California Health and Human Services Agency
Department of Public Health

Statement of Deficiencies and Plan of Correction

(x1) Provider/Supplier/CLA Identification Number:
050272

(x2) Multiple Construction
A. Building
B. Wing

(x3) Date Survey Completed:
03/02/2015

(name of provider or supplier) Redlands Community Hospital
Street Address, City, State, Zip Code:
350 Torrance Blvd, Redlands, CA 92373-4850 SAN BERNARDINO COUNTY

Provider's Plan of Correction (Each corrective action should be cross-referenced to the appropriate deficiency)

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix Tag</th>
<th>Summary Statement of Deficiencies</th>
<th>Providers' Plan of Correction</th>
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<tbody>
<tr>
<td></td>
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<td>The following reflects the findings of the Department of Public Health during an inspection visit:</td>
<td>Facility ID # 240000046</td>
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<tr>
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<td>Complaint Intake Number: CA00388156 - Substantiated</td>
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<tr>
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<td>Representing the Department of Public Health: Surveyor ID # 26774, HFEN</td>
<td>Redlands Community Hospital (“Hospital”) was notified by the involved physician (“MD 2”) that a retained foreign object had been observed in Patient A.</td>
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<td>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</td>
<td>A. Immediately upon receiving notice from MD 2, the Hospital’s Quality and Patient Safety Manager notified the Hospital’s leadership team, including the CEO, Chief of Staff, and vice-president and director level personnel from the areas at issue.</td>
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<td>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.</td>
<td>Reflecting its collaborative focus and commitment to involving all stakeholders in ensuring patient safety and quality of care, additional notification was made to the following:</td>
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<td>Health and Safety Code Section 1279.1(c): “The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.”</td>
<td>- Quality &amp; Patient Safety Council by the Patient Safety Manager.</td>
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<td>The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.”</td>
<td>- Medical Executive Committee by the Vice President of Patient Care Services.</td>
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<td>REGULATION VIOLATION: Health and Safety Code sections 1271.1, 1280.1 and Title 22, California Code of Regulations, section 70433 Cardiovascular Surgery Service General Requirements</td>
<td>- Hospital’s Board of Directors Patient Care Committee by the Vice President of Professional and General Services.</td>
</tr>
</tbody>
</table>

Event ID: L42111 3/12/2015 1:49:37PM

By signing this document, I am acknowledging receipt of the entire citation packet. 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.
From: #567 P.003/011

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

<table>
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<tr>
<th>PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER:</th>
<th>MULTIPLE CONSTRUCTION</th>
<th>DATE SURVEY COMPLETED</th>
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<tr>
<td>050272</td>
<td></td>
<td>03/02/2016</td>
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NAME OF PROVIDER OR SUPPLIER: Redlands Community Hospital

STREET ADDRESS, CITY, STATE, ZIP CODE: 350 Terracina Blvd, Redlands, CA 92373-4850 SAN BERNARDINO COUNTY

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<th>ID PREFIX</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
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| 1271.1    | (b) | (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, Excluding objects intentionally implanted as part of a planned intervention and objects prior to surgery that are intentionally retained. | 1280.1    | (a) | For purposes of this section, "adverse event" includes any of the following: (a) Subject to subdivision (d), prior to the effective date of regulations adopted to implement Section 1280.3, if a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 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 dollars ($25,000) per violation. (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. (d) This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties

The Quality and Patient Safety Manager promptly initiated an internal investigation of the matter, which was undertaken by a multidisciplinary team comprised of: the Director of Quality & Medical Staff Services; Quality & Patient Safety Manager; VP Patient Care Services, VP Professional and General Services, Director of Imaging Services; Director of Surgical Services; Director of Risk; the Special Procedures Area RN, Scrub Tech and Procedure Tech; and MD1 and MD2, the two cardiologists who participated in the survey process (the "Multidisciplinary Team"). The Hospital’s VP of Patient Care Services reported the event to the California Department of Public Health ("CDPH") via facsimile correspondence. The Director of Imaging Services and the Nurse Manager of the Cardiac Catheterization Lab ("CCL") informed Patient A that the occurrence was reported to the CDPH, consistent with State of California requirements. The provision of this notice was documented in Patient A’s medical record.

Event ID:L42111 3/12/2015 1:40:37PM

Event ID:L42111 3/12/2015 1:40:37PM
### Immediate Corrective Actions

The Director of Surgical Services and the Director of Imaging Services reviewed the content of the Hospital’s existing Surgical Services Policy C-18 “Counts of Surgical Items” (“Policy C-18”), including the process and equipment to use during open procedures (i.e., the Count-EZ Sponge Counter Bag System), and determined that its content was appropriate to enhance the standardization in the cardiac catheterization lab (“CCL”).

The Director of Surgical Services and the Director of Imaging Services prepared a new Special Procedures Policy, 5.06, “Counts of Sponges, Sharps, and Other Applicable Items” (“Policy 5.06”) the content of which mirrored the relevant content of Policy C-18 with minor changes to address particular supply and personnel needs in the CCL.

