POC ACCEPTABLE
YES ☑ NO ☐
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Name: [signature]
Date: 4/11/18
Time: [handwritten]
Notified By: [signature] Name

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050568	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED 3/1/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MADERA COMMUNITY HOSPITAL	1250 EAST ALMOND AVENUE MADERA, CA 93637-5606 MADERA COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit:		Issue: The hospital failed to prevent a surgery on the wrong side of the body, which led to an unnecessary surgery for the patient and the possibility of the cancer spreading to other parts of the patient's body.	
	Complaint Intake Number: CA00501908 – Substantiated			
	Representing the Department of Public Health: Surveyor ID #3016		Once the hospital was made aware of the potential wrong side surgery by the insurance carrier (IC) on 9/6/16, a full evaluation of the case, establishment of a timeline and determination of a corrective action plan was completed. This documentation is available on-site for review. The incident, the analysis and corrective action plan was reported to the Department of Surgery Medical Staff committee and the hospital Board of Trustees (appendices A, B, C).	9/8/16 10/6/16 9/14/16
	The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.		Responsible party: Chief Executive Officer, Chief Operating Officer, Director of Surgical Services.	
	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.		Changes were made to the pre-operative processes utilized in the Pre-operative Holding Area to include:	
	DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY		1. Documentation of the agreement of the surgery schedule and the physician order. If the two items did not agree, the RN is responsible for contacting the MD and resolving the issue prior to the patient being taken to OR. The RN would document the resolution on the pre-operative checklist. The "Pre-Operative Checklist" policy was updated to reflect this process. (Appendices D & E)	9/2016
	T22 DIV 5 Section 70223 (b) (2) and (d) 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. (d) Prior to commencing surgery the person responsible for administering anesthesia, or the surgeon if a general anesthetic is not to be administered, shall verify the patient's identity, the		2. Any records from pre-operative testing including records sent in an envelope from the correctional facility will be received in the pre-operative holding area and sent with the patient to OR. The "Pre-Operative Checklist" Policy was updated to reflect this process. (Appendix E)	9/2016

Event ID:626Z11 3/9/2018 10:07:20AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE [signature: Jane Wenning] TITLE VP Chief Nursing Officer (X6) DATE 4/12/18

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.

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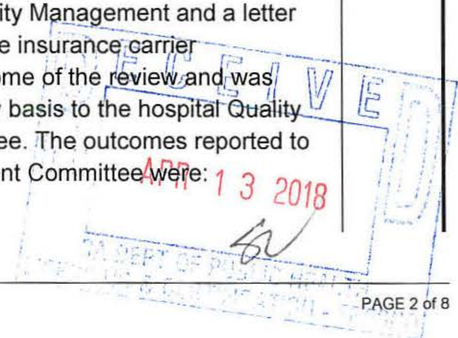
	site and side of the body to be operated on, and ascertain that a record of the following appears in the patient's medical record: (2) Appropriate screening tests, based on the needs of the patient, accomplished and recorded within 72 hours prior to surgery (3) An informed consent, in writing, for the contemplated surgical procedure.		3. Patient confirmation of laterality of surgery site will be confirmed by the patient initialing the "side" (either left or right) on the "Authorization/Consent to Surgery or Diagnostic/Therapeutic Procedure" form. This is in addition to the site marking that is completed. The "Consents for Surgery and Procedures" policy was updated to reflect this process (Appendix F).	9/2016
	Based on interviews, clinical record and administrative document review, the hospital (Hospital A) failed to verify the correct body site to be operated on when Medical Doctor (MD) 2 performed a right hemicolectomy (removal of the right side of the large intestine or colon) instead of the correct left hemicolectomy. MD 2 did not review the colonoscopy (A procedure using a long, flexible tube with a light and tiny camera on one end to look inside the rectum and colon) for Patient (Pt) 1 prior to surgery; the colonoscopy for Pt 1 indicated a large tumor mass in the left colon. MD 2 failed to review the clinical record for Pt 1 that indicated how the left colon cancer was identified and where the colon cancer was located. MD 2 failed to clarify prior to surgery the scheduled surgery procedure with the reason for surgery (the scheduled surgery site did not match the site of the cancer).		Education was provided by the Director of Surgical Services on all changes listed during huddles and 1:1 for staff not in attendance. Education & Training record attached (Appendix J) Responsible Party: Director of Surgical Services, Informatics Staff (changes to the electronic record) Ongoing monitoring of the system changes was completed starting in October 2016 and submitted to the insurance carrier for the CF through December 2017 and the hospital's Quality Improvement Committee quarterly.	9/27/16
	These failures resulted in an unnecessary surgery and removal of a portion of Pt 1's right colon; a delay of nearly nine months (from 4/26/16 to 1/13/17) in removal of the cancer; and the possibility of the cancer metastasizing or spreading to other sites in the body.		The first quality review undertaken was the verification of the same surgical procedure on the surgical schedule and the physician orders (Numerator: Number of patients with documented verification of same surgical procedure on Surgical Schedule and Physician orders; Denominator: Number of total cases reviewed). Twenty cases per month which were randomized per type of surgery and physician were reviewed by the Director of Surgical Services. The goal was 100% compliance and the goal was met in all months except 1, where 98% compliance was achieved. This was a documentation issue that never reached the patient. There was re-education provided to the staff involved in that case by the Director of Surgical Services. A secondary review was performed by the Director of Quality Management and a letter was sent monthly to the insurance carrier documenting the outcome of the review and was reported on a quarterly basis to the hospital Quality Improvement Committee. The outcomes reported to the Quality Improvement Committee were:	Formal Reports to Ins Co. 12/2017, Internal reports 6/2018



