POC accepted 3/21/14

Donna Hayes notified

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California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING	(X3) DATE SURVEY COMPLETED
	CA070001349		C 02/06/2014

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

NAME OF PROVIDER OR SUPPLIER: LUCILE SALTER PACKARD CHILDREN'S HSP

STREET ADDRESS, CITY, STATE, ZIP CODE: 725 WELCH ROAD, PALO ALTO, CA 94304

MAR 2 6 2014

L & C DIVISION

(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 000	Initial Comments The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident conducted on 2/6/14. For Entity Reported Incident CA00304291 regarding State Monitoring, Loss of Medical Record, a State deficiency was identified (see California Health and Safety Code, Section 1280.15(a)). Representing the California Department of Public Health: 25721, Health Facilities Evaluator Nurse. Inspection was limited to the entity reported incident investigated and does not represent the findings of a full inspection of the hospital. The facility detected the breach on 4/19/12. The facility notified patients of the breach on 4/23/12. The facility notified the Department of the breach on 4/23/12.	A 000	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. As acknowledged in the 2567 (p.3), the Hospital notified the agency of a "potential" incident, during an ongoing investigation in order to err on the side of timely notice under the statute. The Hospital learned of the potential incident on March 19, 2012 (not April 19, 2012, as reported in the 2567). In an abundance of caution, it notified the agency and possibly affected individuals on March _, 2012 (not April 23, 2012, as reported in the 2567). The Hospital pursued and subsequently	
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	A 001		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Donna Hayes | TITLE: Assistant Director, Policy | (X6) DATE: 3/21/14

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A 001	Continued From page 1 access, use or disclosure of the patient's medical information.	A 001	concluded its investigation, and found no "unauthorized" access as defined in CA Health & Safety Code 1280.15(j)(2) ("'Unauthorized' means the inappropriate access, review, or viewing" of patient medical information).	
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	Contemporaneously with its internal review two years ago, the Hospital checked its policies and procedures and confirmed that it had several reinforcing, preventative policies, tools, and training in place. These are described below. In addition, because the Hospital believes its program can always be further enhanced and improved, it took additional actions to prevent recurrence. These actions were taken in 2012, as described below, and in subsequent years (2013 and 2014), prior to the Department's visit on February 6, 2014 to inquire about the preliminary notice of a	

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A 017	Continued From page 2 This Statute is not met as evidenced by: Based on interview and record review, the hospital failed to prevent unauthorized access to medical information for 45 patients (1-45). A pharmacist resident (PR) entered medical information for the 45 patients on a flash drive (a small electronic media storage device which plugs into the USB port of a computer). PR placed the flash drive in a coat pocket and left the hospital. Later that day PR could not find the flash drive. After a search the flash drive was not recovered. The patient information included name, date of birth, medical record number, medication administration record, and the department where the patients were treated. The flash drive was not encrypted (made secure by locking the information into code) and could therefore be accessed by anyone in possession of the flash drive. Findings: The Department received a self-report dated 4/23/12 via facsimile indicating the hospital detected a potential event of unauthorized disclosure of medical information for 45 patients. During an interview and record review on 2/6/14 at 11:19 am., the privacy officer (PO) provided a list of 45 patient names and stated medical information for these patients had been reported lost by PR. During an interview on 2/11/14 at 9 a.m., PR stated the following: She worked as a physician in the hospital pharmacy department. In order to work at home on a presentation for other staff, PR entered the name, date of birth, medical record number, medication administration record for a specific medicine (intravenous immunoglobulin or "IVIG") and the department where 45 patients were treated, on a flash drive.	A 017	potential incident given in March 2012. Contrary to Hospital policies, procedures, tools, and training previously established to prevent unauthorized or unlawful access to patient medical information, a pharmacy resident (PR) failed to take sufficient action to protect patient information in her possession. While the PR had legitimate work-related access to and use of the patient information for a pharmacy project, the PR did not adhere to explicit, written policy and training that prohibited medical information from being stored on an unencrypted device. In addition, the PR did not adhere to written policies and training that staff must ensure physical control of the device at all times. The PR placed the device in her coat pocket while at work and did not store it	

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A017	Continued From page 3 The flash drive was not encrypted. On 4/17/12, in the afternoon, PR stated she placed the flash drive in a coat pocket and went to a shopping area and then home. Later that evening she noted the flash drive was not in the coat pocket. On 4/18/12 PR searched the areas she had been the day before but did not find the flash drive. On 4/18/12 PR notified her manager of the lost flash drive. On 2/11/14 review of the 9/2011 policy and procedure titled "HIPPA Security; Media Use, Transport, and Storage" indicated when media which contained protected health information was being transported, it must be secure. The policy further indicated media which contains protected health information must be encrypted.	A017	securely in her office when she left for the day. Rather, after leaving work with the thumb drive in her coat pocket, and being in a public area for a period, she returned to her car, removed and folded her coat, and placed it in the back seat of her car. It was later that evening when the PR noticed the thumb drive was missing. The thumb drive likely fell from the pocket when the PR removed her coat, folded and placed the coat in her car that was parked in the parking lot. It is also likely that the device was destroyed by the PR's vehicle or another vehicle during parking as there continues to be (two years later) no evidence of unauthorized access, review, or viewing of information that was on the device. No one has contacted the hospital regarding this incident.	

