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

**Complaint Intake Number:**
CA00514753 - Substantiated

**Representing the Department of Public Health:**
Surveyor ID # 1977, 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 1280.3(g):** 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.

**HSC Section 1279.1(a):**
A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

**HSC Section 1279.1(b)(1)(D):**
For purposes of this section, "adverse event" includes any of the following: Surgical events,

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**Event ID:** 5MLV11
**Date:** 3/27/2018, 4:32:25PM

**LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE**: Janet Balash, MSN, RN, Chief Nursing Officer
**TITLE**: 04/13/18

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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.
including the following: Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as a part of a planned intervention and objects present prior to surgery that are intentionally retained.

HSC 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.

Health and Safety Code section 1280. (3)
(a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars ($75,000) for the first administrative penalty, up to one hundred thousand dollars ($100,000) for the second subsequent administrative penalty, and up to one hundred twenty-five thousand dollars ($125,000) for the third and every subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to

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Surgical Services General Requirements, Title 22, Division 5, Chapter 1, Article 3, Section 70223(b)(2):

A committee of the medical staff shall be assigned responsibility for: 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.

Based on interview and record review, the facility failed to ensure their policy titled, "Surgical Counts," was developed and implemented to account for all surgical items entering the surgical field. This failed practice resulted in:

1. Retention of a blue towel in the Patient 1's abdominal cavity for ten months and four days;
2. Multiple additional diagnostic tests for Patient 1;
3. Two additional hospital admissions for Patient 1;
4. Two additional major surgeries where Patient 1 underwent induction of general anesthesia and open abdominal surgery;
5. Increased risk of infection; and,

Policy "Surgical Counts" was revised to "keep a running total on the white board in the OR suite or the count sheet for items counted". An addition to the policy "items counted" list was added "Towels and 36 inch lap sponges". These changes in the policy were approved by the Governing Board.

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6. The potential for death.

Findings:

During an interview with the Director of Quality (DQ) on December 29, 2016, at 9:50 a.m., the DQ stated during a surgical procedure on December 14, 2016, a blue towel was found in Patient 1’s abdominal cavity. The DQ stated the towel was from an initial surgical procedure performed at the facility in February 2016 (10 months earlier). The DQ stated blue towels were not counted during surgical procedures; they were non-countable items.

The record for Patient 1 was reviewed on December 29, 2016. Patient 1, an 86 year old female, was admitted to the facility on February 10, 2016, with diagnoses that included Colon Cancer. According to the record, the following occurred:

1. On February 10, 2016, Patient 1 underwent open abdominal surgery to remove a cancerous tumor. The operative report indicated the tumor was thick in nature, wrapped almost all the way around, and nearly causing an obstruction of the bowel. The report indicated all sponges that were used were accounted for. There was no mention of blue towels being used in the surgical procedure/field.

The pre, relief, and post op documentation indicated four Registered Nurses (RN) verified the sponge and instrument counts were correct and performed “Per policy.”

Patient 1 was admitted to the facility for 10 days,
and was discharged on February 20, 2016;

2. On March 19, 2016, Patient 1 presented to the Emergency Department (ED) with complaints of abdominal pain associated with nausea and vomiting. Laboratory results indicated the patient had an infection. The patient was admitted.

   a. A computerized axial tomography (CAT) scan of the abdomen and pelvis indicated Patient 1 had a bowel obstruction with a possible abscess (a collection of pus built up in the body tissues) and a pelvic mass.

   b. A repeat CAT scan of the abdomen and pelvis performed March 21, 2016, indicated there was mild improvement of the obstruction, but the pelvic "mass" had not changed (indicating it could be an abscess or a tumor from the cancer spreading);

   c. A small bowel follow through (a test performed by taking serial x-rays of contrast [dye] passing through the patient's intestines after drinking it) performed March 21, 2016, indicated there was normal passage of the contrast.

   d. A gastrografin enema (a test performed by taking serial x-rays of contrast [dye] passing through the patient's colon, rectum, and anus after injecting it through an enema catheter), performed March 22, 2016, indicated there was no obstruction of flow, but they could "not completely exclude malignancy" (cancer).

   e. A pelvic ultrasound, performed March 22, 2016,
indicated Patient 1 had a large mass in the pelvis measuring 4.5 inches by 3.6 inches by 3.6 inches, “possibly” an abscess.

