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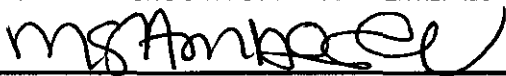
PRINTED: 11/15/2013
FORM APPROVED

California Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA930000162	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/06/2012
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NAME OF PROVIDER OR SUPPLIER RONALD REAGAN UCLA MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 757 WESTWOOD PLAZA LOS ANGELES, CA 90095
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E 000	<p>Initial Comments</p> <p>The following reflects the findings of the Department of Public Health during an entity reported incident investigation.</p> <p>Intake Number: CA00278023 – Substantiated</p> <p>Representing the Department of Public Health:</p> <p>Evaluator ID #26040, RN, Sr.HFEN</p> <p>The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.</p> <p>1280.1(c) Health and Safety Code Section</p> <p>For purposes to 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.</p>	E 000	<p style="text-align: center;">HEALTH FACILITIES INSPECTION DIVISION ADMINISTRATION 2013 NOV 27 PM 3:26 RECEIVED</p>	
E 347	<p>T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements</p> <p>(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.</p> <p>This Statute is not met as evidenced by: Based on interview and record review, the facility failed to implement its written policy and</p>	E 347	<p>11/18/13</p> <p>Since this incident in 2011, our facility has taken many measures to ensure the safety of our patients. Our plans of action include:</p> <p>8/1/11</p> <p>The facility introduces our yearly Failure Effectiveness Mode Analysis (FEMA) topic: Surgicount Initiative.</p> <p>Surgicount is a bar coding system using RFID sponge technology as an adjunct system to assist with surgical sponge count practice. The FEMA included a review of the new system as well as the development of an anagram that descriptively includes the new process of mapping.</p>	

Licensing and Certification Division LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE Director	(X6) DATE 11.25.13
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E 347	<p>Continued From page 1</p> <p>procedure on counting sponges and miscellaneous items used for Patient 1 's surgical procedure which resulted in retention of a foreign object (lap sponge). On [REDACTED] 2011, Patient 1 underwent exploratory laparotomy (a laparotomy is a large incision made into the abdominal wall, and is used to visualize and examine the structures inside of the abdominal cavity). A lap sponge was left inside Patient 1 's abdomen just above the liver which required a second surgical procedure, on [REDACTED] 2011, under general anesthesia to remove a retained lap sponge. The facility's failure placed Patient 1 at risk for possible additional complications, including sepsis (invasion of the body by pathogenic microorganisms and their toxins), visceral perforation (damage or puncture wounds to organs), and the need for additional surgery/general anesthesia.</p> <p>Findings:</p> <p>On September 2, 2011, an unannounced visit was made to the facility to investigate an entity reported event regarding retention of a foreign object in Patient 1.</p> <p>Patient 1's medical record was reviewed on September 2, 2011. The face sheet indicated Patient 1 was re-admitted to the facility on [REDACTED] 2011, with diagnosis of pancreatic mass. (A mass is a lump or growth on the pancreas, an organ that produces hormones, such as insulin, and excretes juices utilized in the digestive process.)</p> <p>A review of the Operative Report indicated on [REDACTED] 2011, Patient 1 underwent an exploratory laparotomy with the pre-operative diagnosis of pancreatic mass and biliary obstruction (blockage</p>	E 347	<p>(Continued from page 1)</p> <p>OR dept safety talk Topic: Safe and Quality Care: The importance of Communication and Culture. This OR safety talk continued until all staff involved received the talk</p> <p>FEMA – Surgicount Initiative 8/1/11 FEMA subgroup meets weekly to discuss the progress of implementation of the Surgicount Initiative. This group was primarily responsible for the policy standardization and revision across the health system. This group was responsible for ensuring that staff education was provided to all targeted areas throughout the UCLA Health System.</p> <p>Notification of Medical Staff Informational letter sent out to all Medical Staff from Surgicount representative staff.</p> <p>Email blast to all involved staff Email blast to all staff from the Director of Peri-operative services was sent. The email blast included the pilot kick off schedule, as well as education on the Surgicount system, the letter that was sent to the Medical Staff, and a recent article from the Joint Commission on the Journal on Quality and Patient Safety.</p> <p>Implementation of "Surgi-count" Staff education/In-service was provided and Reviews of the pilot kick-off schedule of the new program "Surgi-Count".</p>	<p>8/14/2011</p> <p>5/01/2012</p> <p>8/8/2011</p> <p>8/24/2011</p> <p>9/7/2011</p>

