

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050394	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  09/22/2017
NAME OF PROVIDER OR SUPPLIER <b>COMMUNITY MEMORIAL HOSPITAL - SAN BUENAVENTURA</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>147 N Brant St, Ventura, CA 93003-2809 VENTURA COUNTY</b>		
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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: CA00540695 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 2895, HFEN</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 (a)</p> <p>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.</p> <p>Health and Safety Code Section 1279.1, subdivision (b)(1)(D)</p>	<p>11/7/19 Attached POC accepted Kathleen Chelms</p>	<p>LICENSING &amp; CERTIFICATION VENTURA DISTRICT OFFICE</p> <p>2019 JAN 16 PM 12:26</p> <p>CA DEPT OF PUBLIC HEALTH</p>	

Event ID: E65911

1/4/2019

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

TITLE

(X6) DATE

*[Signature]* VP, Quality

1-16-19

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s) 1 thru 12*

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.



**Community Memorial Health System**  
*Where Excellence Begins with Caring*

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2019 JAN 16 PM 12:25

LICENSING & CERTIFICATION  
VENTURA DISTRICT OFFICE

**From:** Community Memorial Hospital of San Buenaventura  
 147 North Brent Street  
 Ventura, CA 93003

**To:** California Department of Public Health  
 1889 North Rice Avenue, Suite 200  
 Oxnard, CA 93036

**Re:** Plan of correction for CDPH 2567 – CA00540695 RFO  
 January 15, 2018

	<b>Plan of correction:</b>
<p>Title 22 California Code of Regulations Division 5 Chapter 1 Article 3 Section 70223(b)(2).            Facility failed to ensure surgical counts for instruments were performed according to facility policies and procedures</p>	<p><b>A. Actions taken for patient identified:</b>            On 6/18/2017 upon discovery of the foreign object full disclosure was provided to the patient by her physician and the object was removed. Staff in the L&amp;D OB area were notified of the event and a thorough investigation was completed. Risk strategies were developed along with monitors for compliance and effectiveness.</p> <p><b>B. How other patients are protected from deficient practice. Immediate measures and systemic changes to ensure deficient practice does not recur:</b>            The counting of surgical instruments is identified as a high risk problem prone process having a significant impact on patient safety. As a result of the investigation corrective actions were implemented along with an auditing process with iAuditor and observations:</p> <p>1. <b>The Count Process:</b></p> <ol style="list-style-type: none"> <li>Risk Reduction strategies reviewed on 08/10/17 &amp; 08/14/17 for prevention of Retained foreign objects (RFO) at L&amp;D staff meetings. Staff educated to importance of speaking up for patient safety. Count policy reviewed including when to get an X-ray: in cases where initial count was not performed, count was incorrect or if any member of the team has concerns about the validity of the count. Discussed importance of minimizing distraction during surgical cases. The count process is initiated prior to incision at the start of the case, when wound closure begins, prior to dressing or skin adhesive.</li> <li>Items are counted with the circulator visualizing the field and verbally participating. This process ensures that all counted items are visualized and verbally identified.</li> <li>"Stop the line" was implemented and education was provided. On 06/21/17, an email was sent to L&amp;D staff regarding counting and speaking up for patient safety, using C-U-S (I am concerned, I'm uncomfortable, this is a safety issue.) This process was implemented to assure staff that if they have any concerns related to the count they are empowered to speak up and will be supported by management.</li> <li>Education module was developed for Prevention of RFO for RNs and Scrub Techs.</li> </ol>

	<p>closing the wound are removed from the wound and returned to the scrub.</p> <ol style="list-style-type: none"> <li>5. Items added to the sterile field are noted on the dry erase count board of instrument count sheet immediately</li> <li>6. If the count is interrupted the count is resumed with recounting of items currently being counted.</li> <li>7. Items are counted with circulator visualizing the field and verbally participating.</li> <li>8. Hand off report to relief circulator includes report of any counted items removed from the field and held for final count.</li> <li>9. Appropriate actions are taken for count discrepancies</li> <li>10. Minimal talk/distractions during the case</li> <li>11. Minimal talk distraction during the counts</li> </ol> <p>The ongoing audit of counts has shown improvement. Data since Feb. 2018 to Jan 11, 2019 has shown full compliance.</p> <p>The audits and reporting of compliance is the responsibility of the Director, Maternal &amp; Children's Health Services</p> <p><b>D. Dates corrective actions will be completed.</b></p> <p>All corrective actions have been completed. Dates of implementation are noted above. Monitoring of compliance remains an ongoing process.</p>
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Cindy DeMotte

