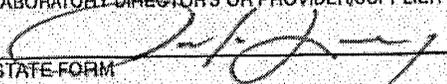


California Department of Public Health

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 06/17/2015
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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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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 16 2015</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 an investigation of two entity reported incidents conducted on 5/29/15 to 8/17/15.</p> <p>For Entity Reported Incidents CA00438860 and CA00446380 (same incident), regarding State Monitoring, Breach of IT system/theft/loss of medical records 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</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>	

Licensing and Certification Division LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE CEO	(X6) DATE 10-29-2015
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STATE FORM 5899 GG6P11 If continuation sheet 1 of 7

11/19/15 @ 1140 POC accepted, spoke to patient privacy manager - AH

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A 000	Continued From page 1 Health: 32398, Health Facilities Evaluator Nurse. The hospital detected the Breach of Protected Health Information (PHI) for 10 patients on 3/25/15, and an eleventh patient on 6/8/15. On 4/14/15, the hospital reported to the Department the Breach of PHI for the first 10 patients and on 6/8/15 reported the eleventh patient. The hospital notified the first 10 affected patients of the Breach of PHI on 4/14/15, and the eleventh patient on 6/11/15.	A 000		
A 170	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 Section 56.05 of the Civil Code and consistent with Section 1280.18. For purposes of this section, internal paper records, electronic mail, or facsimile transmissions inadvertently misdirected within the same facility or health care system within the course of coordinating care or delivering services shall not constitute unauthorized access to, or use or disclosure of, a patient's medical information. 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 patient's medical information. For purposes of the investigation, the department shall consider the clinic's, health	A 170	1. The Ethics & Compliance Office sent breach notification letters to the 10 patients initially identified as impacted by this incident (who had addresses on file). 2. The Ethics & Compliance Office sent a breach notification letter to the 11th patient identified as impacted by this incident. No other patients were impacted. 3. The employee reported this incident to Valley Homeless Healthcare Programs Assistant Nurse Manager on April 1, 2015. 4. On 4/1/15 the VHHP Assistant Nurse Manager met with the employee involved and provided verbal and written counseling on protecting patient health information and the importance of notifying management as soon as possible should this type of incident happen again and to not wait 4 days later to report such an incident.	4/14/15 6/11/15 4/1/15

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A 170	Continued From page 2 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 whether to investigate and the amount of an administrative penalty, if any, pursuant to this section. This Statute is not met as evidenced by: Based on interview and record review, the hospital failed to prevent the unauthorized disclosure of protected health information (PHI) for 11 of 11 sampled patients (Patients 1-11), when 11 patient paper charts were discovered missing from a mobile dental van. This failure resulted in the loss/temporary loss of 11 patients' PHI to unauthorized individual(s). Findings: The California Department of Public Health received a faxed report on 4/14/15, which indicated on 4/1/15 the compliance office was made aware charts for 10 patients were missing from the dental mobile van. An internal investigation revealed the 10 charts were missing from the hospital's dental mobile van on 3/25/15 at an offsite location in a nearby city. The charts contained the names, dates of birth, medical record numbers, and dental clinical information for 10 patients. On 6/8/15, the hospital's compliance office	A 170	5. The VHHP Health Center Manager, (HCM), was made aware of the incident on 6/10/15. The Health Center Manager met with the Assistant Nurse Manager on the details of the incident. 6. The Health Center Manager than met with the staff member involved on 6/10/15 and provided verbal counseling and instructions on how to better protect patient confidential information and the importance of reporting these types of incidence right away. 7. The HCM ordered locked secure safety bags for each mobile unit for the purpose of keeping patient information locked and secure on the mobile units. The handheld bag has the lock combination. The dentist, dental assistant and Health Service Representative/driver have access to the handheld secure bag. The handheld secure bag will be put in the locked designated area on the van during transport and after completed treatment 8. The Health Center Manager developed a Corrective Action Plan and Procedure to be followed by all VHHP staff. The policy was implemented and is now in practice (Attachments) 9. VHHP HCM met with all VHHP Health Service Representatives, Outreach Drivers and Public Health Community Workers to go over the importance of protecting patient records and discussed the new policy and procedure to address the recent issues she developed that would be implemented effective immediately.	6/10/15 6/10/15 7/17/15 6/15/15