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Findings:

Pt 1's clinical record titled, "Colonoscopy Report," dated 3/30/16, indicated a colonoscopy was performed at the Correctional Facility (CF), where Medical Doctor (MD) 1 found a cancerous tumor in the left colon 35 cm (centimeter, a unit of measure) from the anus. MD 1 requested a surgical consult (obtaining advice from a specialist) from Hospital A regarding the tumor.

Pt 1's clinical record document titled, "Operative Notes" dated 4/26/16, indicated MD 2 at Hospital A performed a right hemicolectomy for the removal of "right colon carcinoma [cancer]." Pt 1's clinical record document titled, "Surgical Pathology Consultation" dated 4/29/16 and signed by MD 4, a pathologist (MD specialist who examines tissue for evidence of cancerous cells), indicated a specimen of the colon removed during Pt 1's right hemicolectomy on 4/26/16 showed "no evidence of malignancy."

Pt 1's clinical record titled, "Colonoscopy Report" dated 9/1/16, indicated, Pt 1 had a follow up colonoscopy performed by MD 1 at the CF. The report indicated that Pt 1 had a tumor 35 cm from the anus.

Pt 1's clinical record document titles, "Health Care Services Physician Request for Services" dated 9/1/16, indicated MD 1 wrote, "…Colon mass at 35 cm from (anus) persists!!??...Pt (patient) needs tumor REMOVED!..."

Q4 2016 (October –December): 59/60 98%

Q1 2017 (January – March): 60/60 100%

Q2 2017 (April – June): 60/60 100%

Q3 2017 (July – September): 60/60 100%

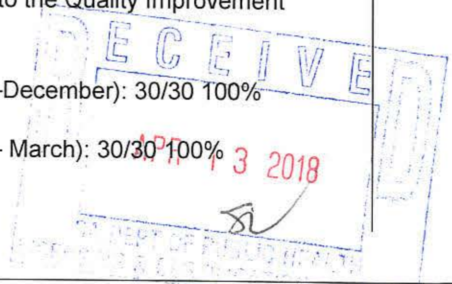
Q4 2017 (October – December): 60/60 100%

Formal reporting to the insurance carrier continued until December 2017 and internal hospital tracking and reporting will continue to June 2018. This indicator will be evaluated in June 2018 and if the goal has been met and sustained over the approximately 2 year period, the indicator will be discontinued. To ensure sustained process change, the Director of Surgical Services and the Director of Quality Management will perform an audit of random cases annually to ensure sustained process change. (Appendices G, H) — 12/2017; 6/2018