Patient 1 remained in the facility for five days, being treated for the abscess with interventions to include the placement of a nasogastric tube (a tube placed in the nose and into the stomach) and antibiotics. The patient was discharged on March 23, 2016, with orders for continued antibiotic therapy;

3. On June 15, 2016, Patient 1 was admitted to the facility for a workup for continued abdominal pain and pelvic mass. The workup indicated Patient 1 “now has formed a dense mass in the pelvis, which is questionable for some foreign body or abscess.” The mass was now measuring 4.1 inches by 3.9 inches. According to the record, this was “a persistent mass.” Patient 1 agreed to proceed with surgery to remove the mass, and underwent an exploratory laparotomy (opening the abdomen to explore the area) on June 15, 2016.

The operative report indicated the surgeon saw no collection of fluid, mass lesion, or foreign body, so he terminated the surgery. The wound was closed and the patient was taken to the recovery room.

Patient 1 remained in the facility for three days and was discharged on June 18, 2016.

4. On December 10, 2016 (six months later and 10 months after the original surgery), Patient 1 presented to the ED with complaints of abdominal pain and swelling for two weeks. The patient was
admitted.

a. A CT scan indicated the patient had an enlargement of the mass, now measuring 5.9 inches by 5.5 inches by 5.1 inches. The report indicated the mass was "likely representing large recurrent colonic neoplasm" (return of the colon cancer).

b. A gastrograffin enema, performed December 12, 2016, indicated there was a large mass in the pelvic area, with "severe compression and narrowing of the descending colon."

c. A colonoscopy, performed December 13, 2016, indicated the mass was creating a sharp angle in the colon that the scope could not go past, so the procedure was terminated. The physician recommended another surgical follow up, and, "probably diverting colostomy rather than another bowel resection at her age with a large residual pelvic mass" (removing the mass from the bowel and, instead of attempting to sew the bowel back together, creating a colostomy where the feces would come out through the abdomen).

On December 14, 2016 (10 months and four days after the initial surgery), Patient 1 underwent a third surgical procedure, an exploratory laparotomy (opening and exploring the abdominal cavity). According to the operative report, Patient 1 had been seen in the physician's office several times following the first surgery on February 10, 2016 with complaints of nausea. The report indicated the patient was admitted two times following the first surgery undergoing multiple tests, and a second
surgical procedure.

The operative report further indicated "She had multiple areas of enterotomy (openings in the intestine) where extensive dissection (to cut into pieces) was performed. She had significant retroperitoneal (behind the membrane covering the abdominal organs) swelling simulating a retroperitoneal malignant mass...I then tried to incise (cut through) this area to obtain some tissue to sent (sic) to pathology and while this was done, it was noted that this was a retained foreign body in the form of a blue towel which was used in the previous surgery to packed (sic) away her bowel. I proceeded to perform a segmental resection (remove and reattach) areas of small bowel, that were devitalized (dead or necrotic) and this was including about (sic) multiple segments with a total of about 4-5 feet of small bowel resected and subsequently a primary and hand sewn anastomosis (a channel to connect) was used to re-anastomose (connect) the small bowel..." 

The report indicated following surgery, Patient 1 was taken to the Intensive Care Unit (ICU) on a ventilator (breathing machine) in guarded condition.

Patient 1 remained in the facility for 13 days, and was discharged on December 23, 2016, to a skilled nursing facility with orders to include wound care (suture removal, and dressing changes).

During a concurrent interview on December 29, 2016, at 10 a.m., with the Operating Room Scrub Technician (ORST) and the Operating Room
Supervisor (ORS) who were both present at the time of the last (third) surgery on December 14, 2016, the ORST stated she prepared for the surgery thinking they were looking for a tumor. She stated the surgeon felt a mass "very posterior" (behind the bowels/intestines), and thinking it was a tumor, the surgeon started to plan a transfer to a higher level of care due to the difficulty he would have "getting to the tumor." The ORST stated the surgeon decided to do a biopsy prior to closing the incision and transferring Patient 1 to a higher level of care, and when he scraped the mass, he saw it was a blue towel. The ORST stated, "When he saw blue, he knew right away it was a towel," and he used a towel clamp (a surgical instrument) to remove it.

The ORST stated they did not count blue towels because they did not "normally" use them in a surgical case, and the doctors did not "usually" ask for them. She stated they only used blue towels during bowel resections when the surgeon would place the bowel on a wet blue towel to keep the bowel moist while it was outside of the body. Then the surgeon would remove the bowel from the blue towel and put it back into the abdominal cavity, and throw the blue towel away. The ORST stated they "never" put blue towels in a surgical site. The ORST stated she was taught in her scrub technician training that blue towels were "not countable," because they were not supposed to enter the surgical field.

