

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 060300	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/08/2010
NAME OF PROVIDER OR SUPPLIER St. Mary Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 18300 Us Highway 18, Apple Valley, CA 92307-2208 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: CA00224633 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 16499, 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. Title 22 70223 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>Based on interview and record review, the facility</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 for entity reported incident number CA00224633 during the investigation which was completed on April 8, 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>	

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE President - CBZ TITLE (X5) DATE 5/21/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 4

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>failed to follow their Policy and Procedure for Surgical Fire Prevention, and failed to ensure Patient A's safety during a surgical procedure on the patient's face.</p> <p>FINDINGS: Patient A received 1st and deep 2nd degree burns on the face and upper lip on [REDACTED] 2010, when the physician engaged the Bovie cautery (a device used for burning and/or cutting the skin or other tissues by means of heat and electric current) while the patient was receiving oxygen via cannula (a tube) into the mouth, causing a flash fire on the patient's right cheek and upper lip.</p> <p>During an interview with the Operating Room (OR) manager, on April 7, 2010 at 9:30 AM, she stated she was not in the OR for the procedure, and when she and the Risk Manager got there, the patient was already bandaged and treated. No pictures were taken. The surgical staff told them that as soon as the Bovie engaged, there was a flash fire.</p> <p>During an interview with the Risk Manager, on April 7, 2010 at 9:20 AM, she stated that the Bovie machine was taken out of service and checked by Biomedical maintenance staff on [REDACTED] 2010. The machine checked out with no problems noted. She also stated that Biomed had previously checked the machine in January, 2010 and it checked out with no problems noted then. She stated, "The physician did not let the anesthesiologist know that he was going to engage the Bovie". She also stated that the "Surgical Fires, Prevention OP" Policy and Procedure (P&P)</p>		<p>TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS: SMMC has an effective governing body legally responsible for the conduct of the hospital as an institution and ensures that medical staff are held responsible for maintaining quality provided to patients, ensures that Quality Assurance Performance Improvement (QAPI) programs focuses on prevention of surgical errors, and ensures that surgical care services are achieved at the highest standards of medical practice and patient care. SMMC has established policies and procedures to prevent surgical fires, specifically the Policy and Procedure titled "Surgical Fires, Prevention of" effective March 24, 2010.</p> <p>The following plan of correction details the actions undertaken by SMMC to correct each deficiency listed on the State 2587 and provides credible evidence of compliance to the SMMC Policy and Procedure titled "Surgical Fires, Prevention of" and to ensure patient safety.</p> <p>IMMEDIATE ACTION(S) TAKEN: Upon cauterization of the basal cell on the right side of the nose, a spark was noticed and then a flame around Patient "A"'s cheek (approximate size of a 1/2 dollar). Immediately, the surgeon instructed the anesthesiologist to turn off the O₂ (oxygen). The surgeon removed the nasal cannula, placed a wet sponge on the operating site, and the circulating RN pulled off all the drapes. The surgeon and anesthesiologist performed an assessment of the burned area.</p>	02/26/10	

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	<p>Instructs surgical staff to turn off the oxygen for 1 minute prior to engaging the Bovie. Surgical staff did not follow the facility P&P.</p> <p>Review of Patient A's clinical record on April 7, 2010, noted Patient A, a 58 year old female, had minor surgery on her nose to remove a basal cell carcinoma (skin cancer) on [REDACTED] 2010. Surgical notes showed a detailed timeline of the event, documenting that the anesthesiologist turned off the oxygen after the flame appeared, and the circulating nurse removed the sterile drapes</p> <p>During an interview with the plastic surgeon on 4/7/2010 at 1:40 PM, he stated that "he did the wound care himself for approximately 2 weeks". He also stated that the patient was "still applying ointment to an area about the size of the tip of an eraser". When asked if he had taken pictures, he stated " No, but the patient did, and she sent them to me".</p> <p>During an interview on 4/8/2010 at 2:40 PM, the anesthesiologist stated that in this case, "no warning was given that the Bovie was going to be used. The Bovie was not holstered, the physician picked it up and began using it ", without letting the surgical team know. The anesthesiologist stated that the surgical team did not follow the facility P&P.</p> <p>Review of the facility P&P titled "Surgical Fires, Prevention Of "dated May 2009, under Use of Electrocautery, noted. "stop supplemental oxygen at least one minute before and during use of the</p>		<p>TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS (Continued): Subsequently, Patient "A" was transferred from OR#1 to Post Anesthesia Care Unit (PACU). The surgeon and anesthesiologist notified the patient and family about the incident. Orders for Arterial Blood Gases (ABG) and Carbon Monoxide tests were ordered by anesthesiologist; carbon monoxide results were negative and Anesthesiologist immediately informed the patient and family members with results.</p> <p>On February 26, 2010, upon discovery of the event, SMNC Risk Management immediately initiated an investigation into this event in collaboration with the Surgical Services Leadership Team to ensure immediate processes were implemented for the safety of other patients that could be affected by the same outcome.</p> <p>On February 26, 2010, the Interim Perioperative Services Director initiated 1:1 verbal education to the Surgical Services staff members to raise awareness of the risk of surgical fires and to reinforce the policy and procedure titled "Surgical Fires, Prevention of". During this education, the staff members were made aware of the requirements when electro-cautery is used with an open oxygen delivery system to stop supplemental oxygen at least one minute before and during cautery use.</p> <p>On February 26, 2010, an immediate containment strategy was initiated to ensure the five (5) steps listed below are followed when electro-cautery is used with an open oxygen delivery system during cases that include head/neck surgeries:</p>	<p>02/26/10</p> <p>Initiated: 02/26/10 Completed: 03/10/10</p> <p>Initiated: 02/26/10 Completed: 03/10/10</p>