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A 170	Continued From page 3 notified the Department via telephone that eight of the charts had been found by a peace officer on or around 5/12/15. The eight charts included another patient chart, bringing the total number of missing charts to 11. During an interview on 5/29/15 at 9:35 a.m. the patient privacy manager (PPM) stated on 4/1/15 the hospital was notified 10 patient charts were missing from the dental mobile van on 3/25/15. PPM stated the van was at a nearby city providing services to homeless patients. PPM stated none of the charts had been located. PPM stated the charts were prepared at a location next to the hospital (TTF), picked up by the driver (PHS), loaded into the van, then driven to the service location. PPM stated at the end of the day all 10 charts were accounted for but as the van's equipment was being secured for the drive back to TTF there were still people coming in and out of the van asking questions. PPM stated PHS noticed the charts were missing when he arrived at TTF. PPM stated the charts contained patient demographics, social security numbers, dental treatments/procedures, and previous visits. During an interview on 5/29/15 at 10 a.m. PHS stated the back of the van had a door in the middle of the passenger side which led to the registration desk. PHS stated the charts were kept in a bin on top of the registration desk and during the drive were secured with bungee cords. PHS stated he last saw the charts when he secured them with the bungee cords before locking the drawers, securing the equipment, exiting the van, locking the door, and departing the site. PHS stated before arriving at TTF, he opened the locked door to retrieve the used instruments and to drop them off, when he noticed the charts were not there. PHS stated	A 170	10. This event has been reviewed at the Risk, Quality and Compliance Committee. 11. The HCM will conduct a monitoring audit for all procedures listed in the "Valley Homeless Healthcare Program, Protecting Confidential Information Policy and Procedure", and a compliance rate of 100% is expected. If 100% compliance is not achieved, the staff will be retrained and the period of audit will be extended. The HCM will present results at the monthly Quality, Risk and Compliance Committee and internal meetings.	8/3/15

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A 170	<p>Continued From page 4</p> <p>while they were closing services, there were people coming in and out of the van including patients, visitors, and staff. PHS stated on 3/28/15 he spoke with the dental assistant who helped him close the van, and she confirmed the charts were still missing.</p> <p>During a telephone interview on 6/10/15 at 2:05 p.m. PPM stated a California Highway Patrol (CHP) officer found the charts and wrote a letter to dentist A (DDS A) indicating the CHP officer had found some items which belonged to her including dental charts. PPM stated DDS A picked up the charts from the CHP station and took them to the hospital. PPM stated she viewed the charts which were worn and dusty. PPM stated the cover of one had to be replaced, as "it looked like it had been sitting outside for a long time, it seems like it got wet, dirty, damaged."</p> <p>During a telephone interview on 6/17/15 at 8:40 a.m. DDS A stated the CHP sent a letter to one of the hospital clinics. A staff member at the clinic saw the letter was for DDS A and sent DDS A an email on 5/21/15. DDS A stated when she did not reply to the staff member the staff sent the CHP letter to DDS A's home. DDS A stated she opened the letter on 6/1/15 and saw it was from the CHP. DDS A stated the letter indicated CHP had some items they believed belonged to DDS A along with some dental items, which were found on the highway. DDS A stated she went to the CHP station and picked up a clear plastic bag containing charts, but did not open it. DDS A stated the bag contained dental charts which were dirty, weathered, crumpled, and looked "like they have been run over and outside". DDS A stated she gave the envelope to her mobile van driver, who gave it to the hospital. DDS A stated</p>	A 170		

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A 170	<p>Continued From page 5</p> <p>she learned of the missing charts the week after they disappeared when some of the patients she had seen the week before had brand new charts without the previous paperwork and she asked her assistant the reason for the new charts. That was when DDS A was notified of the missing charts.</p> <p>A review of a copy of a letter sent on 5/12/15 from the California Highway Patrol to DDS A indicated, "We have in our possession the following items(s): Dental records (Items were found on the right shoulder of [name of highway])." "Please claim the items(s) as soon as possible."</p> <p>A review of copies of pictures of Mobile Dental Services charts indicated dirty, crinkled chart covers.</p> <p>A review of a copy of a letter dated 4/14/15 from the hospital to the affected patients (who had an address on file) indicated on 4/2/15 the hospital was notified of dental charts missing from the dental mobile unit. The charts disclosed patient names, dates of birth, medical record numbers, and dental clinical information.</p> <p>A review of a copy of dental charts for Patient 4 and Patient 9, along with a blank sample copy, indicated the same following information was disclosed: name; medical record number; date of birth; age; gender; a page indicated each tooth, if there was a problem with the tooth and the recommended treatment, along with any other dental information and medical history; progress notes; medical history form; Medicare Benefits page; Notice of Privacy Practices page; and a registration form. This matched the hospital's information faxed to CDPH which indicated the charts contained the names, dates of birth,</p>	A 170		

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A 170	Continued From page 6 medical record numbers, and dental clinical information for the affected patients. A review of the hospital's 12/27/13 "Workforce General Obligations Regarding Uses and Disclosures of Protected Health Information" policy indicated all workforce members must take reasonable steps to safeguard PHI/ePHI from any intentional or unintentional disclosure.	A 170		