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

Complaint No: CA 00187039
Category: State Monitoring - Retention of Foreign Object in Patient

Representing the California Department of Public Health, [redacted], HFES and [redacted], Medical Consultant

1280.1 (c) For purpose 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.

Title 22 - 70703 Organized Medical Staff (b)
(b) The medical staff, by vote of the members and with the approval of the governing body, shall adopt written by-laws which provide formal procedures for evaluation of staff applications and credentials, appointments, reappointments, assignment of clinical privileges, appeals mechanisms and such other subjects or conditions which the medical staff and governing body deem appropriate. The medical staff shall abide by and establish a means of enforcement of its by-laws. Medical staff by-laws, rules and regulations shall not deny or restrict within the scope of their licensure the voting right of staff members or assign staff members to any special class or category of staff membership based upon whether such staff members hold an...
Continued From page 1

M.D., D.O., D.P.M., or D.D.S degree or clinical psychology license.

Based on interview and record review, the facility failed to ensure that health care providers were familiar with medical devices prior to the use of the device in surgery. As a result, a health care provider inserted the wrong end of a lumbar CFS [cerebral spinal fluid] catheter drain into the spinal column of Patient A. The health care provider had never used this device before. The insertion of a lumbar CFS catheter drain procedure was not clearly listed on the health provider’s privileging sheet. Nor was the procedure listed on the surgery schedule the day of the incident. When the health care provider attempted to remove the lumbar drain, the tip of the catheter was sheared off, and approximately 3.5 centimeter [cm] of the catheter was retained. Nine days after discharge from the facility, Patient A was re-admitted with diagnoses that included, “Rule out meningitis.”

On 5/21/09 at 4:15 P.M., the Department called immediate jeopardy because of the facility’s failure to ensure that the health care providers would be familiar with infrequently used specialized medical devices, prior to using the device in surgery; the listed approved privileges for MD 1 did not clearly state that he had been approved to place the lumbar CFS Drain, which MD 1 described as, “Tricky,” and the insertion of the lumbar CFS drain should have been listed on the surgery schedule as a procedure. At 7:10 P.M., the Department received an acceptable plan of correction and the immediate jeopardy was abated. The plan of

Process
Scheduling
Effective immediately we will not schedule or perform any procedures that may require a lumbar drain placement (i.e., open or stented aneurysm repair or aneurysm clipping) until appropriate credentialing and in-service training process is developed

Educate schedulers on new process and decision before shift starts.

Implement immediately new process with schedulers to ensure appropriate detail is translated to schedule for all cases and verify appropriate credentialing by physician. Policy effectively immediately. Educated schedulers on new process before shift began on 5/22; communicated with appropriate physicians on 5/22.

Review all cases scheduled for next day to verify appropriate detail is on schedule and confirm appropriate credentialing.

Review all future cases to ensure appropriate detail and credentialing. Cancel any cases not in compliance with new process

Responsible Person
Manager, Peri-Op Services

Event ID: EYS11


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

STATE-2567

Object

2 of 7
CALIFORNIA HEALTH AND HUMAN SERVICES
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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

SUMMARY STATEMENT OF DEFICIENCIES

1. Effective immediately the facility would not schedule or perform any procedures that might require a lumbar drain placement until appropriate credentialing and in-service training process is developed.
2. Implement immediately a new process with surgery schedulers to ensure appropriate detail is translated to schedule for all cases and verify appropriate credentialing by physician.
3. Review all case scheduled for surgery on 5/22/09 to verify appropriate detail is on schedule and confirm appropriate credentialing.
4. Review all future cases to ensure appropriate detail and credentialing. Cancel any cases not in compliance with new process.
5. Enhance core privileges to ensure all applicable specialty procedures. List already revised by Chairman and to be approved during emergency Credentialing Committee and MEC.
7. Work with Anesthesiology leadership to ensure appropriate existing items are being in-serviced with physicians as well as staff. Implement process to cover all new items in OR.
8. Through PI/Risk Management complete monthly audit for full year to determine compliance with all steps above.

Findings:

Patient A was admitted to the facility on 4/28/09.
with diagnosis that included expanding thoracic aneurysm, status post thoracic stent per the discharge summary. On 4/29/09 the patient underwent a thoracic endovascular stent repair. The patient was discharged from the facility on 5/1/09. The patient was re-admitted to the facility on 5/10/09 with symptoms of headache, rule out post spinal drainage headache, and rule out local CSF [cerebral spinal fluid] leak. On 5/19/09 Patient A was transferred to a skilled nursing facility with discharge diagnoses that included aseptic meningitis, malnutrition, and cardiomyopathy per the transfer summary.

