The following represent the findings of the California Department of Public Health during an investigation of Entity Reported Event #CA00198637 regarding retention of a foreign object during surgery. The investigation of the reported event was substantiated.

The inspection was limited to the specific reported event investigated, and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

[Name], RN, Health Facilities Evaluator

Health and Safety Code Section 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.

Corrective Action:

The Surgical Services Policy #27.2.1.54, "Counts, Surgical" has been revised to include the use of sponge pocketed holding bags.

- Separate and unfold all sponges prior to placing in the counter bag pockets.
- Once the bags are full, the sponges are counted audibly and concurrently, viewed by the scrub person and the circulating RN. An empty bag is then placed on top of the counted filled.

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<td>Please Note: The following constitutes California Pacific Medical Center (CPMC) - Pacific Campus Hospital's credible evidence of correction of all of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form CMS-2567 dated 11/18/09. Preparation and/or execution of this credible evidence submission does not constitute admission or agreement by the provider of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies.</td>
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California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

| (X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER: | CA22000022 |
| MULTIPLC CONSTRUCTION | A. BUILDING | C |
| | B. WING | 11/18/2009 |

NAME OF PROVIDER OR SUPPLIER | CALIFORNIA PACIFIC MEDICAL CTR-PACIFIC |
STREET ADDRESS, CITY, STATE, ZIP CODE | 2333 BUCHANAN STREET, SAN FRANCISCO, CA 94115 |

| (X4) ID |
| PREFIX |
| TAG |
| SUMMARY STATEMENT OF DEFICIENCIES |
| (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) |
| E 264, E 269, E 271 cont. |
| E 269 |

(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy.

This Statute is not met as evidenced by:

E 271 T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures.

(d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.

This Statute is not met as evidenced by:

Based on interview and record review, the hospital failed to develop a surgical count policy that mandated that bagged surgical sponges be recounted during the final count. This resulted in a surgical sponge having been retained in Patient 2, who was forced to undergo a second surgical procedure to remove the retained foreign object.

Findings:

1. Patient 2 was admitted to the hospital on 7/9/09, and on 7/15/09 had a sigmoid colon resection, repair of colovesical fistula and colorectal anastomosis. Patient 2 had a history of hypertension, chronic obstructive pulmonary

PROVIDER'S PLAN OF CORRECTION |
| EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY |
| COMPLETION DATE |

17. Final and closure counts... the Circulator then exposes the previously counted bags to the scrub in order to reconcile the total number documented on the count board/sheet.

The policy and procedure includes "Guidelines on using Sponge Bags".

Monitoring Process:

Surgical Services staff complete concurrent audits in order to ensure compliance to the Count Policy and Procedure at each step of the process.

The monitoring results are reported to the Surgical and Operating Room Committee and the hospital wide Quality Improvement Committee.

Responsible Persons:

Senior Director Surgical Services and Director, Outcomes Management

The Surgical Services Count Policy and Procedure, count forms and audit tool are attached for reference and review.

Licensing and certification Division
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disease and underwent kidney transplant surgery in 2007. On 7/29/09, he was discharged from the facility. In August 2009, Patient 2 was seen at an outside facility for recurrent fevers, abdominal pain and pneumaturia. Tests done at the outside facility determined the presence of a retained foreign body in his abdominal cavity. Patient 2 was transferred back to the hospital on 8/11/09 and on 8/13/09 he had surgery that included the removal of a surgical sponge retained in his right upper quadrant.

On 11/16/09 at 11:00 a.m., Patient 2's intraoperative case record dated 7/15/09 was reviewed, and revealed that the initial, closing, and final sponge counts were documented as correct. There was an intraoperative case record dated 8/13/09 which listed the surgical procedure as revision of colorectal anastomosis, takedown of colovesical fistula, diverting loop ileostomy and removal of retained foreign object.

Patient 2's operative note dated 8/13/09 indicated a pre and post operative diagnosis of recurrent colovesical fistula and possible foreign body. The name of the procedure included "removal of right upper quadrant foreign body." The description of the procedure included the following: "Attention was first paid to the possible right upper quadrant mass. There was a large area of matted bowel in the right upper quadrant. Careful palpation was able to free this wad of bowel from the retroperitoneum and the colonic mesentery. It was entirely composed of small bowel. The adhesions between loops of bowel were carefully dissected free using Metzenbaum scissors. As the center of this wad of bowel was reached, some pus was visualized and suctioned out and sent for culture. The intraloop adhesions were dissected free very carefully over a period of time,
taking care not to injure the bowel. In the course of this, the foreign body was visualized and carefully brought out from between the bowel using a combination of blunt and sharp dissection. This was passed off the field."

On 11/16/09 at 1:50 p.m., RN 4 was interviewed and stated she was the circulating nurse for Patient 2's first surgery on 7/15/09. She stated she did the initial count with a registered nurse who no longer works at the facility and the closing and final count with ST 1 (surgical technician). RN 4 was asked to describe how the surgical sponges were counted during Patient 1's surgery. She said when surgical sponges were removed from the surgical field during the surgery, she would "count off five, show them to the scrub, then bag them." When asked if the bagged sponges were recounted during the final count, she responded "No, we don't open the bags, we just count each bag and assume it contains five sponges."

ST 1 was interviewed on 11/16/09 at 2:25 p.m. He stated that surgical sponges used during Patient 2's surgery were discarded into a bucket, the circulating nurse counted off five, showed them to him and "wrapped them up." He said the bags of sponges were not opened and recounted, during the final count unless the count was incorrect. ST 1 added that at the time of Patient 2's surgery, the operating room did not use clear bags when bagging the sponges. When asked how a surgical sponge could have been retained in Patient 2, ST 1 responded, "Maybe four sponges got packaged as five, I think that's what happened, so the count would still be correct even if a sponge was missing."

During an interview on 11/17/09 at 10 a.m., RN 5
The facility's Counts, Surgical (Sponge, Sharps, Needles, Miscellaneous Items and Instruments) policy and procedure was reviewed and indicated the following:

"Surgical counts will be performed utilizing the following guidelines. The use of a standardized systematic method of accounting for instruments, sponges, needles and specific small items used during a surgical procedure will promote patient safety by helping to prevent retained foreign bodies."

B. Sponge Counts

11. The scrub person shall open soiled sponges when possible before discarding. Discard soiled sponges into kick buckets with impervious liners.

15. Once counted, the sponges are confined in an impervious wrapper.

16. As part of the ongoing count process and during the closure counts, the total number of bagged sponges must be reconciled with the total number documented on the count board/sheet."

The policy was ambiguous in that it did not specify that the bags had to be opened and the sponges contained in them needed to be recounted during the final sponge count.

The facility failed to develop and implement a surgical count policy and procedure which specified that bags of sponges counted during...
the course of the surgery be opened and recounted during the final count. This resulted in a surgical sponge having been left in Patient 2, who had to undergo a second surgery to remove it. This failure 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 1280.1.