CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050376	A. BUILDING _____ B. WING _____	07/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LAC/Harbor UCLA Medical Center	1000 W Carson St, Torrance, CA 90502-2004 LOS ANGELES COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00446587 - Substantiated Representing the Department of Public Health: Surveyor ID # 21262, 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. Health and Safety Code Section 1279.1(b). For purposes of this section, "adverse event" includes any of the following: (1)(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 present prior to surgery that are intentionally retained. 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. The CDPH verified that the facility had informed the			

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Event ID:XXZ111 6/29/2016 8:13:16AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Kim McKenzie, RN, MSN, CPHQ | Interim Chief Executive Officer | July 5, 2016

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

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.

Received: 21262
7/8/16

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	patient or party responsible for the patient of the adverse event by the time the report was made. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY: Title 22, Division 5, Chapter 1, Article 3 §70223: Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) 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. The above regulation was NOT MET as evidenced by: Based on interview and record review, the hospital failed to ensure the medical staff and surgical staff consistently implemented the hospital's P&Ps (policy and procedures) regarding counting of gauze rolls and using gauze rolls marked with radiopaque material (x-ray detectable element) during and after Patient E's surgical procedure on 4/30/15. The surgical staff were unable to describe one consistent procedure for accounting for gauze rolls used either as packing during surgery or as dressing after surgery to ensure that no gauze rolls were unintentionally left in the patient. Also, a gauze roll with a radiopaque marker was used as a dressing after the procedure, which was prohibited		**E 294** **T22 DIV5 CH1 ART3 § 70223 SURGICAL SERVICE GENERAL REQUIREMENTS** ***CORRECTIVE ACTIONS*** **A. New/Revised Processes, Policies and/or Procedures** 1. Vaginal Packing Limitations: Discontinue use of vaginal packing within peritoneal cavity, and instead use laparotomy pad. Restrict use of vaginal packing as vaginal dressing only. Actual date of completion: 9/11/2015 2. OR Pick Lists: Revise existing OR pick lists to place vaginal packing on "hold" so that the packing is not opened until the wound is closed or the case is completed. Actual date of completion: 9/11/2015 **B. Personnel Training/Notification** 1. Vaginal Packing Limitations: Educate OB/GYN providers and OR nursing staff on the following limitations on use of vaginal packing: • Discontinue use of vaginal packing within peritoneal cavity. • Restrict use of vaginal packing as vaginal dressing only.	7/5/2016 7/5/2016 7/5/2016

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by the hospital's policy. These failures resulted in the retention of a gauze roll in Patient E after surgery, with adhesions to numerous internal organs (small bowel intestines, colon and urinary bladder), causing pain, infection, the need for additional surgery on 6/3/15, and the loss of a part of Patient E's bowel.

Findings:

On 6/5/15, the hospital reported to the Department that after Patient E's surgery on 4/30/15, a surgical sponge was inadvertently retained.

On 7/21/15 at 1100 hours, during an interview with the Risk Manager, she stated a retained sponge of the type called a vaginal pack, which consisted of a gauze roll with a radiopaque marker, was found inside Patient E's pelvis on 6/3/15. The gauze roll was believed to have been left in Patient E during the surgery conducted at the hospital on 4/30/15.

The hospital's policy on Surgical Counts revised 6/23/15, defined "sponges" as "soft goods used to absorb fluids, protect tissues, or apply pressure or traction. Examples include laparotomy sponges, raytec sponges, cottonoids, peanuts, tonsil sponges, cotton balls, vaginal packs, etc." The policy showed a complete count of all sponges should be performed and documented prior to the beginning of all surgical procedures, and that dressings were not included in the counts. The policy included:
- Radiopaque sponges are not to be used for dressing.

Notification to occur by means of:

- Conference call between Chief Medical Officer, OB/GYN interim chair, and all members of the Urogynecology Division (the only surgical group that had been temporarily placing vaginal packing in the peritoneal cavity.)
- Distribution to all OB/GYN providers of a notification memo from the Chief Medical Officer reiterating limitations discussed in the above-referenced conference call.
- Distribution to OR nursing staff of a notification memo regarding the new limitations on use of vaginal packing; inclusion of the notification memo in the OR nursing communication log; discussion during shift reports of the new vaginal packing limitations.

