

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

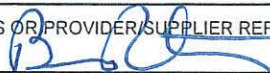
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050295	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  08/01/2018
NAME OF PROVIDER OR SUPPLIER <b>Mercy Hospital</b>		STREET ADDRESS, CITY, STATE, ZIP CODE 2215 Truxtun Ave, Bakersfield, CA 93301-3602 KERN COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00565272 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 2638</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>HEALTH AND SAFETY CODE SECTION 1279.1(b) (1) (D) Retention of foreign object in a patient (b) For purposes of this section, "adverse event" includes any of the following: (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 present prior to surgery that are intentionally retained.</p> <p>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.</p>		<p>Corrective Actions:</p> <p>The OR craniotomy procedure process was revised to include a small sterile basin for placement of Raney clips upon removal.</p> <p>The Raney clip was an item included in the surgical count for craniotomy procedures. The accounting process was revised to include the team communicates the number of clips prior to incision and at closing of dura.</p> <p>OR Staff were educated on revised Prevention of Retained Surgical Items policy which included management of small miscellaneous items.</p>	<p>12/13/2017</p> <p>12/13/2017</p> <p>12/14/2017</p>

Event ID:Z6DS11

8/3/2018

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE



TITLE

President

(X6) DATE

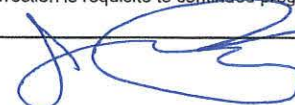
8/16/18

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 9

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.

8/16/18

POC accepted



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	<p>DEFICIENCY CONSITITUTING IMMEDIATE JEOPARDY:</p> <p>T22 DIV5 CH1 ART3 - 70223(b) (2) Surgical Services 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.</p> <p>Based on interview and record review, the hospital failed to follow the policy and procedure in the accounting for all the surgical items, which were used during one patient's (Patient 1) surgical procedure. This failure resulted in the retention of a "Raney scalp clip (a neurosurgical [a medical specialty for the prevention, diagnosis, and surgical treatment which affect the nervous system including the brain, spinal cord, and peripheral nerves] instrument used to pinch the wound edge to stop bleeding) inside Patient 1's left parietal lobe of the brain (one of the four major lobes of the brain located at the top of the brain) for approximately 10 days before it was discovered and surgically removed.</p> <p>Findings: During a review of Patient 1's clinical record, the "Perioperative (the time period for a patient's</p>		<p>Competency completed on all active surgical nurses and techs to include the management of small miscellaneous items. Annual education calendar was updated to include Prevention of Retained Surgical Items annual competency for surgical nurses and techs by November 2018 including the management of small miscellaneous items.</p> <p>Dignity Health System Office Consultant conducted education to OR staff at both Mercy sites focusing on the management of small miscellaneous items per the revised "Prevention of Retained Surgical Items" policy. "Small miscellaneous items that enter the patient or are on or near the surgical incision should be counted and documented on the dry erase board and accounted for at the end of the case in addition to other strategies to prevent retention.</p> <p>The revised "Prevention of Retained Surgical Items" policy was approved by Policy and Procedure Committee, CNEO, Surgical Supervisory Committee, MEC and the Governing Body for final approval 01/24/2018.</p> <p>The OR practices were revised to include management of small miscellaneous items. The White Boards in Surgical Suites were updated to include section for small miscellaneous items.</p>	<p>12/15/2017</p> <p>01/05/2018</p> <p>01/05/2018</p> <p>01/15/2018</p>

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RECEIVED & CONFIRMATION  
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 AUG 16 PM 1:59

