

11/12/14 ABC accepted - *Spahr & Vanessa Ritter* - JH


PRINTED: 10/02/2014
FORM APPROVED

California Department of Public Health

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070000149 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____ | (X3) DATE SURVEY COMPLETED C 08/26/2014 |
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| NAME OF PROVIDER OR SUPPLIER SANTA CLARA VALLEY MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128 |
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| (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 |
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| A 001 | <p>Informed Medical Breach</p> <p>Health and Safety Code Section 1280.15 (b)(2), " A clinic, health facility, agency, or hospice shall also report any unlawful or unauthorized access to, or use or disclosure of, a patient's medical information to the affected patient or the patient's representative at the last known address, no later than five business days after the unlawful or unauthorized access, use, or disclosure has been detected by the clinic, health facility, agency, or hospice."</p> <p>The CDPH verified that the facility informed the affected patient(s) or the patient's representative(s) of the unlawful or unauthorized access, use or disclosure of the patient's medical information.</p> | A 001 | <p>CALIFORNIA DEPARTMENT OF PUBLIC HEALTH</p> <p>NOV 07 2014</p> <p>L & C DIVISION SAN JOSE</p> | |
| A 000 | <p>Initial Comment</p> <p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident conducted from 8/20/14 to 8/28/14.</p> <p>For Entity Reported Incident CA00364764, regarding State Monitoring, Theft of Medical Record, one State deficiency was identified (see California Health and Safety Code, Section 1280.15(a)).</p> <p>Inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the hospital.</p> <p>Representing the California Department of Public Health: 32396, Health Facilities Evaluator Nurse.</p> | A 000 | | <p>Preparation and execution of this plan of correction does not constitute an admission or agreement of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared and executed solely because it is required by federal/state law. The following constitutes Santa Clara Valley Medical Center's credible allegation of compliance</p> |

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| Licensing and Certification Division LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|  | CEO | 11-6-14 |

11/2/14 DC accepted

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| A 000 | Continued From page 1 The hospital detected the Breach of Patient's Health Information (PHI) on 8/5/13. The hospital reported the Breach of PHI to the Department on 8/6/13. The hospital notified the patients of the Breach of PHI on 8/6/13. | A 000 | | |
| A 017 | 1280.15(a) Health & Safety Code 1280 (a) 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 CMI 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. For purposes of the investigation, the department shall consider the clinic's, health facility's, agency's, or hospice's history of compliance with this section and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring, and factors outside its control that restricted the facility's ability to comply with this section. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section. | A 017 | a. The Ethics & Compliance Officer sent the 17 patients a letter with notification of the breach. b. The Ethics & Compliance Officer met with the employee (MD A) whose briefcase was stolen from a locked car to discuss the privacy violation. The Compliance Officer and MD A developed a new process for MD A to obtain a copy of his patient schedule. MD A agreed to have a staff member scan and email or fax the document to his main office, thus eliminates the need to remove paperwork containing PHI off campus. c. The Ethics & Compliance Officer and the employee's supervisor, OB/GYN Department Chair, met and implemented corrective actions, including: 1. The OB/GYN Department Chair emailed all department staff reminding them of the importance of protecting PHI and providing examples of how to reasonably safeguard PHI. A copy of the email message is attached. | 8/6/2013 8/19/2013 8/20/2013 11/9/2013 |

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| A017 | <p>Continued From page 2</p> <p>This Statute is not met as evidenced by: Based on interview and record review, the hospital failed to prevent the theft of patient health information (PHI) for 17 of 17 sampled patients (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, and 17), when a briefcase containing PHI was stolen from a hospital physician's (MD A) locked car. The failure resulted in disclosure of 17 patients' PHI, to an unauthorized individual(s). Findings:</p> <p>The California Department of Public Health received a faxed report on 8/6/13, which indicated, on 8/6/13, MD A's car had been burglarized, and a briefcase was stolen which contained PHI for 17 patients. PHI disclosed included patients' names, ages, and diagnoses or reason for visit, clinic name, and appointment times.</p> <p>During an interview on 8/20/14 at 12:20 p.m., the ethics and compliance officer (ECO) stated MD A's car had been broken into on Friday 8/2/13, and his briefcase stolen. The briefcase contained a schedule book of his appointments, with the names, ages, and diagnoses or reason for visits for 17 hospital patients. ECO stated MD A did not file a police report, but on Monday, 8/5/13, reported the theft of the schedule book to the hospital affiliated clinic.</p> <p>During an interview on 8/26/14 at 09:15 a.m., MD A stated he went to an event from work, and placed his briefcase in the passenger compartment of his car. MD A stated his car was stationed in a parking lot and someone broke a car window to get in, and took the briefcase,</p> | A017 | <p>2. All staff members were required to confirm receipt and review of Department Chair's email. A copy of the staff training tracking log is attached.</p> <p>d. The Ethics & Compliance Office will review all thefts that were reported during a three-month period, from August through September 2014. Analysis will be conducted to confirm that any potential patient privacy issues have been appropriately addressed. Monitoring results will be reviewed at a convened monthly meeting of the Quality & Compliance Working Group, and additional corrective actions will be implemented as indicated.</p> | <p>11/21/2013</p> <p>12/9/2014</p> |

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| A 017 | <p>Continued From page 3</p> <p>which was not locked. MD A stated it was late at night when he returned to his car, and he needed to return home, so he did not call the police. MD A also stated he had been able to print another schedule for the 17 patients, which indicated patient names, dates and times to be seen, medical record numbers, and possibly the reason for the appointment, e.g., diabetes follow-up, but no social security numbers were disclosed.</p> <p>A review of a copy of a letter dated 8/6/13, from the hospital to the affected patients, indicated MD A had reported his briefcase had been stolen on 8/2/13. Inside the briefcase was a schedule book of the patients MD A was to see. The disclosed information included patient names, ages, diagnoses/reason for visit, clinic name, and appointment times.</p> <p>A review of a copy of an electronic schedule for MD A, indicated patient names, ages, diagnoses or reason for visit, clinic name, and date and time of appointment had been disclosed for 17 patients.</p> <p>A review of a copy of the hospital's 10/15/09 "Safeguarding Protected Health Information" policy indicated, files and documents containing PHI must be adequately safeguarded against unauthorized access and disclosure.</p> | A 017 | | |