Actual date of completion: 9/22/2015

2. OR Pick Lists:
NA

3. Hospital Policy No. 314 "Operating Room Protocol":
   a. Coach involved Obstetrics & Gynecology (OB/GYN) providers on the policy's requirements, specifically including:

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7/5/2016

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	- Keeping dressing materials separated from the actual counted sponges will help prevent mixing dressings with the sponges used during the procedure. - The sponge and sharp counts should be performed as initial (1st count), closing (2nd count), and final (3rd count). - The sponges should be separated and counted individually and should not be used if the package is incomplete or contains extra sponges. Review of the Operative Report for Patient E on 4/30/15, showed the patient had a total vaginal hysterectomy (surgical removal of the uterus and cervix through the vagina) and surgical repair of the vaginal wall including the perineum (the area between the vagina and the anus) to correct the pelvic organ prolapse (vaginal protrusion of pelvic organs, such as the bladder or uterus, which were lowered from the normal position). Review of the Intraoperative Record by the circulating nurses dated 4/30/15, showed the procedure was started at 1320 hours and completed at 1638 hours. There was no documentation of any retained packing being intentionally left in place in the pelvic cavity. Operative documentation in the electronic health record of Patient E on 4/30/15, showed an item for "Dressing/Packing". The section for documenting dressing contained the comment, "vagina". The section for packing had documentation: "Vaginal Packing" with the site listed "other". The electronic record did not show any pack left in the pelvis and did not show the total number of vaginal packs		• When a sponge [laparotomy pad] is packed, even temporarily, into a body cavity or deep wound for therapeutic purposes, the surgeon will announce to the Operating Room nursing staff the number of sponges packed, and into which body cavity or deep wound. The circulating nurse will record this on the count worksheet. The removal of the packed sponges [laparotomy pad] will be announced and recorded. Actual date of completion: 6/4/2015 b. Review with all OB/GYN providers Hospital Policy No. 314 "Operating Room Protocol" in its entirety and reinforce the policy's requirements that: • When a sponge [laparotomy pad] is packed, even temporarily, into a body cavity or deep wound for therapeutic purposes, the surgeon will announce to the Operating Room nursing staff the number of sponges packed, and into which body cavity or deep wound. The circulating nurse will record this on the count worksheet.	7/5/2016

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	used either as intraoperative packing or postoperative dressing. Medical record review showed Patient E was readmitted to the hospital on 6/1/15. Review of a History and Physical examination dated 6/1/15, showed Patient E experienced copious thick foul smelling discharge and left leg pain since the surgery on 4/30/15. Patient E's CT scan (a computerized tomography scan uses X-rays to make detailed pictures of structures inside of the body) result dated 6/2/15, showed an "8 x 6 x 4 cm air-filled cavity in the mid pelvis, compatible with an abscess in evolution at the site of the patient's prior transvaginal hysterectomy. The cavity is filled with packing material and there is no focal fluid collection." The Gynecology progress note dated 6/2/15, showed "It was explained to the patient that there may be a retained sponge or vaginal packing in her abdomen and that this may be the cause of her vaginal discharge." The physician planned to perform a diagnostic laparoscopy (operation performed though small incisions to remove the foreign object and drain the fluid collection). Review of Patient E's Operative Report dated 6/3/15, showed a vaginal pack was found in the pelvis with adhesions to small bowel, recto-sigmoid colon, and urinary bladder. The report showed the surgeon was unable to remove the pack safely by laparoscopy, so the surgery was converted to an open laparotomy (operation to open the abdominal		The removal of the packed sponges [laparotomy pad] will be announced and recorded. Actual date of completion: 9/10/2015 4. Nursing Specialty Manual Policy No. 333 "Surgical Count": a. Coach involved Operating Room (OR) Nursing staff on the policy's requirement to perform an accurate count of any item opened intra-operatively and use the count worksheet to accurately document all counted items. Actual date of completion: 6/4/2015 b. Review and reinforce with all OR nursing staff – as part of in-service conducted during unit council meetings -- that dressing materials are not to be placed on the sterile field until the wound is closed or the case is completed. Actual date of completion: 6/4/2015 ***QUALITY IMPROVEMENT*** **A. Planning** Monitor -- as part of documented Operating Room QI activities – audits of Urogynecology operative procedures to assess compliance with: • Restricted use of vaginal packing, i.e. placement only intravaginally.	7/5/2016 7/5/2016

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through a large incision to access into the abdominal cavity) for the surgeons to be able to separate the scar tissues that could twist/block other organs. Approximately 30 cm of Patient E's bowel had to be cut out to remove the pack and injured or dead areas of the bowel.

