

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050300	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/23/2010
NAME OF PROVIDER OR SUPPLIER ST. MARY MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 18300 Us Highway 18, Apple Valley, CA 92307-2206 SAN BERNARDINO 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: CA00228810 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25179, 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 1280.1(c): 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>REGULATION VIOLATION: California Code of Regulations, Title 22, sections 70203 Medical Service General Requirements and 70703 Organized Medical Staff</p> <p>70203(a)(2): (a) A committee of the medical staff shall be assigned responsibility for: (2) Developing, maintaining and implementing 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>INITIAL COMMENTS: St. Mary Medical Center (SMMC) promotes personal and professional development, accountability, innovation, teamwork, and a commitment to quality (SMMC Core Value of Excellence). SMMC is committed to adhering to the requirements of the Medicare Conditions of Participation and all other relevant Federal and State laws. This document is submitted as evidence of correction of the deficiencies identified during the investigation of an entity reported incident, following a full validation survey completed on June 23, 2010.</p> <p>Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. The Plan of Correction is prepared and executed solely because it is required by provisions of federal and state law. None of the actions taken by SMMC pursuant to its Plan of Correction should be considered an admission that a deficiency existed or that additional measures should have been in place at the time of the survey. The provider submits this Plan of Correction with the intention that it is inadmissible by any third party in any civil or criminal action or proceedings against the Provider, its employees, agents, officers, directors, or shareholders. This Plan of Correction is submitted to meet requirements established by state and federal law.</p>	

Event ID: 8QNP11

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

TITLE

(X5) DATE

President - CEO

4/11/14

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.

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	<p>AND</p> <p>70703(a)(e):</p> <p>(a) Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the care rendered to patients.</p> <p>(e) The medical staff shall provide in its by-laws, rules and regulations for appropriate practices and procedures to be observed in the various departments of the hospital. In this connection the practice of division of fees, under any guise whatsoever, shall be prohibited and any such division of fees shall be cause for exclusion from the staff.</p> <p>Based on interview and document review, the facility failed to implement their policy and procedures in regards to the integration of the ED (Emergency Department) and radiology services. This deficient practice resulted in a miscommunication of an X-ray reading that lead to a delay in treatment of Patient 1 for over 30 hours. As a result Patient 1 suffered serious injury that consisted of the following: a hole in the bowels that allowed digestive contents to spill into the abdominal cavity causing acute respiratory failure, septic shock, acute peritonitis (inflammation of the lining of the abdomen), multiple intra-abdominal abscesses (pockets of infection), and extensive necroses (tissue death) of gastric (stomach) and surrounding tissue.</p> <p>FINDINGS:</p>		<p>70203(a)(2) Medical Services General Requirements and 70703 Organized Medical Staff - Continued</p> <p>The SMMC Governing Body Bylaws outline the responsibilities of the Board of Trustees (Board). The Board of Trustees requires that those responsible for each basic and supplemental medical services (Medical and Administrative) have policies and procedures approved by the Board, governing the overall quality and efficiency of patient care. The Board also requires the review and evaluation of activities to assess preserve and improve the quality and safety of patient care. Ongoing monitoring of patient care practices through the defined functions of the Medial Staff, and other services take place as well.</p> <p>CORRECTIVE ACTION(S) TAKEN:</p> <p>1. The Provision of Care/Emergency Department policy titled "Diagnostic Follow Up" was reviewed and revised to reflect clear communication between the Emergency Department and Imaging Services (Radiology).</p> <p>2. The following revisions were made to the Provision of Care/ Emergency Department policy titled "Diagnostic Follow Up" to ensure provider communication:</p> <ul style="list-style-type: none"> ❖ ED Providers will enter a preliminary report into the Picture Archive Communication Systems (PACS) on plain radiographic examinations that have not been previously reported by a radiologist in PACS. 	<p>09/22/10</p> <p>09/22/10</p>