The Director of Surgical Services, the Director of Imaging Services, and the Imaging Services Manager provided an in-service to all hospital employees who work in the CCL to review the new Policy 5.06, the Association of Operating Room Nurses guidelines entitled “Perioperative Standards and Recommended Practices” (2013 Ed., p. 305-319) (“AORN Guidelines”), and Joint Commission Sentinel Event Alert entitled “Preventing Unintended Retained Foreign Objects” (Issue 51, Oct. 17, 2013) (“SE Alert”).
From: CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(NAME OF PROVIDER OR SUPPLIER)
Redlands Community Hospital

STREET ADDRESS, CITY, STATE, ZIP CODE
350 Terracina Blvd, Redlands, CA 92373-4850 SAN BERNARDINO COUNTY

A. BUILDING
050272

B. WING

NAME OF PROVIDER OR SUPPLIER
Redlands Community Hospital

IDENTIFICATION NUMBER
050272

STATEMENT OF DEFICIENCIES (X1)
PROVIDER/SUPPLIER/CLIA (X2)
MULTIPLE CONSTRUCTION (X3)
CATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED

A. BUILDING
050272

B. WING

SUMMARY STATEMENT OF DEFICIENCIES (X4)
PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCE TO THE APPROPRIATE DEFICIENCY)

(Date)

2/14/14

The Chief of Staff sent a memorandum outlining required training for physicians who performed procedures in the CCL, which included a review of Policy 5.06, the process and equipment identified in the policy (i.e., the Count-EZ Sponge Counter Bag System) for use during open procedures, AORN Guidelines, and the SE Alert.

All physicians who performed open procedures in the CCL were required to and did complete training prior to performing any additional CCL cases. The Director of Surgical Services provided this training.

The Surgical Specialties Chairman approved the merger of Policy 5.06 and Policy C-18 into a hospital-wide Patient Care Policy C-127, entitled "Counts of Surgical/Procedural Items" ("Policy C-127"). This merger was undertaken by the Hospital in order to ensure consistency in practice across all locations performing open procedures. Policy C-127 includes content consistent with the former Policy 5.06 and former Policy C-18.

Event ID:L4211
3/12/2015 1:49:37PM
A review of the "Chronological Log," recorded by the nursing staff at the time of the procedure on August 14, 2013, indicated Patient A arrived in the procedure room at 11:45 AM. At 12:06 PM, the antibiotic-impregnated sponge was documented as being placed in the pocket portion (where the AICD had been removed). At 12:11 PM, the antibiotic-soaked sponge was removed, and the pocket was flushed by antibiotics. Under the Chronological Log section entitled, "End Studies," the following information was listed: Sponge count (pre-count and post count) "40 pre-cath and 40 post-cath."

Patient A was discharged to home on August 14, 2013 at 12:35 PM, with a prescription for Keflex 500 mg (an antibiotic), and written instructions for a follow up appointment with MD 1.

A review was conducted of the MD 2's notes summarizing a visit with Patient A dated February 10, 2014 (six months after the defibrillator was placed). The summary indicated that Patient A called to say there was leaking from the defibrillator pocket. MD 2 documented Patient A’s skin had eroded through an area about 2 cm by 2 cm (1 cm is equal to 2.54 inches) size, and a sponge had protruded through the eroded area of skin. MD 2 further described his attempt to remove the sponge, however he was only able to remove a portion and was unsuccessful in extraction of the entire sponge. MD 2 further noted the decision to leave the retained sponge in the patient along with the defibrillator until explantation (removal) of both could occur later that week. MD 2 further indicated, "The
Audits were then conducted quarterly until 100% compliance for three (3) consecutive quarters was achieved.

Audit results are reported by the Director of Imaging Services or designee to the Medical Staff's Quality and Patient Safety Council ("QPSC").

Per the QAPI Process, the QPSC reports results to the Medical Executive Committee, which in turn reports results to the Patient Care Committee of the Hospital's Board of Directors, which in turn reports to the Hospital Board of Directors.

The VP of Patient Care Services and the VP of Professional & General Services share the overall responsibility for these corrective actions and monitoring of continued compliance.

Event ID: L42111 3/12/2015 1:49:37PM

MD 1 further described how Patient A was seen at his office by another doctor while MD 1 was on vacation on January 28, 2014. At that time there was some erythema and the patient was started on Bactrim twice a day for seven days (antibiotic). MD 1 described further that Patient A's symptoms did not improve. MD 1 described how he eventually spoke to Patient A on February 12, 2014 and explained, "that the retained sponge was the cause of the ICD pocket problem. I took responsibility for this error."

MD 1 further documented he told Patient A to come in for the procedure to explant the AICD generator and remove the retained surgical sponge.

