

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070000137	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED C 07/14/2015
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NAME OF PROVIDER OR SUPPLIER COMMUNITY HOSPITAL OF THE MONTEREY F	STREET ADDRESS, CITY, STATE, ZIP CODE 23625 W R HOLMAN HIGHWAY MONTEREY, CA 93940
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A 000	Initial Comment The following reflects the findings of the California Department of Public Health during an investigation of an entity reported incident conducted from 7/13/15 to 7/14/15. For Entity Reported Incident CA00446171, regarding State Monitoring, Breach to Person Outside Hospital, a state deficiency was identified (see California Health and Safety Code, Section 1280.15(a)). Inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health: 32398, Health Facilities Evaluator Nurse. The hospital detected the Breach of Protected Health Information (PHI) on 5/27/15. The hospital reported the Breach of PHI to the Department on 6/10/15. The hospital notified the affected patients of the Breach of PHI on 6/10/15.	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 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,	A 017		

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
DEC 11 2015
L & C DIVISION
SAN JOSE

Licensing and Certification Division
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

[Handwritten Signature]

TITLE

CEO

(X8) DATE

12/7/15

12/24/15 POC accepted, speech & privacy officer - 76

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A 017	Continued From page 1 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. This Statute is not met as evidenced by: Based on interview and record review, the hospital failed to prevent the unauthorized access to and/or the disclosure of protected health information (PHI) for three of three sampled patients (1, 2 and 3) when a staff member (MA) of an outside entity (OE) accessed Patient 1's clinical record through the hospital's business associate (BA) without consent or a job related need. The failure resulted in providing access to and/or disclosure of three patients' PHI to an unauthorized individual. Findings: The California Department of Public Health (CDPH) received an online report on 6/10/15, which indicated MA had accessed the clinical record for Patient 1 on 8/18/14 and 8/19/14	A 017	Question a: What corrective action(s) will be accomplished for the patient(s) identified to have been affected by the deficient practice? Response: Access to the merged medical record was immediately shut down to prevent further unauthorized access. Letters were mailed to the patients notifying them of the disclosure. Responsible person: Manager Clinically Integrated Systems, Community Health Innovations and Privacy Officer, Community Hospital of the Monterey Peninsula Completion date: June 10, 2015	6/10/15

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A 017	<p>Continued From page 2</p> <p>without a job related need. The access to Patient 1's clinical record gave MA access to the clinical records for Patients 2 and 3 whose clinical records had been incorrectly merged into Patient 1's clinical record on 7/2/13. The merge was not discovered until 5/21/15.</p> <p>After an internal investigation, the hospital discovered the clinical records of Patients 2 and 3 had been merged into the clinical record of Patient 1 in the clinical data base repository which was run by the BA. MA was a staff member of an entity which had access to clinical records in the repository. MA, who was on a leave of absence during the internal investigation, had accessed Patient 1's clinical record. Her manager was unable to explain why MA had accessed Patient 1's clinical record.</p> <p>During an interview on 7/13/15 at 9:55 a.m., the director of risk management and privacy (PO) stated a staff member of an outside entity, which had access to the repository run by the BA, had incorrectly merged three patients' clinical records. The PO stated the hospital identified the merged records and the PO asked for a copy of the activity log for Patient 1 which indicated MA had accessed Patient 1's clinical record. The PO stated MA had accessed Patient 1's Clinical Summary page which disclosed his name, telephone number and medications, then MA accessed Patient 1's Results page which disclosed test results. The PO stated she had spoken to MA's manager who had stated MA did not have a job related reason to access Patient 1's clinical record since Patient 1 had not been to the OE "for awhile."</p> <p>A review of a copy of the audit, indicated MA had accessed Patient 1's Clinical Summary and</p>	A 017	<p>Question b:</p> <p>How other patients having the potential to be affected by the same deficient practice be identified, and what corrective action will be taken. Response: Working with the vendor, audit logs for the involved individuals and the patients' medical records were reviewed to confirm there were no other disclosures.</p> <p>Responsible person: Manager Clinically Integrated Systems, Community Health Innovations and Privacy Officer, Community Hospital of the Monterey Peninsula</p> <p>Completion date: August 13, 2015</p>	8/13/15

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A 017	<p>Continued From page 3</p> <p>Results pages of his clinical record on 8/18/14 at 4:01 p.m. On 8/19/14 at 10:02 a.m. and 1:08 p.m., she accessed the Clinical Summary page of Patient 1's clinical record.</p> <p>During an interview on 7/13/15 at 11 a.m., MA stated she did not remember accessing Patient 1's clinical record.</p> <p>A review of a copy of the Clinical Result pages for Patient 1, disclosed his name, address, date of birth, medical record number, telephone number, gender and the hospital name and address, Patient 2's name, date of birth, medical record number, name of a radiology test, diagnosis, findings of the radiology test, impression, ordering provider for the radiology test and the primary provider. A review of a copy of Patient 1's Clinical Summary pages, disclosed Patient 1's name, telephone number, medical record number, gender, date of birth and seven medications along with the dosages.</p> <p>A review of a copy of a letter, dated 6/10/15, from the hospital to Patient 1, indicated in 11/2014 MA had accessed radiology results from 2011 and 2013 without authorization. A review of a copy of letters, dated 6/10/15, from the hospital to Patients 2 and 3, indicated in 11/2014 MA had accessed radiology results from 2013 without authorization.</p> <p>A review of a copy of the 6/15/12 Business Associate Addendum between the BA and the hospital, indicated the addendum did not authorize the BA to make any use or disclosure of the PHI the hospital would not be permitted to make. The BA would use appropriate safeguards and comply, where applicable, with the HIPAA Security Rule with respect to the electronic PHI to</p>	A 017	<p>Question c:</p> <p>What immediate measures and systemic changes will be put into place to ensure that the deficient practice does not recur?</p> <p>Response: Medical record repository access was inactivated for the staff member who accessed the record without authorization. The individual who merged the records incorrectly had resigned prior to this investigation and access had been terminated. Staffs attest to completion of an online training program prior to being granted access to the online repository.</p> <p>Responsible person: Manager Clinically Integrated Systems, Community Health Innovations</p> <p>Completion date: June 1, 2015 and ongoing.</p>	June 1, 2015 and ongoing.

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A 017	Continued From page 4 prevent the use or disclosure of the PHI. A review of a copy of the hospital's revised 3/2012 policy, "Confidentiality of Patient and Hospital Business Information", indicated "Employees shall comply with all hospital information security measures, policies, and procedures to protect the confidentiality of all hospital information, both patient-and business-related."	A 017	Question d: A description of the monitoring process and positions of persons responsible for monitoring. How the facility plans to monitor its performance to ensure corrections are achieved and sustained. The plan of correction must be implemented, corrective action evaluated for its effectiveness, and it must be integrated into the quality assurance system. Response: Community Hospital of the Monterey Peninsula routinely monitors the Health Information Exchange repository. Actual or potential disclosures are reported to the Privacy Officer for investigation. Aggregate data is included in the quarterly report to the hospital Compliance Committee. Responsible person: Privacy Officer, Community Hospital of the Monterey Peninsula Completion date: July 2015 and ongoing	July 2015 and ongoing

Sam Parker 50 12/15