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	<p>A review of the medical record on 6/22/10 (June 22, 2010) revealed that Patient 1 was a patient with advanced metastatic cancer. An ED record dated [REDACTED] 10 [REDACTED] 2010, timed 3:38 AM, indicated the patient presented to the ED with abdominal pain. Patient 1 also complained of nausea and was evaluated by a physician in the ED and given Dilaudid (a strong pain medicine) and Intravenous (IV) fluid hydration. Various tests were done, including blood chemistry, complete blood count (CBC), an ultrasound of her gallbladder and a 3 view series of X-rays of her abdomen. The ED physician's record documented that abdominal X-rays were normal ("nI" was checked) and the ultrasound of her gallbladder revealed the patient had gallstones. The patient was discharged at 6:40 AM, feeling somewhat better, to follow-up with her physician in 1-2 days.</p> <p>The "Imaging Report" for the abdominal series of X-rays was interpreted by Radiologist Physician A at 11:16 AM on [REDACTED] 10 [REDACTED] 2010). The first paragraph of the report showed "Gas is identified underneath the right hemidiaphragm (right half of diaphragm muscle) consistent with free intraperitoneal gas. (Gas in the abdominal cavity, not inside any of the organs) If the patient has not had a recent surgical procedure, perforated viscus (rupture of stomach or intestine) should be considered."However, notwithstanding this notation, there was lacking any documentation in the medical record that the radiologist had conferred with the ED physician regarding the perforation.</p> <p>Patient 1 returned to the ED on [REDACTED] 10 [REDACTED]</p>		<p>70203(a)(2) Medical Services General Requirements and 70703 Organized Medical Staff – Continued</p> <ul style="list-style-type: none"> ❖ At the time of final interpretation by the radiologist: <ul style="list-style-type: none"> (a) If the ED provider fails to enter an interpretation note in PACS and the radiologist's interpretation of the examination is unremarkable, the radiologist will save the examination in the PACS "No Note" folder. (b) If the ED provider fails to enter an interpretation note in PACS and the radiologist interpretation of the examination is an abnormal finding requiring a clinical follow up, the radiologist will save the exam in the PACS "Variance" folder. (c) If discrepancy exists between the ED provider's interpretation and the radiologist's interpretation, the radiologist will save the examination in the "Variance" folder for clinical follow up by the designated ED provider. (d) All critical values interpreted by radiologist will be called to the ED provider and documented as defined by the SMMC Critical Values policy. (e) Radiologists are available at all times, twenty-four hours a day, for consultation and discussion of exams. 	

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	<p>2010) for a second visit. The medical record for this second visit by Patient 1 was reviewed. The visit occurred on [REDACTED] 10 [REDACTED] 2010) at 8:12 AM approximately one and half hours since the patient's initial discharge from the ED. The chief complaint of Patient 1 was chest pain. A different ED provider evaluated the patient on this second visit, had her take antacids and pain medication. A ventilation/perfusion scan was performed. This was a test administered to identify pulmonary embolism (large blood clots in the arteries of the lungs). This test was negative. Several other tests were performed. However, there was no evidence that the X-rays from the previous visit were reviewed or that the ED physician ever conferred with the Radiologist regarding the notation on the interpretation for the abdominal X-ray of the perforation. The patient was discharged at 2:00 PM.</p> <p>The third ED visit by Patient 1 occurred on [REDACTED] 10 [REDACTED] 2010) at 12:58 PM (23 hours after discharge from the second ED visit). This medical record was reviewed. The medical record revealed that Patient 1 arrived by ambulance. The chief complaint was pain in the right upper part of the abdomen. She had visited her primary doctor, and fainted in his office. She had a low blood pressure, was diaphoretic (cold sweat). Her blood pressure continued to drop in spite of multiple therapeutic measures, suggesting the patient was in shock. The ED physician's examination showed her to have a diffusely tender abdomen. Under the X-ray section of the record was the entry "CT Ap-perf viscus, met breast." (Computerized tomography scan, to rule out appendicitis, a perforated viscus</p>		<p>70203(a)(2) Medical Services General Requirements and 70703 Organized Medical Staff – Continued</p> <p>3. The "Interpretation of Emergency Room Films by Imaging Services" policy was deleted to establish one policy ("Diagnostic Follow-up") for integration of department communication between Imaging Services (Radiology) and the Emergency Department.</p> <p>4. A list of Radiological Exams that are deemed "critical values" is posted at each radiologist's work station as a reminder of situations requiring them to call the results to the Emergency Department Provider with documentation of such.</p> <p>5. A memorandum from the Radiology Department Chief was distributed to all radiologists in regards to critical value reporting and communication between Radiology and the Emergency Department physicians when indicated.</p> <p>6. A memorandum from the Emergency Department Medical Director was distributed to all Emergency Department Providers notifying them of policy changes and expectations of the Radiographic Discrepancy Procedure in anticipation of the revised Provision of Care/Emergency Department policy titled "Diagnostic Follow-up."</p>	<p>09/22/10</p> <p>09/22/10</p> <p>09/22/10</p> <p>06/01/10</p>