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	<p>surgical procedure which include admission, anesthesia, surgery, and recovery) Record" dated 12/2/17, the record indicated Patient 1 underwent a scheduled procedure performed by Medical Doctor 1 (MD 1). The procedure was a "Craniotomy Hematoma Evacuation (Left) (a surgical opening into the skull to access the brain underneath to remove or evacuate blood debris) due to a diagnosis of "Left Sided Epidural Hematoma (a traumatic accumulation of blood between the inner skull and the dural membrane - lining that surrounds the brain)."</p> <p>During a review of the x-ray "Skull 1-3 Views" dated 12/11/17 (nine days after the surgical procedure on 12/2/17), the x-ray results indicated ". . . INDICATIONS: . . . possible metal clip in the brain per ct scan (computed tomography - makes use of a computer - processed combinations of many x-ray measurements taken from different angles to produce images of specific areas). . . FINDINGS: . . . SKULL: Postsurgical changes consistent with left temporal craniectomy (a procedure in which a skull is removed to allow a swelling brain room to expand without being squeezed) and low density metallic 1.5 x 0.8 cm (centimeter) somewhat tubular shaped foreign object left parietal convexity (the aspect of the skull that lies in contact with the flat bones of the skull). . . CONCLUSION: 1. Postsurgical changes consistent craniectomy and bone flap left tempo parietal (an area of the brain where the temporal [lying beneath the temples] and parietal lobes meet) calvarium [skullcap] . . . 2. Nonspecific 1.5 cm foreign body left parietal (lobes of the brain at the top of the head) extra-axial (a lesion -injury</p>		<p>Monitoring: 10 surgical observation audits for cases with small miscellaneous item(s) are conducted monthly by the Director of Surgical Services or designee. Results of the audits are reported monthly to Quality Assurance/Utilization Review Committee, Nursing Council, MEC and Governing Body until 100% compliance has been sustained 3 months.</p> <p>Responsible Party:  Director of Surgical Services</p>	

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 STAFF  
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	<p>such as wound, ulcer, or tumor that are external to the brain tissues)."</p> <p>During a review of Patient 1's clinical record, the History and Physical, dated 12/11/17, indicated Patient 1 had a seizure during his first admission of 12/2/17 and was discharged with an anti-seizure medication. He was taken to another hospital due to a right facial droop, numbness in the right upper extremity and right sided weakness. He had a seizure in the ambulance during transport and at the Emergency Department and was noted to have slurred speech and blurry vision. The CT scan taken at the other hospital indicated Patient 1 had an acute on chronic subdural hematoma (new bleeding in an area where previous bleeding had occurred).</p> <p>During a review of Patient 1's clinical record, the Operative Report, dated 12/12/17, indicated ". . . PREOPERATIVE (before surgery) DIAGNOSIS 1. Subdural hemorrhage (a pool of blood between the brain and its outermost covering) 2. Subdural foreign body... POSTOPERATIVE (period following a surgical operation) DIAGNOSIS: 1. Subdural hemorrhage 2. Subdural foreign body . . . PROCEDURES: 1. Craniotomy for subdural hemorrhage evacuation [a surgical opening into the skull to access the brain underneath to remove or evacuate blood debris] 2. Resection [surgically removing part of an organ] of foreign body. . ."</p> <p>During an interview with the Certified Surgical Technician (CST), on 1/4/18, at 1:19 PM, she stated, "I was the scrub technician [assist surgeons in the operating room which include passing</p>			

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	<p>instruments to the surgeon]." The CST stated Registered Nurse 1 (RN 1) was the circulating nurse [manages all the necessary care inside the surgery room and assisting the team] and RN 2 was the Circulating Registered Nurse First Assist (CRNFA) during the surgical procedure performed on 12/2/17. She stated she set-up the sterile field and passed instruments. The CST stated the "Raney clips" were placed on the edge of the scalp to pull the skin of the scalp back. The CST added, "For this case [of Patient 1] the blood loss was excessive. When the doctor gave me the bone flap [a portion of cranium removed] it was really bloody." She stated, "Usually the [Raney] clips are on the skin. I don't know how it got under the bone flap. Sometimes it's possible he could [have] missed the clip. A loaded [Raney] gun has 10 clips. If needed I have extra clips to reload. If needed I have extra 30 [Raney] clips to reload. The skin on the front part of head used 20-30 clips routinely for this type of surgery with bone flap removal." The CST added, "The policy now is to count Raney clips."</p> <p>During a subsequent interview with the CRNFA, on 1/4/18, at 1:19 PM, he stated during surgery he retracted (pull in or pull back), suctioned and helped close the incision with MD 1 for Patient 1's surgery. The CRNFA added, "We now have a new policy of counting Raney clips. Before we did not count [the Raney clips]."</p> <p>During an interview with the Director of Quality Performance Improvement (DQPI), on 1/4/18, at 1:58 PM, he stated the hospital took Patient 1 back for a second surgery, on 12/12/17 from another</p>			