The post-operative follow-up visit note conducted dated 6/3/15, cosigned by MD 1 showed Patient E's severe pain was described as "incompletely controlled despite the use of patient controlled narcotic pain reliever." The note also showed Patient E was being given three antibiotics for the abdominal abscess (a collection of pus that has built up within the tissue of the body).

During the interviews on 7/21 and 7/30/15, with the hospital's physician and surgical staff, they indicated the radiopaque rolls of gauze called a vaginal pack were used both as packing and as a dressing for Patient E, despite the policy precluding the use of radiopaque sponges as dressings.

On 7/21/15 at 1215 hours, during an interview with MD 10, the attending surgeon for Patient E's 4/30/15 surgery, she stated during the procedure, a vaginal pack was usually placed in the pelvis by a member of the surgical team to help visualize structures and was usually removed by a member of the surgical team during the surgery after a few sutures were placed. Additionally, she stated at the end of the procedure, a vaginal pack was placed in the vagina as a dressing to the wound and was usually taken out the day after surgery.

- Requirement that vaginal packing is not opened and placed on the sterile field.
- Accuracy of the documentation on the count sheet.

B. Monitoring

Aggregate and analyze data. Report results monthly to the Operating Room Committee and the Quality/Risk/Safety committees, Patient Safety Council, Medical Executive Committee, and Executive Leadership Council; quarterly to the Governing Body. Audits to continue until average 90% compliance has been achieved for 4 consecutive months.

RESPONSIBLE POSITION(S)

- Chief Medical Director; Clinical Director/Perioperative Services; Interim Chair, Obstetrics & Gynecology

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Review of the OR Intraoperative Record dated 4/30/15, showed the initial surgical counts of instruments, sharps, and sponges were completed by Circulating RN 1 and Scrub Tech 1, and the procedure started at 1320. At 1515 hours, Circulating RN 1 and Scrub Tech 1 were replaced by a Circulating RN 2 and Scrub Tech 2, and instruments, sharps, and sponges were again counted, and the counts documented as correct. Subsequently, there were closing and final counts of instruments, sharps, and sponges documented as correct by Circulating RN 2. Additional scrub techs and nursing staff were identified as being present during portions of the surgery to provide breaks.

In an interview with Circulating RN 3 on 7/21/15 at 1140 hours, she stated the dressings were not included in the count because the dressings were applied after the surgical counts were completed. Circulating RN 1 was not available for interview.

In an interview on 7/30/15 at 1100 hours, Scrub Technician 2 stated only one sponge count sheet was used, and different types of materials used were to be documented, including the vaginal packs. Scrub Technician 2 stated the radiopaque vaginal dressings were included in the sponge counts. She stated a vaginal pack was placed in the vagina at the end of surgery as a dressing. Scrub Technician 2 stated only the OB-Gyn department staff were using radiopaque vaginal packs for dressings.

In an interview with Scrub Technician 1 on 7/30/15

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at 1200 hours, she stated the vaginal packs should be counted whether or not it is used as dressing. She stated staff members who were not routinely assigned in gynecology surgical cases might not add the vaginal packs to the count sheets.

More than one surgical team was involved in Patient E's surgery, but the surgical staff interviewed were not able to verbalize a consistent policy for accounting for the radiopaque vaginal packs. The departure from policy through the use of a radiopaque vaginal pack as a post-operative dressing indicates surgical staff's lack of understanding of the hospital policy on Surgical Counts because some staff believed that radiopaque sponges were to be included in the sponge count, whether they were used intraoperatively or as post-operative dressings.

During an interview with the Risk Manager on 7/21/15 at 1100 hours, she stated the vaginal packs were commonly used in the vaginal hysterectomy procedure. She stated the investigation showed the vaginal pack was probably not included in the surgical count for the 4/30/15 surgery.

The deficiency 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 1280.3, subdivision (g).