

AMENDED

PRINTED: 06/09/2015
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070001357	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 02/23/2015
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NAME OF PROVIDER OR SUPPLIER STANFORD HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 300 PASTEUR DRIVE STANFORD, CA 94305
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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><u>Background</u></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. This plan of correction is prepared and/or executed solely because it is required by state law.</p> <p>E1952: T22 DIV5, CHI, ART7-7070799(b)</p>	<p>CALIFORNIA DEPARTMENT OF PUBLIC HEALTH AUG 24 2015 I & 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 1/21/15 to 2/12/15.</p> <p>For Entity Reported Incident CA00411253, regarding State Monitoring, Intentional Breach of Protected Health Information (PHI) by health care worker, 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>The provider protects the confidentiality and privacy of all patient records and communication and provides training to workforce members on privacy policies and also trains contractors prior to permitting access to PHI. In a continual effort to improve its Privacy Assurance Program, the provider will review its existing policies and procedural controls that pertain to staff access to medical records.</p>	

Licensing and Certification Division
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
Miguel R. Martinez Senior Privacy Assurance Specialist
TITLE
DATE 8/18/15

STATE FORM 8/27/15 POC accepted, spoke to senior privacy assurance specialist - JH
6899 YVF311 If continuation sheet 1 of 5

California Department of Public Health

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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) on 8/21/14. The hospital reported the Breach of PHI to the Department on 8/28/14. The hospital notified Patient 1 of the Breach of PHI on 8/28/14.	A 000	<i>The Hospital had established multiple layers of safeguards prior to the incident to prevent unauthorized access.</i> Policies:	
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, 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	<ul style="list-style-type: none"> • <i>HIPAA: Internal Access to Protected Health Information: V.E.1.a. "Access to PHI is limited to that which is necessary to perform one's job function", and "Inappropriate access to PHI can lead to disciplinary action up to and including termination."</i> • <i>Patient Privacy and Information Security Incidents: Corrective Action: (For the purposes of this policy, "Corrective Action" means sanctions/disciplinary action.) "Accessing (including searching to see if a record exists), using, or disclosing PHI without a job-related need to know..." (Offense for which sanctions were applied.)</i> 	

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A 017	<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 unauthorized disclosure of protected health information (PHI) for one patient (1), when a staff member intentionally accessed the electronic medical record of Patient 1 without a business related reason. The failure resulted in the disclosure of Patient 1's PHI to an unauthorized individual. Findings:</p> <p>The California Department of Public Health received a faxed report on 8/28/14, which indicated on 8/21/14 the hospital discovered a staff member (MA) had accessed Patient 1's electronic medical record without a business related reason. After an internal investigation, the hospital identified MA had accessed Patient 1's medical record disclosing demographic and medical information. MA had not cared for Patient 1, nor had a business related reason to access Patient 1's medical record.</p> <p>Review of a copy of the internal investigation by the hospital indicated an audit indicated MA had accessed Patient 1's medical record for a total of approximately five minutes on 7/23/14 and 7/28/14. "The investigation confirmed unauthorized access to [Patient 1's] record." MA was terminated and placed on the "do not rehire" list.</p> <p>Review of a copy of the audit for access of Patient 1's medical record by MA indicated access on 7/23/14 disclosing demographics and medical reports disclosing dates of service,</p>	A 017	<p>Contracted Staff focused training:</p> <ul style="list-style-type: none"> Privacy and Security policies and safeguards. "Protecting Patient Privacyone patient at a time." [July 9, 2014] <p>Section 1.3: Preventing Privacy Breaches states, "You have a duty to ensure that your access to, use, and disclosure of patient information is appropriate."</p> <p>Section 1.5: Consequences for Failing to Protect Patient Privacy. Eight examples reiterated the prohibition on unauthorized access to medical records and discussed the consequences up to and including termination.</p> <p>Section 2.2: Basic Privacy and Security Principles</p> <p>Principle 2: Need to Know "You are permitted only to access, use or disclose patient information when you have a job-related need to know. If the</p>	

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A 017	<p>Continued From page 3</p> <p>treating lab, attending physician; and also access on 7/28/14 disclosing demographics and images.</p> <p>During an interview on 1/21/15 at 11:45, the compliance and privacy officer (CPO) stated she had spoken to both Patient 1 and MA about the incident. On 8/21/14, Patient 1 called the hospital and was upset that MA had accessed her medical record. MA had accessed Patient 1's medical record without authorization, and without stating a reason. CPO stated Patient 1 became aware of the unauthorized access of her medical record when MA's family member (FM 1) notified Patient 1's family member. CPO stated Patient 1's demographics, dates of service, treating department, and provider physician had been disclosed. MA told CPO she had accessed Patient 1's medical record and knew she should not have accessed it.</p> <p>Review of a copy of MA's training indicated "confidentiality" training on 7/9/14, "Protecting Patient Privacy...one patient at a time" training on 7/9/14, and hospital "Code of Conduct" training on 7/9/14.</p> <p>Review of a copy of a letter dated 8/28/14 from the hospital to Patient 1 indicated on 8/21/14 MA had accessed Patient 1's medical record without a business related reason.</p> <p>Review of a copy of the hospital's 04/2013 "HIPAA: Internal Access to Protected Health Information" policy indicated access to Protected Health Information (PHI) is limited to that necessary to perform one's job function. Each member of the workforce has the responsibility to ensure his or her access to PHI is appropriate. Access to PHI is limited to only those purposes where one has a need to know subject to the</p>	A 017	<p>information is not specifically required for you to do your job at Stanford, then you do not have a job-related need to know".</p> <ul style="list-style-type: none"> • Hospital Code of Conduct training. [July 9, 2014] "We access use and disclose only the minimum amount of patient information needed to perform our jobs." • Confidentiality training [July 9, 2014] "Access to protected health information (PHI) is limited to only the minimum necessary PHI required to do that function of your job." <p>Awareness Reminders</p> <ul style="list-style-type: none"> • Within a broader privacy and security awareness campaign, specific awareness posters were posted throughout the hospital for entire staff and 	