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	<p>hospital who reported the x-ray and CT scan result. The DQPI stated, "Patient [1] was having facial droop, stroke like symptoms and slurred speech." The DQPI stated the other hospital transferred Patient 1 'due to a bleed.' The DQPI stated two days prior to the first surgery Patient 1 reportedly had a headache and bleeding from his ear.</p> <p>During an interview with the Operating Room Director (ORD), on 1/3/18, at 3 PM, she stated, "I don't know how it got to be. We now require that clips are counted." She added, "It was a large Subdural Hematoma (a type of hematoma associated with traumatic brain injury) per the report [first surgery on 12/2/17].</p> <p>During an interview with the Director of Risk Management (RMD), on 4/23/18, at 2:20 PM, the RMD stated the name of the foreign body retained was Raney clip. She added, "It comes in a kit. The whole kit includes the clip gun, three magazines, with ten clips each with a clip removal tool. The set/kit has 30 Raney clips."</p> <p>During a subsequent interview with the Operating Room Director (ORD), on 4/23/18, at 3:08 PM, the ORD stated the Raney clips were used on the edge of the scalp. She added, "They can use up to 30 clips which helped to control bleeding. We were not counting the Raney clips before. It was not part of the official count. We were not aware that it was left behind until we heard on 12/11/17."</p> <p>During an interview with MD 1, on 5/18/18, at 2:14 PM, MD 1 stated the hospital set the rules. He</p>				

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	<p>stated the process of counting the surgical instruments including the Raney clips determined by the hospital. He added, "It's the hospital who determines what to count. They should count the Raney clips. The hospital is the boss of the counting. Hospital is in charge what to count and make the rules. I expected them to count. There's no reason for the hospital not to count the Raney clips." MD 1 stated the Raney clips were used on the scalp to stop the bleeding. He stated if it was a large incision, 25 Raney clips were usually used. For small incisions 12 Raney clips were usually used. He stated Raney clips were smaller than a penny. MD 1 stated the second admission for Patient 1 was for bleeding and it was very unlikely due to the retained Raney clip.</p> <p>During an interview with MD 1, on 6/11/18, at 12:50 PM, MD 1 stated Patient 1 had the second surgery because of an additional blood clot. He stated, "No one was hurt with the Raney clips. The risk was very little - very tiny risk to no risk at all. Retention of Raney clips had no reason to cause bleeding. [There was] no connection between the two. The patient [Patient 1] had a huge blood clot, bleeding and accumulation of blood was not from the Raney clip. Retention of the Raney clips had at most no risk at all." MD 1 was unable to state whether the second surgery would have been done if the patient had not shown symptoms of a bleed.</p> <p>The hospital policy and procedure titled "Prevention of Retained Surgical Item" undated, indicated " . . . Purpose: A. Procedure: To provide safety rules for perioperative registered nurses [RN] and surgical</p>			

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	<p>technologists in the performance of sponge, sharp, instrument and miscellaneous item counts. . . b. To provide safety rules for surgeons in the performance of a methodical wound exam [a methodical exploration of the operative wound must be conducted prior to closure in every operation], and actions to prevent unintentional retention of surgical items. . . F. To assist in accounting for all surgical items and minimize inventory loss. . . SCOPE AND APPLICABILITY: . . . This policy applies to operating rooms (OR), procedure rooms . . . and all other areas where a wound is created (any incision is made in the skin) or procedures are performed . . . and surgical items are used in or on a patient . . . Documentation: A. A Registered nurse is responsible for medical record documentation . . . C. Counts and other required information should be entered concurrently with an occurrence or at the end of the case . . . E. MISCELLANEOUS SMALL ITEMS AND DEVICE FRAGMENTS 1. MISCELLANEOUS SMALL ITEMS a. Miscellaneous items should be accounted for all procedures . . ."</p> <p>According to the AORN (Association of Operating Room Nurses - who provide guidelines for perioperative practices) article titled "Guidelines for Prevention of Retained Surgical Items (RSI)" revised on 10/16, 2017 edition, indicated ". . . Health care organizations are responsible for employing standardized, transparent, verifiable, reliable practices to account for all surgical items used during a procedure. Counts of . . . miscellaneous items, and instruments are performed to account for all items used on the surgical field . . . Accurately accounting for items used during a surgical</p>				

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	<p>procedure is a primary responsibility of the surgeon and surgical first assistant. The American College of Surgeons recognizes patient safety as "the highest priority and strongly urges individual hospitals and health care organizations to take all reasonable measures to prevent the retention of foreign bodies in the surgical wound . . ."</p> <p>The hospital failed to follow the policy and procedure for counting surgical items, which resulted in the unintended retention of a Raney scalp clip in Patient 1. This failure 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).</p> <p>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).</p>				

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