The second quality review was performed by an RN Quality Analyst and did 10 tracers per month to observe the Pre-Operative nursing staff complete the pre-operative checklist that documented the pre-operative verification of physician orders matching the surgical schedule and consent form with laterality of surgery initialed by the patient if applicable. The observations were conducted randomly based on day of week, time of day, surgeon, nursing staff member and surgery type. The goal was 100% compliance and the goal was met in all months. These reviews were reported to the Director of Surgery and sent monthly to the insurance carrier documenting the outcome of the review and was reported on a quarterly basis to the hospital Quality Improvement Committee. The outcomes reported to the Quality Improvement Committee were: — 12/2017

Q4 2016 (October –December): 30/30 100%

Q1 2017 (January – March): 30/30 100%



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Pt 1's clinical record titled, "...Surgical Consult" dated 11/17/16, indicated, MD 3 performed surgical consult on Pt 1 at Hospital B.

Pt 1's clinical record document titled, "Elective Surgery Service, Post-Operative Note" dated 1/13/17, indicated MD 3 performed a "Sigmoid Colectomy" (a surgery in which the last section of the colon is removed), the correct site, at Hospital B.

On 9/8/16 at 10:00 a.m., during an interview, MD 2 stated he read Pt 1's clinical record titled, "Health Care Services Physician Request for Services," dated 4/5/16, that indicated "PRINICIPAL DIAGNOSIS adenocarcinoma (a form of cancer) proximal (toward the center of the body) ascending (a path that goes upward) colon," which is anatomically (with respect to the body structure) on the right side of the body. MD 2 stated he read Pt 1's clinical record titled, "Health Care Services Physician Request for Services," dated 4/5/16, that indicated, "...REQUESTED SERVICE(S) G. (general) surgery consult for L(left) Hemicolectomy." MD 2 stated he read the requested service asking for a left hemicolectomy, but according to the principal diagnosis, the cancerous growth would be on the right side. MD 2 stated, during the procedure, when he removed the right intestines, there was a definite scar from where a polyp (a small clump of cells that forms on the lining of the colon) was removed. He said he thought the tumor was removed, since the sampled tissue (portion of tissue from the suspicious are to determine the presence or extent of disease) came back negative

Q2 2017 (April – June): 30/30 100%

Q3 2017 (July – September): 30/30 100%

Q4 2017 (October – December): 30/30 100%

Formal reporting to the insurance carrier and Quality Improvement Committee continued until December 2017. This indicator was discontinued since the goal will be met and sustained over the approximately a year period. To ensure sustained process change, the Director of Surgical Services and the Director of Quality Management will perform an audit of random cases annually to ensure sustained process change. (Appendix I)

Responsible Party: Director of Surgical Services, Director of Quality Management & Quality Analyst

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for cancer.

On 2/2/17 at 11:25 a.m., during an interview, MD 2 stated he did not review the report of Pt 1's colonoscopy performed at the CF on 3/30/16. He stated, "I do not recall ever requested the colonoscopy report." MD 2 stated that he usually reviews his patient's reports prior to surgery. He stated, "The [CF] brought them [the colonoscopy report] on the day of surgery. I did not review them." MD 2 stated that if he had reviewed the colonoscopy report prior to the surgery for Pt 1, the operation would have been performed on the correct site. MD 2 stated that the report indicated exactly where the tumor was located.

On 2/2/17 at 12:00 p.m., during an interview, the Chief Nursing Officer (CNO) at Hospital A stated Pt 1 came in the day for surgery (4/26/16) with a manila envelope carrying supporting documentation for the patient's procedure. CNO stated she was unaware if anyone reviewed the documents in the manila envelope, but the colonoscopy report was included.