During an interview on February 27, 2014 at 2:40 PM with the Director of Quality and Patient Safety, she stated that Patient A had the generator explanted on February 25, 2014, and was given a Life Vest to wear.
A review of the patient care notes dated 2/26/14 at 5:39 PM reflected that the Life Vest was placed on Patient A and activated. Patient A was instructed to keep it on 24 hours per day and 7 days per week.

Review of Patient A's discharge instructions dated February 26, 2014, showed that Patient A was discharged home with the Life Vest in place and with orders for daily intravenous (through the vein) antibiotics and weekly lab tests.

Review of the physician's procedure report dated 8/19/14, reflected that Patient A received a new generator that was implanted on 8/19/14, approximately 5 1/2 months after the prior generator was removed and Patient A had been fitted with a Life Vest to wear.

During a phone interview with MD 1 on February 28, 2014, at 11:15 AM, MD 1 explained, "I may have put two sponges in inadvertently and forgot I had put two in. I just remember thinking Patient A had a high risk for infection at the time." When asked why sponge counts in the cardiac catheterization lab were not done as is the process in the operating room, he replied that the scrub tech was meticulous in being sure to say, "sponge in," and "sponge out." MD 1 stated he later tried to recreate the scenario by intentionally placing a second sponge in another patient and then feeling the area with his gloved finger. He stated, "I could not feel the sponge, it felt like tissue, and then I removed them both MD 1 stated during the interview on
February 28, 2014 that "the facility was now doing visual of the sponges and a count before and after." MD 1 also stated that since this incident, the facility is also "doing fluoroscopy to ensure no sponge can be left in because the sponges are radio-opaque, and show up on X-ray." MD 1 further advised that at the time Patient A's generator was changed on August 14, 2013, X-rays only were completed on new implants. MD 1 advised that since this incident he will now slightly retract the wound edges and look inside the pocket I have created." MD 1 further advised, "It was a systems error, but I was responsible. It was unfortunate, but resulted in a systems change and we were able to fix the problem."

During an interview with the Director of Quality and Patient Safety (DOPS) on February 27, 2014 at 3:55 PM, the DOPS confirmed there was no procedure for pre-operative or post-operative counting of sponges in the cardiac catheterization lab on August 13, 2014, the date of Patient A's procedure.

On February 27, 2013 at 4:35 PM, an interview was conducted with a Catheter Lab Assistant (Scrub Tech 1). When asked to describe the process for accounting for surgical sponges, she stated, "Prior to the sponge being left in Patient A, we had not counted sponges. One would get soaked in antibiotic solution, one goes in, and one comes out. On initial pacemaker and generator implants, we would do X-rays, but this was not a new one."

During further interview, when asked to describe the
process of performing implants and explants, Scrub Tech 1 stated, "They (the physicians) make a pocket but small, kind of like a pita pocket. The antibiotic sponge goes in first, then the leads are placed. The sponge would then be removed, the pocket flushed with an antibiotic solution. The device would then be hooked up, and then placed inside of the pocket. This was when the X-ray would be taken to ensure no lead wires came loose, then the pocket would be sewn up."

During an interview conducted with the circulating Registered Nurse 1 (RN 1) on February 27, 2014 at 4:45 PM, she indicated that she had functioned as the circulating nurse during the procedure on August 14, 2013 for Patient A. When asked if they counted sponges pre and post operatively she replied, "At the end of the procedure, the scrub tech would call out the count and we would document it on the record."

An interview was conducted with Registered Nurse 2 (RN 2) on February 28, 2014 at 9:30 AM. When asked how many sponges the procedure started with for Patient A, she replied, "We start with 40 and end with 40, and the scrub tech just says the amount [of sponges] and we write it down." When asked if there were any unusual distractions during this procedure for Patient A she stated, "No, it went smoothly."

When asked for a copy of the facility's policy and procedure for counting surgical sponges in the cardiac catheterization lab, RN 2 stated they did not have a policy at the time Patient A had the defibrillator replaced.
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLA
IDENTIFICATION NUMBER: 050272

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED 03/02/2015

NAME OF PROVIDER OR SUPPLIER Redlands Community Hospital
STREET ADDRESS. CITY. STATE. ZIP CODE 350 Terracina Blvd, Redlands, CA 92373-4850 SAN BERNARDINO COUNTY

(X4) ID PREFIX TAG

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG PROVIDER’S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

(X5) COMPLETE DATE

The facility’s failure to create and implement policies and procedures for the counting of surgical sponges before, during and after a procedure in the cardiac catheterization lab, resulted in retention of a surgical sponge in Patient A’s chest wall, infection and skin breakdown. Patient also had to undergo physician’s attempts to remove the sponge, and further required both a surgical explantation procedure to remove both the sponge and AICD, as well as a further surgical re-implantation of Patient A’s AICD. In addition, Patient A had to wear a Life Vest while waiting for the prior pocket to heal before re-implantation. The facility’s failure to account for surgical sponges during a procedure 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 1280.3.

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).