Community Memorial Hospital Representatives Signature:

Title: VP, Quality

Date: 1/16/2019

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	<p>(b) For purposes of this section, "adverse event" includes any of the following:</p> <p>(1) Surgical events, including the following:</p> <p>(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 &amp; Safety Code Section 1280.3 (a) and (g):</p> <p>(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.</p> <p>(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>Title 22, California Code of Regulations, Division 5, Chapter 1, Article 3, Section 70223 (b)(2):</p>			

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	<p>Surgical Service General Requirements</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(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 facility failed to ensure surgical counts for instruments were performed according to facility policies and procedures.</p> <p>This failure resulted in the retention of a surgical ribbon malleable instrument, measuring 12.99 inches in length by 2 inches in width, inside one patient (Patient 1), after Cesarean Section (C-Section) and Tubal Ligation surgery (delivery of a baby through a surgical incision in the mother's abdomen and uterus and having the fallopian tubes tied or permanent birth control).</p> <p>On 6/22/17, an entity-reported event (ERI) was submitted by the facility to the California Department of Public Health indicating the discovery of a retained foreign object inside Patient 1's abdomen following surgery.</p> <p>On 9/12/17, an on-site abbreviated survey was</p>			

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 2019 JAN 16 PM 12:26  
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	<p>initiated to conduct an investigation of the entity-reported event (ERI). A review of Patient 1's medical records was conducted on 9/12/17. According to the "Delivery Report," dated 5/20/17, Patient 1 had a C-Section and Tubal Ligation on 5/20/17. Patient 1 returned to the facility Emergency Department (ED) on 6/18/17 (29 days later), complaining of abdominal pain. A report of CT scan (series of special X-rays) completed on 6/18/17 in the ED set forth the following: "Very large foreign body within the abdominal cavity as detailed below likely representing retained foreign body from surgery."</p> <p>The same CT scan report, dated 6/18/17, set forth the following under stomach/bowel/mesentery: "There is a large oblong metallic density foreign body within the abdominal cavity extending from the left upper quadrant to the right lower quadrant measuring up to 33 cm (33 cm is equal to 12.99 inches)."</p> <p>An undated photograph was provided by the facility's quality vice president on (9/12/17). This photograph was identified by the facility's quality vice president as the retained foreign body located within Patient 1's abdominal cavity. The photograph was observed and demonstrated a to be a retractor (a surgical instrument used to separate the edges of a surgical incision or wound, or to hold back underlying organs and tissues so that body parts under the incision may be accessed). The facility representative confirmed that the retractor retained in Patient 1's body was measured at 33 cm (12.99 inches) in length and 2 inches in width.</p>			


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	<p>During an interview with Patient 1 on 9/18/17 at 1:25 p.m., Patient 1 explained she was discharged home with abdominal pain radiating to her back. Patient 1 stated the following: "Every time I bent down I felt a grinding feeling, like my muscles were rubbing something." Patient 1 was taking Percocet (medication used to relieve moderate to severe pain) for 4 weeks to alleviate the pain. However, according to Patient 1, the pain got worse and when she could not tolerate it anymore she returned to the facility's ED on 6/18/17.</p> <p>The facility's policy and procedure entitled, "Counting Surgical Items and Prevention of Retained Surgical Items," revised 6/5/14 and in effect during Patient's 1 surgical procedure, was reviewed. Section 111, part A, entitled, "COUNTING SURGICAL ITEMS" set forth the following:</p> <p>"Number 1. Time must be allowed for counts to be performed carefully and precisely. The following processes must be followed:</p> <p>(d) Surgical items are counted audibly and viewed concurrently by the operating room nurse/technician and the circulating nurse."</p> <p>The same policy, under Section III, Part A, Number 7, set forth the following:</p> <p>"Counts must be performed in the same sequence each time. The count should begin at the surgical site and the immediate surrounding area, proceed to</p>				<p style="text-align: right;">  </p>

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	<p>the Mayo stand and back table, and finally to the counted items that have been discarded from the field."</p> <p>Further review of the policy, under subpart (D), entitled, "INSTRUMENTS COUNTS," under Number 1, set forth:</p> <p>"Instruments are counted on all procedures entering the abdominal and thoracic cavities in which the likelihood exists that an instrument could be retained. If there is a question about whether a case will need a count, an initial count is to be done."</p> <p>Further, Number 3 of Subpart D states:</p> <p>"Counts of instruments should be performed:</p> <ul style="list-style-type: none"> <li>a. Before the procedure has begun to establish a baseline count,</li> <li>b. When wound closure begins,</li> <li>c. At the time of permanent relief of either the scrub person or the circulating nurse, although direct visualization on all items may not be possible." <p>The "Delivery Report," dated 5/20/17 at 3:50 p.m., was reviewed and set forth that Patient 1 had a C-section and Tubal Ligation on 5/20/17. The report further documented that the surgical item counts were performed by licensed nurse (LN 1) and specialty technician (Tech 1) during Patient 1's surgical procedure. The surgical counts included on the report were documented as performed on the initial, first, second, and third counts. Instrument</p> </li></ul>			