On 5/21/09 at 3:00 P.M., the health care provider [MD 1] that inserted the lumbar drain into Patient A immediately prior to surgery on 4/29/09 was interviewed. MD 1 said that he had been putting in lumbar cerebrospinal fluid drains, "on and off" for more than 30 years. MD 1 estimated that he has performed about 15 of these procedures in the last thirty years; the last time being about two years ago, when he, "helped with" the procedure. MD 1 was asked to describe what happened in the O.R. [operating room] at the time of the event [4/29/09]. MD 1 said that just prior to starting the surgery, the surgeon asked MD 1 to insert a lumbar drain in Patient A. The lumbar drain tray was set out on a stand in the operating room. MD 1 said that he had never seen this type of catheter drain before. MD 1 further stated that because he had not used this particular device before, he took about 10 minutes to go through the brochure. The catheter had a pigmented [darkened] end that he assumed was the end to be inserted, since this is how other

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Continued From page 4

types of catheters are used. He noted that there were small holes in the pigmented end, as he expected of the distal end of a drainage catheter. He did not notice that the other end of the catheter also had holes. MD 1 then inserted the pigmented end of the catheter, thru the trocar, into the spinal column of Patient A. MD 1 then realized that he had inserted the catheter backwards when he noticed that the other end of the catheter also had drainage holes. He then realized what had happened and tried to remove catheter drain, but the tip of the catheter drain sheared off (approximately 3.5 centimeters) and remained inside the patient. MD 1 mentioned that one of his partners had made the same mistake with this type of catheter but had been successful in removing it without breakage.

Joint review of Patient A’s medical record was conducted with MD 1. Patient A was discharged from the facility on 5/1/09, and then re-admitted on 5/10/09 with "generalized weakness, lethargy, minor headache" per the history and physical. Per a consultation report, Patient A was evaluated to, "Rule out meningitis." On 5/13/09 at 11:00 P.M., a CT [computerized tomography] of the lumbar spine with the use of a contrast material was performed. Per the radiologist’s report, the CT showed, "tiny 2 mm opaque foreign body consistent with catheter tip marker just beneath the lamina just distal to the plane of the L3 - L4 disc." In the interview with MD1 on 5/21/09 at 3:00 P.M., MD 1 said that the retained tip of the lumbar drain catheter was held in position by the ligaments, and that there would be no attempt to remove the...
Continued from page 5

catheter piece.

MD 1's credential file with approved privileges was reviewed. MD 1 was privileged to do, "regional and local anesthesia." There was no listing on the privilege sheet for placement of a lumbar CFS drain. The Department and MD 1 jointly reviewed his approved privilege sheet. When asked if the procedure of a lumbar drain placement was covered by any of the categories for which he had been approved, MD 1 stated that his listed privileges did not include placement of a lumbar CSF drain. MD 1 also stated that the insertion of the lumbar drain for Patient A was not listed on the per-OP schedule. MD 1 stated that, "Had he known the night before" he could have reviewed the information about the lumbar drain. MD 1 said that he had not spent enough time reviewing the product literature before attempting the insertion. MD 1 stated that he "hates doing them" [lumbar drains] and that they can be "tricky and they are a sophisticated drain.

According to the facility's medical staff by-laws, Article VI, Clinical Privileges, "6.1 Exercise of Clinical Privileges - Except as otherwise provided in these Bylaws, a member providing independent clinical services at this hospital shall be entitled to exercise only those clinical privileges specifically granted. The listed approved privileges for MD 1 did not clearly state that this provider had been approved to place the lumbar CSF drain.

MD 1 was not familiar with a specialized device that was used infrequently. The insertion of this device was not clearly listed on the privileging sheet for

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LAbORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [Signature]

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S TITLE: [Title]

(x6) DATE: [Date]

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**MD 1.** The facility's Bylaws stated that, "A member providing independent clinical services at this hospital shall be entitled to exercise only those clinical privileges specifically granted." The facility failed to develop a formal procedure to evaluate medical staff assignment of clinical privileges related to the insertion of a lumbar CSF [cerebral spinal fluid] catheter.

The facility's failure to ensure that health providers were familiar with medical devices prior to the use of the device in 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 12801 (c)

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**Event ID:** E9YS11

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

**DATE**

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