Penalty # 240006904

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050300	A. BUILDING _____ B. WING _____	06/18/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. MARY MEDICAL CENTER	18300 Us Highway 18, Apple Valley, CA 92307-2206 SAN BERNARDINO 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
	The following reflects the findings of the Department of Public Health during a complaint/breach event visit: AMENDED Complaint Intake Number: CA00187117 - Substantiated Representing the Department of Public Health: Surveyor ID # 28502, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.15(b) A clinic, health facility, home health agency, or hospice licensed pursuant to Section 1204, 1250, 1725, or 1745 shall prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information, as defined in subdivision (g) of Section 56.05 of the Civil Code and consistent with Section 130203. The department, after investigation, may assess an administrative penalty for a violation of this section of up to twenty-five thousand dollars ($25,000) per patient whose medical information was unlawfully or without authorization accessed, used, or disclosed, and up to seventeen thousand five hundred dollars ($17,500) per subsequent occurrence of unlawful or unauthorized access, use, or disclosure of that patients' medical information.		**E000 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 on June 18, 2009. 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.	

Event ID: UT1011 12/2/2013 2:27:02PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
	President / CEO	3/11/2014

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 6

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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ST. MARY MEDICAL CENTER	18300 Us Highway 18, Apple Valley, CA 92307-2206 SAN BERNARDINO COUNTY

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	Based on interview and record review, the facility failed to maintain the privacy and confidentiality of Patient 1's electronic medical record when two (2) hospital employees inappropriately accessed the electronic medical record without Patient 1's authorization. This deficient practice had the potential for unauthorized individuals to use the disclosed information in a way not authorized by the patient, such as identity theft or other unauthorized use. On 5/12/09, a self reported facility incident was investigated regarding two (2) hospital employees breaching the electronic medical record of Patient 1. According to a facility letter to the California Department of Public Health received on 5/4/09 at 4:16 PM and the facility's investigative report both confirmed, that two (2) hospital employees, without any clinical reason, inappropriately accessed Patient 1's electronic medical record without authorization at 5:13 PM and at 5:15 PM on 4/30/09 and at 7:42 AM on 5/1/09. In an interview with the facility's Compliance Officer (CO) on 5/12/09, at approximately 9:20 AM, she confirmed the breaches and stated that the unauthorized access of Patient 1's electronic medical record was done by Staff Member A (C.T. tech.-Computerized Axial Tomography technologist) at 5:13 PM and at 5:15 PM on 4/30/09 and by Staff Member B (A Medical-Surgical Nurse) at 7:42 AM on 5/1/09. In addition, the Compliance Officer stated that when she routinely		**E1953 T22 DIV 5 CH1 ART7-70707(b)(8) PATIENTS' RIGHTS** St. Mary Medical Center patients' rights including the right to confidential treatment of all communications and records pertaining to the care and the stay in the hospital are posted in both Spanish and English in appropriate places within the hospital so that such rights may be read by patients and family members. Health Insurance Portability and Accountability Act (HIPAA) policies and procedures are in place to ensure the confidential treatment of all communication and records containing protected health information (PHI). **E1953 T22 DIV 5 CH1 ART7-70707(b)(8) PATIENTS' RIGHTS** The following immediate and ongoing steps were taken to address the plan of correction. **Immediate Action(s) Taken:** 1. Staff members received 1:1 verbal education on the need to know basis and the consequences from accessing Personal Health Information (PHI) when the patient is not assigned to his/her care. **Action(s) Taken:** 1. Employees involved in this event were counseled and received disciplinary actions after a thorough review of the facts surrounding the breach. The employees were suspended for three (3) days without pay. As it was determined by the Compliance Officer and Human Resources that both employees failed to follow SMMC confidentiality policy and procedures.	Initiated: 05/01/09 Completed: 06/05/09 Initiated: 05/06/09 Completed: 06/05/09

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	ran random monthly computor audits of all patients in the hospital she noted unusual activity on Patient 1's clinical record. The audits indicated that Staff Member A on 4/30/09 at 5:13 PM and at 5:15 PM had accessed Patient 1's clinical record without Patient 1's authorization. The Compliance Officer stated the incident was unusual because Patient 1 already had "expired" and there was no clinical reason for anyone to access Patient 1's medical record. The facility's Compliance Officer also stated that Staff Member B inappropriately accessed Patient 1's medical record without authorization and with no valid clinical reason to do so on 5/1/09, at 7:42 AM, because Patient 1 had already expired. A review on 6/18/09, of the facility's computerized "Patient Care Inquiry" audit sheet, dated 5/5/09, revealed that Staff Member A inappropriately accessed Patient 1's medical record twice from a computer terminal in the Radiology department on 4/30/09 at 5:13 PM, for 1 minute and 14 seconds and at 5:15 PM, for 2 minutes and 30 seconds. Documented evidence in the computerized "Patient Care Inquiry" audit report sheet revealed that Staff Member A was viewing the "Laboratory Results" section of Patient 1's electronic medical record during those times. During an interview with Staff Member A, on 6/22/09 at 1:10 PM, she stated that she accessed Patient 1's medical records because she wanted to know the signs and symptoms of the disease that Patient 1 had contracted that lead to his		**E1953 T22 DIV 5 CH1 ART7-70707(b)(8) PATIENTS' RIGHTS – Continued** 2. Managers educated their staff members in regards to HIPAA legal standards to protect patient's health information, unauthorized access and its consequences of not following the law during their staff meetings. 3. Employees involved in this incident completed the house-wide required HIPAA training, acknowledged the receipt and promised documents as proof that re-education was provided. 4. House-wide staff is required to attend New Employee Orientation (NEO) which covers HIPAA training and employees are required to sign a confidentiality agreement at time of hire and prior to starting work in his/her departments. 5. In addition, house-wide staff is required to complete SWANK module (web-based education module) on HIPAA during the re-orientation process, which occurs annually during the month of April. **Quality Assurance Performance Improvement (QAPI) Monitoring Process:** The Director of Health Information Services or designee conducted monthly audits of medical records for patients classified as confidential, having sensitive information or high-profile to designee to determine if there has been a HIPAA violation caused by an access breach.	Initiated: 05/07/09 Completed: 06/23/09 Initiated, 06/23/09 Completed: 07/15/09 Ongoing Ongoing Initiated: 02/01/10 Completed: 05/03/10