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	<p>counts included on the report were documented as performed during the initial and third counts.</p> <p>During an interview with Tech 1, on 9/12/17 at 11:35 a.m., she reviewed Patient 1's "Delivery Report," dated 5/20/17 at 3:50 p.m., and confirmed there were two instrument counts completed. Tech 1 confirmed these counts included the initial count to establish the instrument count baseline and the third count at wound closure. Tech 1 explained the initial count was conducted with the surgical circulating nurse (LN 1) calling out the names of listed instruments from a count sheet. LN 1 physically checked off the names on the count sheet after she (Tech 1) stated they were present and counted.</p> <p>Tech 1 further explained, during the third count, Tech 1 was holding a retractor while assisting the surgeon to retract the patient's skin. Tech 1 stated that she started counting the retractors from the patient to the table by visualizing the retractor and verbally counting out loud the number corresponding to that retractor. Tech 1 advised she counted 7 retractors. However, she explained that she verbally out loud said the number "8," assuming the eighth retractor was already inside the basket. Tech 1 stated, "I did not have a visual of the eighth retractor. I assumed the eighth retractor was inside or behind the basket." Tech 1 explained the basket is a metal wire container where the instruments are placed.</p> <p>During an interview, on 9/12/17 at 11:53 a.m. with</p>			

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	<p>the surgical services director (Admin 2), and concurrent review of the policy and procedure entitled, "Counting Surgical Items and Prevention of Retained Surgical Items," (last revised 8/5/14), Admin 2 acknowledged the surgical instruments counts for Patient 1's procedure on 5/20/17 were not performed as per the facility's policy and procedure. According to Admin 2, she was involved in a facility investigation of the incident pertaining to the retained foreign object inside Patient 1's abdomen. Admin 2 explained that facility investigation found the surgical team staff had not performed the instrument counts as mandated by facility policy and procedure. Admin 2 further explained the surgical instruments were not counted audibly nor viewed concurrently by the circulating nurse and the scrub technician. Admin 2 was asked if the two surgical staff had visualized the eighth retractor during the third count. Admin 2 confirmed the eighth retractor was not visualized by the two surgical staff. Admin 2 stated: "Yes, this is correct there was no visual of the eighth retractor."</p> <p>Further interview with Tech 1 occurred on 9/21/17 at 9:30 a.m. Tech 1 explained that the "Third" count during Patient 1's surgery occurred at the surgical suturing of the peritoneum (Lining in the stomach area). Tech 1 stated several distractions occurred during this part of the procedure. According to Tech 1, the primary surgeon dismissed the assistant surgeon at this point in the procedure. Tech 1 indicated she then assumed the role of assistant to the primary surgeon.</p> <p>Tech 1 described having to hold an instrument used</p>			

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	<p>to retract (hold back tissue) the wound with her right hand, while holding a needle holder (instrument used to hold the stitch) with her left hand in preparation for the surgeon's next step in the procedure. According to Tech 1, the attention to the surgeon's needs made it difficult for Tech 1 to visualize all of the retractors as counts were performed. When the circulating nurse (LN 1) named a countable item, Tech 1 explained she used her head to point to the countable item. Patient 1 began to cough. Tech 1 wasn't able to visibly see Patient 1, but according to Tech 1 it sounded as if Patient 1 had vomited. At this time, Tech 1 stated the surgeon asked for an instrument to hold back the wound (incision made to deliver baby) as Patient 1's body movement caused an interruption in the surgical suturing of the wound. Tech 1 handed the surgeon a ribbon malleable retractor.</p> <p>Tech 1 stated the "Third" count with the circulating nurse was a count for instruments only. Tech 1 explained when counting instruments out of her range of vision she (Tech 1) used her head to point in the direction of where the instruments were usually placed.</p> <p>Tech 1 also explained that the ribbon malleable retractor was usually placed inside or in the back of the basket (metal wire basket which contained the instruments). Tech 1 stated on the (third) count, she started counting the retractors with the one she was holding in her right hand to retract the skin and continued counting towards the back of the table. Tech 1 stated that she verbally counted out loud "1, 2, 3, 4, 5, 6, 7." Tech 1 also stated that she</p>			