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	<p>seen and suspected due to metastatic breast cancer.) An urgent surgeon consultation was conducted and Patient 1 was taken to the operating room for emergency surgery at 8:00 PM for an exploratory laparotomy (surgery to visualize the structures in the abdomen), and a repair of perforated gastric ulcer.</p> <p>A History and Physical report, dictated by Physician E on [REDACTED] 10 [REDACTED] 2010), was reviewed. The medical record indicated that Patient 1 was admitted into the ICU after the emergency surgery. In the assessment area, the following diagnoses were listed: acute respiratory failure, status post exploratory laparotomy, septic shock, acute peritonitis (inflammation of the lining of the abdomen), multiple intra-abdominal abscesses (pockets of infection), ruptured duodenal ulcer, and extensive necroses (tissue death) of gastric and surrounding tissue.</p> <p>A Consultation Note dated [REDACTED] 10 [REDACTED] 2010) dictated by Physician F, explained that prior to her anticipated discharge after the first surgery, a subsequent gastrografen study (a procedure where radio-opaque material is introduced into the stomach and watched on X-ray to detect leaks) showed there was still leakage from the area of rupture and tumor. Patient 1 underwent a second exploratory laparotomy (no date of the surgery in the note) and had an antrectomy (removal of the lower end of the stomach) and gastrojejunostomy (removal of duodenum, the first part of the intestine, and making an opening in the abdominal wall to attach the lower stomach and second part of the</p>		<p>70203(a)(2) Medical Services General Requirements and 70703 Organized Medical Staff – Continued</p> <p>7. Emergency Department Providers and Radiologists were educated on the Provision of Care/Emergency Department policy titled "Diagnostic Follow Up". An attestation was completed by each Emergency Department Provider and Radiologist ensuring that they received, reviewed, and understood the policy.</p> <p>8. Director of Emergency Department and Imaging Services Department or their designee review variances and critical result folders weekly to ensure appropriate medical follow up is completed and documented accordingly.</p> <p>Quality Assurance Performance Improvement (QAPI) Monitoring Process: The Director of the Emergency Department and the Director of Imaging Services or designee are currently monitoring the following Performance Improvement indicators on a monthly basis:</p> <ol style="list-style-type: none"> 1. The number of radiology exams interpreted by the Emergency Department Providers with notes in PACS. 2. Number of calls made by Radiologist to Licensed providers regarding critical results. 3. The Variance folder is reviewed daily by a designated Emergency Department provider to ensure care and treatment is appropriate and appropriate action will be taken if indicated. 	<p>10/31/10</p> <p>11/01/10</p> <p>01/31/11</p> <p>01/31/11</p> <p>01/31/11</p>

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	<p>intestine to the opening for drainage).</p> <p>The Discharge Summary stated the admission date as [REDACTED] 10 [REDACTED] 2010) and the discharge date as [REDACTED] 10 [REDACTED] 2010) (slightly more than 4 weeks).</p> <p>The radiologist (Physician A) who interpreted the abdominal X- ray of Patient 1 from [REDACTED] 10 [REDACTED] 2010) X-ray and the acting ED Medical Director for the facility (Physician B) were interviewed on 6/22/10 (June 22, 2010) at 2:55 PM. Physician A and B both reviewed the abdominal X-ray for Patient 1 from [REDACTED] 10 [REDACTED] 2010) at the time of their interview and expressed in the affirmative that an emergency physician should have identified the free gas (gas or air present in the abdominal cavity, but not in any of the organs) below the right diaphragm on the X-ray. Physician A stated that he interpreted the film just a few hours after the patient was discharged from the first ED visit. Physician A had assumed (incorrectly) that the treating physicians knew about the free air since he had thought the patient was being admitted. He stated that he should have called the ED physician with this finding. He was questioned about why he had not reported the abnormal X-ray results to the ED. He stated that he did not report the X-ray findings since he had believed the patient was being admitted. Physician A stated that he should have called the ED physician with this interpretation. Physician A was questioned about other causes of free gas or air in the abdomen. He stated, unless there had been a recent surgery, free gas or air in the abdomen is almost always indicative of a ruptured</p>		<p>70203(a)(2) Medical Services General Requirements and 70703 Organized Medical Staff – Continued</p> <p>The Performance Improvement indicators will be monitored for three (3) consecutive months or until goal is achieved. Thereafter, Performance Improvement indicators will be monitored on a periodic basis to ensure ongoing compliance.</p> <p>Reporting Process: The outcome of these audits will be presented to the Performance Improvement Advisory Committee (PIAC) on a regularly scheduled basis as part of the hospital wide Quality Assurance Performance Improvement (QAPI) program. The PIAC reports to the Quality Committee of the Board (QCB), Medical Executive Committee (MEC) and the Board of Trustees (BOT).</p> <p>Responsible Person(s):</p> <ul style="list-style-type: none"> • Chief Executive Officer (CEO) • Chief Operating Officer (COO) • Vice President Medical Affairs (VPMA) • Chief Nursing Officer (CNO) • Director of Emergency Department • Director of Imaging Services • Chief Radiology Department • Emergency Department Medical Director 	