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	<p>unit, if possible "</p> <p>During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn". She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 X 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on [REDACTED] 2010 and [REDACTED] 2010, showing the deep 2nd degree burn.</p> <p>The facility's failure to prevent the surgical fire on the patient's face 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 1280.1(c)</p>		<p>TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS (Continued):</p> <ol style="list-style-type: none"> 1. The surgeon announces aloud to the anesthesiologist the intent to "energize the cautery". 2. The anesthesiologist will acknowledge and announce aloud "the oxygen is being turned off". 3. The anesthesiologist will give the surgeon notification when it is safe to proceed (i.e., after one minute of oxygen being turned off). 4. Thereafter, the surgeon will notify the anesthesiologist when finished with the cautery and, 5. The anesthesiologist will notify the surgeon and the OR nursing staff that oxygen has commenced. <p>On March 8, 2010, the Vice President of Medical Affairs (VPMA) referred the case involving Patient "A" to the Anesthesia Department and on March 17, 2010 to the Surgery Department for Peer Review for initial screening. The case was reviewed and final disposition obtained with a recommendation to follow up with a presentation to the Medical Executive Committee (MEC) during the next scheduled meeting on May 11, 2010.</p> <p>On March 20, 2010, the Interim Director of Perioperative Services Department reviewed and revised the Policy and Procedure titled "Surgical Fires, Prevention of" Revisions included "when electro-cautery is used with an open oxygen delivery system, to stop supplemental oxygen at least one minute before and during cautery use", to ensure this policy meets the guidelines from Association of Perioperative Registered Nurses (AORN) and American Society of Anesthesia (AOA).</p>	<p>03/08/10</p> <p>03/20/10</p>

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	<p>unit, if possible".</p> <p>During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn" She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 X 4 gauze pad, and you could see the swelling involved" The patient sent pictures taken on March 12, 2010 and April 8, 2010, showing the deep 2nd degree burn.</p> <p>The facility's failure to prevent the surgical fire on the patient's face 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 1280.1(c).</p>		<p>TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS (Continued): The revised policy was reviewed and approved by the Interim Director of Perioperative Services Department, Vice President/Chief Nursing Officer (VP/CNO), Senior Vice President/Chief Operating Officer (SVP/COO), Chief Executive Officer (CEO) on March 20, 2010. In addition, this policy was approved by the Medical Executive Committee (MEC) and Board of Trustees (BOT) as noted below:</p> <ol style="list-style-type: none"> 1. Medical Executive Committee 2. Board of Trustees <p>On May 11, 2010, the VPMA presented to the MEC the recommendations from the March 8, 2010 Anesthesia Department Peer Review for their review and approval as follows:</p> <ol style="list-style-type: none"> 1. Establish a clear communication process between surgeon and anesthesiologist 2. Surgeon must announce to the anesthesiologist and OR Team that he/she is ready to start engaging cautery unit (Bovie) for cases that include head/neck surgeries and require the delivery of supplemental oxygen. 3. Mandatory training for OR staff and Medical Staff in regards to the Policy and Procedure titled "Surgical Fires, Prevention of". <p>On May 4, 2010, the Chief of Surgery (COS) and Chief of Anesthesia (COA) developed and sent a memorandum to the anesthesiologists and surgeons including OB/GYN reinforcing the importance of implementing fire precautions in the OR setting.</p>	<p>03/23/10</p> <p>03/24/10</p> <p>05/11/10</p> <p>05/04/10</p>

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	<p>unit, if possible".</p> <p>During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn". She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 X 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on March 12, 2010 and April 9, 2010, showing the deep 2nd degree burn.</p> <p>The facility's failure to prevent the surgical fire on the patient's face 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 1280.1(c).</p>		<p>TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS (Continued): On May 4, 2010, the Anesthesiologist implemented a new process to demonstrate compliance with the established process which includes: After the surgeon communicates aloud to the anesthesiologist and OR Team that he/she is ready to start engaging the cautery unit, the anesthesiologist will also announce to the OR Team that he/she is going to stop the oxygen by documenting in the anesthesia record the time the oxygen was stopped.</p> <p>On May 18, 2010, the surgeon directly involved in the care of Patient "A" provided an in-service to the Surgery Department members present with regards to surgical fires in the OR. The members were apprised that they need to establish a clear communication process between the surgeon, anesthesiologist and OR staff present. In addition, a copy of the policy and procedure titled "Surgical Fires, Prevention of" was shared with the department members.</p> <p>On July 19, 2010, the Chief of Anesthesia, who was directly involved in the care of Patient "A", provided an in-service to the Anesthesia Department members present with regards to the recent case involving the use of "Bovie" in which a patient suffered a burn during the surgical procedure. The policy and procedure titled "Surgical Fires, Prevention of" was presented and every member was requested to adhere to such policy.</p>	<p>05/04/10</p> <p>05/18/10</p> <p>07/19/10</p>

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