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E 347	<p>Continued From page 2</p> <p>of bile duct, usually caused by one or more gallstones). The operative report indicated the sponge and needle counts were correct, the fascia (connective tissue supporting internal organs) was closed with sutures and the skin was closed with staples.</p> <p>A review of the Operating Room Record dated [REDACTED] 2011, indicated under the Sponge Counts section, a preliminary count, a first count and final count conducted by the scrub technician (RN 4) and the circulating nurse (RN 1) were correct. However, the operating room record further indicated an additional first count was done, which was conducted by the physician and the circulating nurse (RN 1) and this count was also correct.</p> <p>During an interview with the Director of Nursing and Operations (RN 3) on September 2, 2011 at 11 :35 a.m., when asked if the physician normally conducted the sponge counts, she stated usually it was conducted by the scrub technician and the circulating nurse and that the physician, at times, may do a closing sponge count.</p> <p>During an interview with the Director of Quality (RN 2) on January 6, 2012 at 9:30 a.m., he stated the counting of the sponges for the surgical procedure (on [REDACTED] 2011) was incorrect and that the counting process failed.</p> <p>During an interview with the scrub technician (RN 4) on January 6, 2012 at 9:55 a.m., she stated she remembered (on [REDACTED] 2011) the first count was a miscount and the count was off. However, after the surgical staff checked the "kick" bucket, the surgeon found the lap sponge in the patient, and that made the count correct (in the record).</p>		<p>(Continued from Page 2)</p> <p>The in-room trials begin The pilot included trialing the system in (5) rooms of the main OR. The system was trialed in 5 OR Suites. The trial continues daily for 12 hours at a time. The trial lasts from 9/12/2011 through 9/23/2011.</p> <p>Administrative Nurse 1 meeting An update of the patient safety initiative was provided to this group. Roles and responsibilities changes targeted to this group were also discussed.</p> <p>Grand Rounds presentation Surgicount education, data review, and implementation information was discussed with the group.</p> <p>Surgical Faculty Group presentation Surgicount education, data review, and the implementation information was discussed with the group.</p> <p>Policy revision The Health System Count Policy final draft submitted for leadership approval. (applies to perioperative services and labor & delivery in the UCLA Health System)</p> <p>On site Go-Live & Staff training Surgicount Team on site for go live ramp up and staff training.</p> <p>In-service Count policy changes and overview and Surgicount training with staff.</p> <p>Data Review 360 reports were reviewed by leadership and selected staff.</p>	<p>9/23/2011</p> <p>12/21/2011</p> <p>2/15/2012</p> <p>4/5/2012</p> <p>7/3/2012</p> <p>7/9/2012</p> <p>7/11/2012</p> <p>7/12/2012</p>

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E 347	<p>Continued From page 3</p> <p>During an interview with the circulating nurse (RN 1) on January 6, 2012 at 10:05 a.m., she agreed the count was off at some point during the procedure (on [REDACTED] 2011), not sure when, but they found the sponge, recounted and it was correct. RN 1 stated when there was a retained foreign object, it meant the count was not correct, however she was not sure how it turned out to be correct count.</p> <p>According to the Radiological Diagnostic Report dated [REDACTED] 2011, Patient 1 received a computed tomography (CT) of abdomen and pelvis (CT is an imaging method that uses x-rays to create cross-sectional pictures of the the area between the hip bones, pelvis, and the abdomen area) due to nausea, increased white blood cells (the cells the body makes to help fight infections) and was to be evaluated for fluid collection. The diagnostic report showed a "lap marker"(the string to grab the sponge) adjacent to the right lobe of the liver with surrounding gas and fluid and that the collection measured 11 x 4 centimeters (ern).</p> <p>A review of the Operative Report dated [REDACTED] 2011, indicated Patient 1 underwent another exploratory laparotomy and removal of an intra abdominal foreign body. The operative report indicated the patient underwent a previous surgery six days ago and in the last few days, the patient had increasing nausea and a rising white cell blood count. The CT scan noted a retained laparotomy sponge in the right upper quadrant and the patient was taken emergently back to the operating room for removal of this foreign body under general anesthesia. In the description of the operation, the report indicated Patient 1's sutures were cut, the skin staples were removed,</p>		<p>(Continued From page 3)</p> <p>Implementation Health System Wide Go Live with Surgicount scanning at RR and SMH Main Operating Rooms and Labor and Delivery Rooms.</p> <p>Morbidity & Mortality Review topic: Preventing RFOs A presentation was made to the group that discussed the FEMA, Surgicount process, Health System policy and procedure changes as related to the implementation of Surgicount.</p>	<p>7/16/2012</p> <p>7/23/2012</p>

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E 347	<p>Continued From page 4</p> <p>the abdomen was opened and the laparotomy sponge identified just above the liver was removed and sent to pathology.</p> <p>A review of the Discharge Summary dated [REDACTED] 2011, indicated Patient 1 was discharged home on post-op day #5, from the second operation, in good clinical condition.</p> <p>A review of the facility's policy and procedure titled, "Counts: Sponges, Sharps, Misc., Instruments," stipulated guidelines for sponges, sharps, miscellaneous and instrument counts during a surgical procedure in order to ensure patient safety and that mandatory counts were to be performed visually and audibly by the scrub person and circulating nurse. Sponges, sharps and miscellaneous items were to be counted at the initial count - prior to the start of the procedure, first count - prior to the closure of a body cavity and final count - skin closure. The policy further stipulated the scrub person, circulating nurse or surgeon may request additional counts as deemed necessary and that the circulating nurse issuing the items for counting must count with the scrub person.</p> <p>The facility's failure to implement its policy and procedure to prevent retention of the lap sponge during a surgical procedure for Patient 1 is a deficiency 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.</p>				