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ST. MARY MEDICAL CENTER	18300 Us Highway 18, Apple Valley, CA 92307-2200 SAN BERNARDINO COUNTY

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	hospitalization. In addition, she stated she accessed Patient 1's medical record only for her own education and personal reference because she had children of the same age group of Patient 1 and did not want to bring home any contaminants when exposed to other patients with the same diagnosis. She further confirmed that there was no clinical reason why she needed to access Patient 1's medical record other than for her personal reasons at 5:13 PM and at 6:15 PM on 4/30/09. A review on 6/18/09, of the facility's computerized "Patient Care Inquiry" audit sheet, dated 5/5/09, revealed that Staff Member B breached Patient 1's medical record from a computer terminal in the medical-surgical unit on 5/1/09 at 7:42 AM for 1 minute and 17 seconds. Documented evidence in the computerized "Patient Care Inquiry" audit report sheet revealed that Staff Member B was viewing the "Department Summary Reports, Radiology Reports, Microbiology Reports and Laboratory Results" of Patient 1's electronic medical record. During an interview with Staff Member B on 6/18/09 at 10:30 AM she stated she accessed Patient 1's medical records because she was curious about Patient 1's admitting diagnosis and wanted to know more about the signs and symptoms Patient 1 presented upon admission to the hospital. She also stated that she had children at home about the same age group of Patient 1 and wanted to know more information surrounding Patient 1's medical history to further her own knowledge. She stated that she needed to know the exact signs and symptoms of Patient 1 should her own children		**Quality Assurance Performance Improvement (QAPI) Monitoring Process - Continued:** The Director of Health Information Services or designee conducted monthly audits of medical records for patients classified as confidential, having sensitive information or high-profile to designee to determine if there has been a HIPAA violation caused by an access breach. The audit sample size consisted of thirty (30) medical records or 100% whichever was greater. The audit was monitored for three (3) consecutive months until goal was achieved with 100% compliance with no breaches **Reporting Process:** The outcome of this audit was presented to the Performance Improvement Advisory Committee (PIAC) on a regularly scheduled basis as part of the hospital wide Quality Assurance Performance Improvement program (QAPI) program. The PIAC reports to the Quality Committee of the Board (QCB), Medical Executive Committee (MEC) and the Board of Trustees (BOT). **Person(s) Responsible:** Chief Operating Officer, Chief Nursing Officer, Chief Financial Officer, Director of Patient Care Services, and Director of Imaging Services.	

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present with those same signs and symptoms in the future. In addition, Staff Member B confirmed that she had no valid clinical reason to access Patient 1's medical record other than for her own personal reasons.

A review on 6/18/09, of the facility's policy and procedure titled: "Confidentiality Agreement for ST Mary Medical Center Employees" dated 9/2006, documented that all employees would sign and agree to:
1. Not misuse, misappropriate, or, disclose any such information, directly or indirectly, to any person, or use such information in any way, either during the term of his/her employment, except as required in the course of his/her employment.
2. Shall not permit access to any such information to any person except as required in the course of his/her employment.
3. To abide by all state and federal law relevant to the confidentiality of patient identifiable health information including but not limited to HIPPA.
4. All employees acknowledge that unauthorized use or disclosure of patient identifiable health information regarding patients is illegal and could cause hospital to sustain significant and irreparable damage.

A review on 6/18/09, of the facility's policy and procedure titled: "HIPAA-Role Based Access Review and Update", dated 5/2003, revealed in section 8 (c), "...Staff may not gain access to information concerning patients, including both medical and enrollment information, except for legitimate clinical and business purposes."

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	(HIPAA-Health Insurance Portability and Accountability Act-requiring health professionals to maintain healthcare information of individuals private and to be held in confidence). During an interview with the facility's Compliance Officer, on 6/18/09, at 11:30 AM, she stated that unauthorized access of Patient 1's medical record by both Staff Member A and B were considered by the facility as being a "drift" from policy as explained in the facility's "The Just Culture Algorithm" model. The Compliance Officer also stated that both Staff Members A and B were suspended for three days without pay and received additional training in HIPPA regulations and attended a hospital wide in-service training in protecting patient confidential information. A review on 6/18/09, of Patient 1's clinical record, revealed that Patient 1 was admitted to the facility on [redacted]/09. There was no documented evidence that Patient 1 had signed a consent or had given authorization for release of medical information to Staff members A and B. Therefore, the facility failed to prevent unauthorized access to confidential medical record information and failed to safeguard Patient 1's medical record against use by unauthorized individuals.			