The ORS stated she got called into the room by the surgeon during the surgery (on December 14, 2016) due to the difficulty the surgeon was anticipating in
getting to the mass. The ORS stated the surgeon reported he may have to close the abdomen and transfer Patient 1 to a higher level of care (different hospital with advanced capabilities) for the mass to be removed, but when he scraped it to do a biopsy he "found the towel."

The ORS stated she had never seen a blue towel placed on a surgical field prior to working at the facility, but when a patient had a bowel resection at the facility, a blue towel was used to keep the bowel moist while it was outside of the abdominal cavity.

The facility policy titled, "Surgical Counts," with a revised date of December 2013, was reviewed on January 18, 2017. The policy indicated the following: "Count [sic] are performed to account for all items and to lessen the potential for injury to the patient as a result of a retained foreign body."

The facility's policy references the Association of perioperative Registered Nurses (AORN) 2013 "Recommended Practices of Retained Surgical Items" which indicated the following:

"Recommendation I:
A consistent multidisciplinary approach for preventing RSIs (retained surgical items) should be used during all surgical and invasive procedures. Retained surgical items are preventable events that can be reduced by implementing multidisciplinary system and team interventions. Retained surgical items may result in morbidity and mortality for the patient and prove costly to healthcare organizations...All items need to be accounted for at
**Recommendation I Continued:**

**Subsequent Actions Taken:**

Policy "Surgical Counts" was revised to "keep a running total on the white board in the OR suite or the count sheet for items counted". An addition to the policy "items counted" list was added "Towels and 36 inch lap sponges". These changes in the policy were approved by the Governing Board.

The policy incorporates surgeons and all on the surgical team to engage in safe practices "Accurately accounting for sponges, before during and after surgical procedure. Sponges should be left in their original configuration and should not be cut. Altering a sponge invalidates subsequent counts and increases the risk of a portion being retained in the wound. Non-radiopaque gauze dressing materials should be withheld from the field until the wound is closed or the case is completed, to avoid discrepancy of counts.

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<td>I. d.1. The surgeon(s) and surgical first assistant(s) should maintain awareness of all soft goods, instruments, and sharps used in the surgical wound during the course of the procedure. The surgeon does not perform the count but should facilitate the count process by;</td>
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the end of a procedure so that all team members can be sure that a surgical item is not left in the patient.

I. d. Surgeons should engage in safe practices that support prevention of RSIs.

I. d.1. The surgeon(s) and surgical first assistant(s) should maintain awareness of all soft goods, instruments, and sharps used in the surgical wound during the course of the procedure. The surgeon does not perform the count but should facilitate the count process by:

* Using only radiopaque surgical items in the wound;
* Removing unneeded soft goods and instrumentation from the surgical field at the initiation of the count process.
* Performing a methodical wound exploration when closing counts are initiated;
* Accounting for and communicating about surgical items in the surgical field.

Recommendation II.

Radiopaque surgical soft goods (e.g., sponges, towels, textiles) opened onto the sterile field should be accounted for during all procedures for which soft goods are used.

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**Recommendation I:**

**Compliance and Monitoring:**

Items to be counted in surgical cases will be monitored for compliance.

The data will be tracked, trended, analyzed and reviewed monthly for compliance and will be reported to the Performance Improvement Committee, the Medical Executive Board and the Board of Directors until 100% compliance is met for three consecutive months.

**Person Responsible:**

Director of Perioperative Services or Designee

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**Recommendation II:**

**Immediate Action Taken:**

Nursing Leadership reviewed the Policy “Patient Safety in the operating room and found no revisions necessary. Nursing Leadership reviewed the Policy “Surgical Counts” and found revisions were necessary.
and increases the possibility of an RSI."

The facility failed to ensure their policy titled, "Surgical Counts," was developed and implemented to account for all surgical items entering the surgical field. This failure resulted in the retention of a blue towel in the Patient 1's abdominal cavity for ten months and four days.

These failures are deficiencies that have caused, or are likely to cause serious injury and/or death to the patient, and therefore constitute an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.3.

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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 1280.3(g).

Recommendation II Continued:

Subsequent Actions

Policy "Surgical Counts" was revised to "keep a running total on the white board in the OR suite or the count sheet for items counted". An addition to the policy "items counted" list was added "Towels and 36 inch lap sponges". These changes in the policy were approved by the Governing Board.

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