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	<p>viscus (hole or rip in the stomach or intestines).</p> <p>Physician C, the surgeon that performed the procedure to repair Patient 1's rupture, was interviewed on 6/23/10 (June 23, 2010) at 8:15 AM. He first saw Patient 1 at her third ED visit. At that time, Patient 1 was in septic shock (a condition in which the body was overwhelmed with an infection to the point that the patient developed shock). Physician C stated that Patient 1 was "a candidate for immediate surgery." When Physician C opened Patient 1's abdomen, he found a leak in the area where the duodenum (the first part of the small intestine) connects with the stomach. He repaired the hole. Post-operatively, she had a persistent leak of intestinal contents into the abdomen and was taken for a second surgery. Physician C stated that he removed the area of stomach and duodenum. Physician C stated that the pathology revealed that the ruptured area had been infiltrated by the patient's cancer, in both the stomach and the duodenum. He was asked about how the delay in performing surgery to repair the rupture, between the time of the first ED visit and the time of the third ED visit when Patient 1 presented in septic shock and the leak was diagnosed, affected Patient 1. He stated, "Every hour makes a difference," (in preventing the complications of septic shock, additional pain and the delay in treating the patient's cancer).</p> <p>The Medical Director of the ED (Physician B) was interviewed 6/23/10 (June 23, 2010) at 10:12 AM. He was asked about when the error in the reading of the abdominal X-ray was recognized. He</p>			

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	<p>answered that the discovery of the error in reading the abdominal X-ray did not occur until Patient 1's third visit to the ED. The X-ray was reread by the treating physician in the ED and the diagnosis of a ruptured viscus was made.</p> <p>The ED Physician was the Emergency Medical Physician that cared for Patient 1 during the first ED visit on [REDACTED] 10 [REDACTED] 2010. She was interviewed by phone on 6/23/10 (June 23, 2010). She recalled treating Patient 1, but not the specific X-ray. She stated that she thought she might have been rushed during Patient 1's treatment and therefore missed the finding of free intraperitoneal (inside the abdominal cavity) gas.</p> <p>The facility policy and procedure entitled "Verbal/Telephone Orders/Critical Test Results" with an effective date of 5/2009 (May 2009) for all patient care areas, hospital wide, noted the following under the section titled "Critical Test Results:"</p> <p>"Critical test results include all diagnostic tests and studies that require an urgent response. If the ordering physician is unavailable, the results are called to the physician covering. If this physician is not available, the House Shift Supervisor or the Medical Staff Director is to be contacted. Critical test results are not limited to Laboratory results and will include, but not limited to all diagnostic tests including imaging studies, electrocardiograms, laboratory tests, etc."</p> <p>The facility policy and procedure entitled "Interpretation of Emergency Room Films By</p>			

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	<p>Imaging Services" with an effective date of 7/2009 (July 2009), noted the following:</p> <p>"1. All exams obtained in the Emergency Room during working hours are formally interpreted by the radiologist the same day of the examination...3. Preliminary interpretations are provided for all ER exams by ER physicians; those are checked by radiologists at time of formal interpretation for variances. Variances are stamped as "VARIANCE" and a copy of the Radiologist's preliminary faxed to the ER for clinical follow-up..."</p> <p>The facility policy and procedure entitled "Diagnostic Follow Up" with a revision date of 1/2009 (January 2009), noted the following under the "Policy" section:</p> <p>"B. The Emergency Department physician is to read x-rays obtained during the course of the patient visit in the department. The films are then to be read by the Radiologist, to validate the findings. C. Upon identification of any variance, the Radiologist is to notify the Emergency Department."</p> <p>The facility's failure to ensure that their policies and procedures were followed regarding the treatment and care of Patient 1 as well as the delayed reporting of an abdominal X-ray reading is a deficiency that 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 1280.1.</p>			

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