p><b>Continued From page 1</b></p> <p>T22 Div 5 CH1 ART 3-70225 (c) Surgical Service Staff</p> <p>( c ) A registered nurse with training and experience in operating room techniques shall be responsible for the nursing care and nursing management of operating room service.</p> <p>This RULE: is not met as evidenced by:</p> <p>Based on observation, interviews and record review, the facility failed to have systems in place in the operating room which would ensure that surgical instruments had been completely processed and sterilized prior to use of the instruments in a surgical procedure for 1 of 1 sampled patients.</p> <p>Findings:</p> <p>On 11/26/07 the facility reported to the Department, that the surgical instruments used 11/20/07 for a knee surgery on Patient A, had not been completely sterilized. The facility said that incident was discovered when the surgical instruments used in this case were returned to the sterile processing area on 11/20/07. These surgical instruments had been sent to surgery in a covered, metal rectangular box. The box been sealed with plastic, snap lock devices, which should have changed color when the final sterile processing took place. On each outside end of the box, were heat sensitive indicator strips. These indicator strips should have changed color to indicate that sterile processing had taken place.</p>			
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	<p><b>Continued From page 2</b></p> <p>Inside the metal box, was an inventory sheet which listed of all the surgical instruments inside the box. A piece of sterilization tape was attached to the inventory list. The sterilization tape on the inventory list should have changed color to indicate that sterile processing had taken place. When the surgical instruments and the metal box were returned from surgery to sterile processing on 11/20/07 around 11:30 p.m., the processing technician observed that none of the sterilization indicators, both inside the box, and outside the box had changed color, which meant that this set of instruments had not been completely processed and sterilized prior to use in surgery.</p> <p>On 11/27/07 at 1:00 p.m., the medical record of Patient A was reviewed. Patient A was admitted to the facility on 11/20/07 with a diagnosis that included Left Knee Trochlea Osteochondritis dissecans lesion per the operating room record. [Osteochondritis dissecans is a joint condition whereby a variable amount of bone and its adjacent cartilage loses its blood supply.] Patient A was discharged from the facility on 11/22/2007 with an IV [intravenous] line, for a 10-day course of IV antibiotic therapy.</p> <p>According to the surgery schedule, Patient A was scheduled for a, "Left Knee Allograft"surgery on 11/20/07 at 1830. [6:30 p.m.] An Allograft surgery involves the transplantation of tissue from one individual to another unrelated individual. According to the document entitled, "Operating Room Record," Patient A was taken into the operating room on 11/20/07 at 2018 [8:18 p.m.] and the knee</p>			

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	<p><b>Continued From page 3</b></p> <p>surgery was completed at 2210 [10:10 p.m.] Per the same document, Staff Person 1 was identified as the scrub nurse [tech] for this surgical procedure.</p> <p>On 11/27/07 at 1:30 p.m., the Director of Surgical Services was interviewed. According to the Director, on 11/20/07 prior to beginning the surgery on Patient A's left knee, the following sequence of events occurred:</p> <ol style="list-style-type: none"> <li>1. A surgical staff member called the Sterile Processing Department (SPD) and requested a knee retractor set of instruments for use in Patient A's knee surgery. The knee retractor instruments are sterilized in a metal rectangular box [Bemis box] prior to use in surgical procedures.</li> <li>2. Staff Person 1 took a knee retractor instrument set which was in a Bemis box, from the SPD over to the operating room suites.</li> <li>3. Staff Person 2 opened the knee retractor instrument set and these instruments were then used in Patient A's left knee surgery.</li> <li>4. After the surgery was completed, [10:10 p.m.] the knee retractor instrument set in the Bemis box was returned to the SPD for cleaning and sterilization.</li> </ol> <p>On 11/27/07 at 2:00 p.m., a tour of the SPD was conducted with the SPD staff. Observations were made of the facility SPD staff decontaminating instruments, placing instruments in the Steris machine, and facility staff preparing instrument trays for sterilization in the autoclave machine. Only one of the facility's two autoclaves was functioning on 11/20/07. SPD staff acknowledged</p>				

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	<p><b>Continued From page 4</b></p> <p>that one of the autoclaves had been non-functioning for the prior 3 weeks.</p> <p>On 11/27/07 at 2:35 p.m., the Lead technician for the SPD who was on duty on 11/20/07 at 10:30 p.m. was interviewed. The Lead technician said the SPD's process for the decontamination and sterilization of surgical instruments included:</p> <ol style="list-style-type: none"> <li>1. The surgical instruments are handwashed and separated prior to placing the instruments in the Steris machine. After the first sterilization, the instruments are removed from the Steris machine, inspected and either placed on metal trays which are wrapped and taped, or the instruments are placed in a rectangular metal box [Bemis box].</li> <li>2. A folded inventory sheet of the instruments is placed inside the wrapped trays or the Bemis Box. Two sterilization indicators are attached to the inventory sheet so that when the Bemis box is opened, the sterilization indicators are immediately visible. The Bemis box is closed, and plastic snap locks with sterilization indicators are applied. A sterilization indicator strip, which also notes the date and time of the sterilization process, is attached at each end of the Bemis box.</li> </ol> <p>On 11/20/07 Staff Person 1 took an unsterilized set of knee instruments in a Bemis box to the operating room. Staff Person 1 did not notice that the sterilization indicators on each end of the box, as well as the 2 plastic snap lock indicators had not turned black. In the operating room, Staff Person 2 opened the Bemis box, and removed the instruments for use in Patient A's knee surgery. Staff Person 2 did not notice that the sterilization indicators on each end of the Bemis box, the 2 plastic snap locks indicators, nor the sterilization</p>			
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	<p><b>Continued From page 5</b></p> <p>indicators on inventory sheet inside the Bemis box had not turned black, to indicate that instrument sterilization had taken place.</p> <p>Facility staff failed to verify that the surgical instruments which were used for the knee surgery of Patient A on 11/20/07 had been completely sterilized. According to the CDC [Centers for Disease Control and Prevention] in their, "Guideline for Handwashing and Environmental Control, Disinfection and Sterilization of patient-Care Equipment – 1985. Section 2: Cleaning, Disinfecting and Sterilizing Patient-Care Equipment, Critical items are instruments or objects that are introduced directly into the bloodstream or into other normally sterile areas of the body. Examples of critical items are surgical instruments, cardiac catheters, implants, pertinent components of the hear-lung oxygenator, and the blood compartment of a hemodialyzer. Sterility at the time of use is required for these items; consequently, one of several accepted sterilization procedures is generally recommended."</p> <p>On 11/27/07 at 4:15 p.m., Department staff met with facility management staff and informed them that Immediate Jeopardy had been called because the facility had no system in place to ensure that all surgical instruments were completely processed prior to the instruments use in a surgical procedure. A Plan of Correction was received from the facility at 6:35 p.m.</p> <p>The Immediate Jeopardy was lifted on 11/28/07 at 4:09 p.m., after observation, interviews with multiple staff, and record reviews, revealed that the facility's plan of correction had been implemented as written.</p>			

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