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	<p>verbally said out loud the number "8." However, Tech 1 stated that she did not actually see the eighth retractor (ribbon malleable). Tech 1 acknowledged she had not visualized the eighth retractor (ribbon malleable) during the third count. Tech 1 stated, "I assumed the (ribbon malleable) retractor was behind or inside the basket in its usual place."</p> <p>During an interview with LN 1, on 8/12/17 at 10:45 a.m., she reviewed the "Delivery Report," dated 5/20/17 at 3:50 p.m. LN 1 confirmed there were two instrument counts. The initial count to establish an instrument count baseline and the third count at wound closure.</p> <p>LN 1 explained that during the third count in Patient 1's 5/20/17 surgery, LN 1 verbally called out, "retractors," and she thought Tech 1 verbally replied out loud the number "8." LN 1 also confirmed not visualizing the eighth retractor during the third count. LN 1 stated "I did not see the eighth retractor. We assumed 8 retractors were there. But clearly, the 8 retractors were not there. Since, there was a retractor left inside the patient (Patient 1)."</p> <p>Another interview was held with LN 1 on 9/21/17 at 1:20 p.m., LN 1 explained that during Patient 1's surgery dated 5/20/17, there were several distractions as the primary surgeon informed the assistant surgeon to leave. LN 1 stated the "Third" count with Tech 1 was the instrument count. LN 1 further explained the surgeon's phone rang several times during the third count process, before being</p>			

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050394	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  09/22/2017
NAME OF PROVIDER OR SUPPLIER  COMMUNITY MEMORIAL HOSPITAL - SAN BUENAVENTURA		STREET ADDRESS, CITY, STATE, ZIP CODE 147 N Brent St, Ventura, CA 93003-2809 VENTURA COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X6) COMPLETE DATE
	<p>answered by the anesthesiologist. LN 1 also stated Patient 1 had thrown up (vomited), which is why the surgeon requested the use of a ribbon malleable retractor.</p> <p>According to LN 1, Patient 1 was moving around a lot during the third count. The surgeon used the retractor to hold down and back Patient 1's tissues. LN 1 also confirmed she had not actually seen the 8th (ribbon malleable) retractor during the third instrument count. LN 1 stated she did not visualize the instrument basket to see if the malleable retractor was there. She remembered the instrument count being a correct count and there were no variances at the end of the case.</p> <p>During an interview with medical doctor MD 1 (the surgeon during Patient 1's surgery), on 9/12/17 at 12:05 p.m., he explained that during Patient 1's surgical procedure on 5/20/17, Patient 1 started vomiting. MD 1 stated, "It was hard to close the stomach incision when the intestines are outside the patient's stomach. I used a (ribbon) malleable retractor to push the bowels in before I closed the patient's stomach incision." MD 1 stated not remembering removing the malleable retractor during wound closure. MD 1 stated, "I don't remember. Obviously I didn't remove it (ribbon malleable retractor). Since, it was left inside the patient. We lost sight, clearly, it was our error."</p> <p>The "Surgical Case Record," dated 6/18/17 at 2:44 p.m., documented that Patient 1 underwent an exploratory laparotomy procedure (surgical operation where the abdomen is opened and the</p>			

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 LICENSING & CERTIFICATION  
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 2019 JAN 16 PM 12:27

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050394	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  09/22/2017
NAME OF PROVIDER OR SUPPLIER <b>COMMUNITY MEMORIAL HOSPITAL - SAN BUENAVENTURA</b>		STREET ADDRESS, CITY, STATE, ZIP CODE 147 N Brent St, Ventura, CA 93003-2809 VENTURA COUNTY		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	<p>abdominal organs examined for injury or disease), and removal of retained instrument under the use of general anesthesia (medically induced coma with drugs rendering a patient unresponsive and unconscious) to remove the retained ribbon malleable retractor. This procedure occurred, 29 days after Patient 1's original surgery.</p> <p>The failure of the facility staff to follow the facility's policies and procedures, pertaining to counting and accounting for any and all items entering the patient during a surgical procedure, and ensuring the items came back out of the patient, resulted in the retention of a ribbon malleable retractor in Patient 1. As a result, Patient 1 underwent a second surgical procedure, under general anesthesia, 29 days after the original surgery to remove the ribbon malleable retractor. This failure is a regulatory violation that has caused, or is likely to cause, serious injury or death to the patient.</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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