pre accepter 3/14/14

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

MAR 10 2014

L & C DIVISION SAN JOSE

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FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070001357	A. BUILDING: _____ B. WING _____	C 08/22/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
STANFORD HOSPITAL	300 PASTEUR DRIVE STANFORD, CA 94305

(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
A 001	Informed Medical Breach 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." 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.	A 001	Preparation and/or execution of the plan of correction does not constitute admission or agreement by the provider of the truth or the facts alleged or conclusion set for on the Statement of Deficiencies. This Plan of Correction is prepared and/or executed solely because it is required by state law. This was an isolated and limited occurrence where a physician inadvertently failed to remove patient name and medical record number (demographic information) on two radiology images when sending the images to his publisher for inclusion in a medical textbook chapter that the physician authored. The images were sent with his draft text to the publisher and were never published, disclosed, viewed or accessed by anyone other than very limited staff involved in formatting the textbook chapter. These individuals do not review text content, but rather edit the text to conform with the textbook layout and likely were not aware of the identifying information contained in the images. Although the hospital does not reasonably believe that the publisher accessed the patient identifiers on the images in a manner that would have been	
A 000	Initial Comment The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident conducted on 8/12/13 to 8/22/13. For Entity Reported Incident CA00335411 regarding State Monitoring, Privacy Breach, a State deficiency was identified (see California Health and Safety Code 1280.15(a)). Inspection was limited to the entity reported incident investigated and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health was 28767, Health Facilities Evaluator Nurse.	A 000		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Asst Director Nursing Assistant TITLE: 3/7/2014 (X6) DATE

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A 017	Continued From page 1	A 017	recognized or recalled, the hospital notified CDPH and the patients in an abundance of caution. It was the physician who noticed the demographic information on the images when the publisher sent the formatted draft chapter back to the physician for approval. The physician takes patient privacy very seriously and immediately reported the occurrence to the Privacy Office upon realizing that the patient names were on the images. Additionally upon learning of the occurrence, he took prompt action to remove the identifiable images from the publisher. In his teaching and publishing capacity, the physician proactively and routinely exercises safeguards to protect patient privacy, such as de-identifying patient information when publishing, which has been his practice for over twenty years. There have been no previous occurrences of demographic information not being removed from images when publishing. There is no evidence that anyone outside the hospital reviewed the content of the textbook chapter as the publisher was in possession of the document for formatting purposes only. The information was in a controlled environment with the publisher and the textbook	
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. This Statute is not met as evidenced by: Based on interview and record review the hospital failed to protect the right for confidential medical treatment for two of two sampled patients (1, 2). Findings:	A 017		

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A 017	Continued From page 2 On 12/7/12, the California Department of Public Health received a faxed report from the hospital chief privacy officer which indicated the hospital identified a potential breach of patients' health information. On 8/12/13 during an interview with the privacy officer, she stated both Patient 1 and Patient 2 had received outpatient oncology (cancer) treatment at the hospital. During a telephone interview on 8/22/13 at 3:30 p.m. with Physician A (MD A), he stated he was writing a chapter for a textbook in November 2011. When submitting his work to the publisher he inadvertently submitted X-ray images of two of his patients (Patient 1 and Patient 2) without removing their names from the images. MD A further stated he was made aware of the above patient disclosure approximately one year later (November 2012) before the text book was published. MD A stated medical information for Patient 1 and Patient 2 was disclosed to the publishing company and their editing associates. On 8/22/13 at 4 p.m. review of the material sent to the publisher indicated the disclosed medical information for Patient 1 and Patient 2 included the patients' names, ages, and medical diagnoses.	A 017	chapter was never publically available and was not published with the identifiable information. The textbook chapter was in draft form and publishers take extensive safeguards to limit access to draft publications in an effort to protect their publishing interests. The publisher had restricted access to the textbook chapter, limited to those editors formatting it for the textbook. There is no indication that anyone else viewed the textbook chapter. Pursuant to policies and protocols, the provider took prompt action after learning of the incident, including a complete and thorough investigation and steps to mitigate, including sanctions. The provider is not aware of any harm caused to patients as a result of this incident. **The following Safeguards were in place *prior* to the incident:** **Policies:** • *HIPAA Uses and Disclosure of Protected Health Information Policy H-14:* Appendix A: "De-Identified Health Information Under HIPAA: Health information is considered de-identified if either identifiers are removed or an expert	