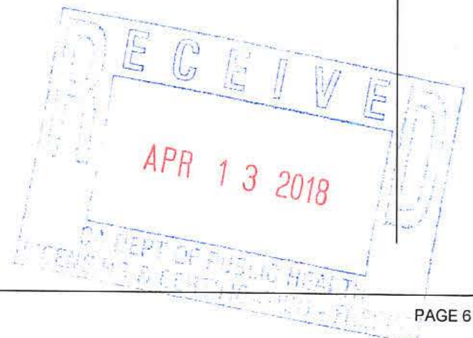
On 2/2/17 at 12:31 p.m., during an interview, the Surgery Scheduler (SS) (clerical person who prepares the facility's surgical schedule) stated the CF schedules surgeries for their patient's with Hospital A by faxing over a "Health Care Services Physician Request for Services" form. SS stated Pt 1's clinical record titled, "Physician Request for Services," dated 4/19/16, indicated MD 5 from the CF requested Pt 1 to have "L Hemicolectomy" scheduled on 4/26/16 at 6:00 a.m. Pt 1's clinical record titled, "[Hospital A] SCH [schedule]

OPERATING LIST From Date 4/26/16 thur [Thursday] Date 4/26/16, dated 4/26/16 indicated, "Pt 1]...Proposed Procedures LAPAROSCOPIC (surgical procedures done that are minimally invasive and use thin instruments along with a video camera) LT (left) HEMICOLECTOMY...Reason for Visit: RT (right) COLON CA (cancer)."

On 2/5/17 at 12:59 p.m., during an interview, MD 3 from Hospital B stated, "I believe the (colonoscopy) report was very clear because it said the growth (tumor) was 35 cm from the sigmoid colon [part of the large intestine that is closest to the rectum and anus]." MD 3 stated, if he saw two different diagnoses on the request form from the CF, he would have called to request more information or have talked to MD 1.

On 3/6/17 at 1:22 p.m., during an interview, the Director of Surgery (DOS) at Hospital A stated the expectation of all surgeons working under his direction is to clarify any discrepancies in question prior to performing surgery.

On 3/7/17 at 8:34 a.m., during an interview, the Admitting Specialist (AS) stated the Admitting Office (Admitting) confirms the surgical procedure with the doctor's order, the schedule and the patient. She stated Admitting confirms that pre-surgical tests are completed and information has been received prior to the scheduled surgery. AS stated, for patients who come from CF, all lab work and information are gathered the day of surgery by the pre-operative nurses, along with confirmation of the surgical procedure.



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On 3/8/17 at 9:00 a.m., during an interview, MD 2 stated the standard of practice is to review the colonoscopy report prior to surgery and to contact the gastroenterologist (physician who specializes in diagnosing and treating diseases of the digestive tract, from the mouth to the anus) prior to surgery, if there are any questions.

Pt 1's clinical record document titled, "AUTHORIZATION/CONSENT TO SURGERY Or Diagnostic/Therapeutic Procedure" dated 4/26/16, indicated Pt 1's procedure to be "Laparoscopic Assisted Right Hemicolectomy"

Pt 1's clinical record document titled, "Surgical Case Record" dated 4/26/16, indicated, "...Procedures: Proposed Procedures LAPAROSCOPIC LT (left) HEMICOLECTOMY. Actual Procedures LAPAROSCOPIC RT (right) HEMICOLECTOMY."

Hospital A's "Medical Staff Rules & Regulations" dated 8/25/16, indicated "ARTICLE V: Consultants...A satisfactory consultation includes examination of the patient and the medical record...The dictated or handwritten consultant reports must contain at least the following elements: 1. Review of history and medical record, 2. Summary of physical findings 3. Diagnostic impression 4. Recommendations for treatment. A written opinion signed by the consultant must be included in the patient's medical record immediately after the consultation has been performed...When operative procedures are involved, consultations

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	performed before surgery shall be reported before the operation…It is the responsibility of the consulting physician to communicate with the primary physician before taking any action." The hospital failed to follow its rules and regulations regarding review of pertinent diagnostic reports prior to surgery, which led to Pt 1 having a right hemicolectomy instead of a left hemicolectomy, the potential harm of unnecessary surgery, and the possibility of the cancer spreading to other parts of the body. The hospital's failure to prevent the deficiency as described above led to the licensee's non-compliance with one or more requirements of licensure, Title 22, DIV 5, Section 70223 (d) (2) (3) and Health & Safety Code 1280.3 (g) and constitutes an Immediate Jeopardy Administrative Penalty. 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 & Safety Code Section 1280.3(g).			