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A 017	Continued From page 4 minimum necessary requirement.	A 017	<p>temporary contractors working at the hospital</p> <p>"Our Shared Commitment and Responsibility... We maintain the confidentiality of all patient information; we access, use and disclose only the minimum necessary patient information needed to perform our jobs."</p> <ul style="list-style-type: none"> Posted on the intranet "HIPAA Do's and Don'ts of Patient Privacy." <p>"DO NOT access patient medical records if you do not have a legitimate job-related need to access the information."</p> <p>"DO NOT access medical records of family members, friends, or co-workers; unless, you have a job-related need to access (e.g., you are on the treatment team). The Hospital Privacy Office conducts audits of who is accessing patient records in Epic."</p>	
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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

AUG 24 2015

L & C DIVISION
SAN JOSE

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A 017	Continued From page 4 minimum necessary requirement.	A 017	<ul style="list-style-type: none"> Contract with vendor: The Hospital used a vendor to provide certain staffing services, as permitted by the administrative services provision of CMIA (H&S Code, 56.10(c) (3)). As added protection, the hospital required the vendor and its employees and agents to keep patient information confidential, to use it only in compliance with state and federal laws and to not disclose it. <p><u>Plan of Correction:</u></p> <p><i>For patients affected by the incident</i></p> <p>The provider notified the patient affected by this incident. The patient was provided with a contact name and number to call the provider with any questions.</p> <p><i>For other patients having the potential to be affected by a similar incident</i></p>	

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AUG 24 2015
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A 017	Continued From page 4 minimum necessary requirement.	A 017	<p>For other patients having the potential to be affected by a similar incident, the provider reviewed existing policies and procedural controls to see where controls may be enhanced and implemented for immediate measures and systematic changes (as described below) to prevent recurrence. The provider identifies patients whose records may have been accessed, used, or disclosed in an unauthorized manner through the provider's existing complaint reporting mechanism.</p> <p><i>Immediate measures to prevent recurrence</i></p> <p>The provider continually seeks opportunities to strengthen its privacy and information security programs for the protection of the medical information of the patients it serves. Immediate measures were taken as follows:</p>	

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AUG 24 2015
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A 017	Continued From page 4 minimum necessary requirement.	A 017	<ul style="list-style-type: none"> A. The Hospital Privacy Office took prompt action after learning of the incident, including a complete and thorough investigation and steps to mitigate, including sanctions. [August 21, 2014] B. Upon confirmation that the temporary contractor employee had accessed her family member's electronic medical record, the temporary contractor employee was immediately placed on leave pending the investigation. [August 21, 2014] C. Contrary to policies, procedures and training, a temporary contractor employee who needed access to patient information for job purposes accessed a family member's record outside of a legitimate business 	
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AUG 24 2015

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A017	Continued From page 4 minimum necessary requirement.	A017	<p>related need. The contracted staff employee was terminated from employment. [August 22, 2014]</p> <p>D. The management staff for the involved department provided staff re-training on the importance of only accessing patient information for a job-related need. The provider will continue to send periodic reminders to staff about the importance of protecting patient privacy and confidentiality and abidance to provider privacy policies. [Ongoing]</p> <p>E. As part of the ongoing program, workforce members are required to complete privacy and security training online.</p> <p>a) Retrained the workforce using</p>	

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AUG 24 2015

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A 017	Continued From page 4 minimum necessary requirement.	A 017	<p>update training [August, 2014]</p> <p>F. Continue to emphasize during contractor staff new hire orientation the importance of adhering to provider policy- <i>HIPAA: Internal Access to Protected Health Information</i>; which states. Access to PHI is limited to that which is necessary to perform one's job function", and "Inappropriate access to PHI can lead to disciplinary action up to and including termination." [Ongoing]</p> <p>G. Continue to emphasize the importance of applying specific principles taught in existing annual mandatory privacy training pertaining to access to protected health information. Existing training content states in</p>	

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AUG 26 2015
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A 017	Continued From page 4 minimum necessary requirement.	A 017	<p>assurance system, the Privacy Assurance staff, under the oversight of Chief Compliance and Privacy Officer, and in conjunction with department managers, will:</p> <ul style="list-style-type: none"> A. Issue reminders to staff on the importance of adhering to the provider's policy on access to records for work-related purposes only. B. Continue to conduct monitoring of the electronic health record under its Privacy Assurance monitoring program to (a) evaluate employee adherence to the provider's access to medical record policies and procedures and (b) improve the effectiveness of its privacy training and awareness program. Specifically, the provider will continue to: <ul style="list-style-type: none"> a) Conduct electronic 	
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A 017	Continued From page 4 minimum necessary requirement.	A 017	medical record reviews for appropriate access. b) Conduct investigation into the access activity; If an aberrant access pattern is identified c) Confirmed access activity that is in violation of provider policy will result in disciplinary action, up to and including termination of staff; and d) Implement improvements based on continuous evaluation, as components of	

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A 017	Continued From page 4 minimum necessary requirement.	A 017	a comprehensive privacy and security program. C. Periodically, evaluate the effectiveness of its privacy training and awareness program and make changes to the program based on proactive review of findings and industry best practices.	

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