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A 017		A 017	determines that the risk of identification is low." • *HIPAA Identifiers: Anonymizing Data Gutdeline:* "... PHI can be anonymized such that it is no longer considered "protected", and can therefore be released without harm. You can anonymize such data by removing all 18 HIPAA identifiers." • *HIPAA: Internal Access to Protected Health Information:* . "Workforce members receiving PHI are responsible for ensuring that the information is safeguarded while in their possession." • *"HIPAA: Use and Disclosure of Protected Health Information:* "The individual or his/her personal representative must authorize the use or disclosure of PHI, except as permitted or required by law." • *HIPAA: Definitions Policy:* " De-identified Information: Health information that cannot be used to identify an individual." **Training:** • Physician received privacy and security training that included de-identifying patient medical information.	

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A 017		A 017	**Plan of Correction:** The hospital proactively protects the confidentiality and privacy of all patient information and provides training to workforce members on its privacy policies. In a continual effort to improve its Privacy Assurance Program, the hospital will review its existing policies and procedural controls that pertain to safeguards for de-identifying information for publishing purposes and will continue to issue periodic reminders and awareness posters specific to de-identifying patient information. **For patients affected by the incident:** The provider notified the two patients who were affected by this incident. Patients were provided with a contact name and number to call the provider with any questions. (12/6/2012). To date (fourteen months after the incident), neither patient has contacted the hospital with questions or concerns regarding this incident and the hospital is unaware of any harm caused the patients by the incident.	

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A 017		A 017	**For other patients having the potential to be affected by a similar incident:** For other patients having the potential to be affected by a similar incident, the provider will review existing policies and procedural controls to identify where controls may be enhanced and has implemented measures and systematic changes (as described below) to prevent recurrence. **Immediate measures to prevent recurrence:** A. Physician immediately notified publisher and directed to immediately return proofs to the physician and delete from the publisher's system.. (11/2012) B. The information was not disclosed beyond the publisher's limited editorial staff and was never published. (11/2012) C. De-identified revisions were submitted to the publisher. (12/2012) D. The physician was re-trained and counseled to prevent recurrence of a similar incident. (11/30/12, 12/3/12, 12/6/12, 12/10/12, 12/11/12, 12/12/12)	

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A017		A017	B. Discussion at departmental faculty meeting regarding de-identifying patient medical information and publishing. (12/12) F. Revised training to include detailed information on the importance of de-identifying patient information with clarification on how to de-identify information and retrained the workforce at the hospital and School of Medicine. (August 2013) G. Posted article on hospital Intranet site specific to instructions for de-identifying patient information .(August 2013) H. Privacy Awareness campaign included specific information reinforcing policy safeguards on de-identification standards for patient information which was widely disseminated throughout the hospital. (December 2013) I. The provider regularly evaluates and strengthens its privacy and information security programs for the protection of the medical information of the patients it serves.	

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A017		A017	**Monitoring performance to ensure corrections are achieved and sustained** **(Revised March 5, 2014)** 1) On a quarterly basis, the physician in question will attest in writing to the Stanford University Privacy Office, that the Physician not submitted any radiographic images for any textbook submissions or that if a submission has been made that prior to the submission it was reviewed by the Stanford University Privacy Office. 2) Following a request from the Dean to add "De-Identification of Manuscripts and/or Publications" to each School of Medicine Medical Department's agenda, the Stanford University Privacy Office will confirm that the topic was addressed by each Medical Department. 3) The Stanford University Privacy Office and the hospital Privacy Office will collaborate to distribute to the medical departments on a bi-annual basis privacy awareness flyers that address the following information privacy topics: a. Minimum Necessary b. De-identification c. Safeguards 4) The Stanford University Privacy Officer will facilitate the distribution of written reminders sent by the School of Medicine Dean to the faculty concerning de-identification as it applies to publications. 5) A quarterly report of the monitoring results will be submitted to the Privacy Governance Council for a period of one year.	

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