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A017		A017	*The following safeguards were in place prior to the incident.* Policies: • *HIPAA: Security Mobile Device Policy: 2.4.1.* "Security Controls for IT and Non- IT Devices: Data at rest on the device must be encrypted using the strongest encryption supported by the device." • *HIPAA:* Mobile Device Management and Usage: prohibiting storage of PHI on a mobile device, defined explicitly to include "USB/Flash Drive," and articulating risks and required precautions ("For example, devices can be easily lost, stolen, or misplaced because of their small size.")	

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A 017	CALIFORNIA DEPARTMENT OF PUBLIC HEALTH MAR 26 2014 L & C DIVISION SAN JOSE	A 017	• User Policy Agreement: "No PHI to USB drives/portable devices without written permission from IT Security *and* your supervisor." **"NEVER store confidential data (including but not limited to PHI) on desktop, mobile device...or departmental media without written approval from the LPCH IT Security Office...."** • *HIPAA: Internal Access to Protected Health Information: V.B.4.* "Workforce members receiving PHI are responsible for ensuring that the information is safeguarded while in their possession." Pharmacy-focused training: • Annual mandatory training on Privacy and Security policies and safeguards. • New hire training on Privacy and Security policies and safeguards.	

Department Health

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A 017		A 017	Awareness • December 2011, within a broader privacy and security awareness campaign, a specific awareness poster was posted throughout the hospital: "The Weakest Link...Failing to Encrypt, Failing to Password Protect...Can Break the Chain of Trust." **Plan Correction:** The hospital proactively protects the confidentiality and privacy of all patient information and provides training to workforce members on its privacy policies. As previously noted, the provider reviewed its policies two years ago in 2012 after the potential incident, but in a continual effort to improve its Privacy Assurance Program, the provider will again review its	

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		A 017	existing policies and procedural controls that pertain to safeguards for protection of portable media storage devices containing patient information and will continue to issue periodic reminders and awareness posters specific to the protection of paper information and not leaving patient information in vehicles. ***For patients affected by the incident*** As mentioned above, in an abundance of caution while an investigation was still ongoing, the provider notified potentially affected individuals. Patients were provided with a contact name and number to call the provider with any questions. To date, the hospital has not received any questions or concerns from recipients of the letter, and the hospital is unaware of any unauthorized	

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A 017		A 017	access, disclosure, or harm, as "unauthorized" is defined in CA H&S Code 1280.15 and as related parts of the Confidentiality of Medical Information Act (CMIA) has been interpreted. (See, e.g., Regents of Univ. of California vs. Superior Court, 163 Cal. Rptr 3d 205, Cal. Ct. App. (2013) (mere loss of possession insufficient to show breach, absent evidence of improper viewing or other unauthorized access to confidential information). ***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 re-reviewed existing policies and procedural controls to see where controls may be enhanced and implemented	

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A 017		A 017	further measures and systematic changes (as described below) to prevent recurrence. ***Immediate measures to prevent recurrence*** Two years ago when the potential incident occurred, immediate measures were taken as follows: A. In April 2012, the Hospital published an advisory to all medical staff from the Office of the General Counsel on data security requirements. This advisory in the Medical Staff Update reiterated State and federal security requirements, and well-established Hospital policies requiring encrypting and securing PHI. B. As a result of the pharmacy resident's violation of policies and training, disciplinary action was imposed. [May, 2012]	4/2012 5/2012

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A017		A017	C. As part of ongoing training, Pharmacy employees including Pharmacists, Pharmacy interns and Students and Pharmacy Technicians attended a staff meeting where HIPAA Privacy and Security training was provided. This is in addition to existing privacy and security training.	4/2012
			D. A Database Query Request process was implemented by Pharmacy requiring any pharmacy personnel involved in a project or audit requiring the extraction of information from the electronic health record system to complete a Database Query Request Form to be signed by the requestor and given to a pharmacy manager for review and signature PRIOR to report generation. [May, 2012]	5/2012
			E. All new hires must receive specific department training on privacy compliance. This is in addition to existing privacy and security training. [May 2012]	5/2012

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A 017		A 017	F. The pharmacy department coordinated with another department for whom the PR did certain work, and such department proactively worked to prevent a similar occurrence, through documented distribution of encrypted flash drives and critical privacy/security reminders to staff.	6/2013
			G. Hospital-wide Privacy Awareness Campaigns in 2012, 2013 and 2014 included specific information reinforcing policy safeguards to encrypt PHI.	12/2013
			H. Retrained the workforce using updated training [August, 2013]	8/2013
			I. To further highlight pre-existing requirements and provide practical, updated guidance, the Hospital issued a new policy, "Privacy and Security Protection for the Removal and Transport of Protected Health Information." To reinforce pre-existing policies and training, hospital-wide training occurred	8/2013

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A 017		A 017	on this new policy. [August 2013]	
			J. To define and standardize sanctions/disciplinary actions, the Hospital issued a new policy, "Patient Privacy and Information Security Incidents: Corrective Action (For the purposes of this policy, "Corrective Action" means sanctions/disciplinary action.) "Taking patient information off premises and failing to protect that information. " (Offense for which sanctions will be applied.)	9/2012
			K. Before the incident, the Hospital implemented many safeguards to prevent unauthorized or unlawful access to patient medical information, including but not limited to encryption policies, training, an Information Security Office Institutional program, and related technical, physical, and administrative controls to protect electronic	2/2014

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A017		A017	patient information. As part of its ongoing updates to its comprehensive proactive program, an assessment of solutions for secure USB models was conducted, and a common model was agreed upon. Advanced current technology that would automatically block downloading of patient data to an unencrypted USB was also assessed. A technology was selected and pilot testing completed for this sophisticated technological initiative. The initiative was announced to the workforce prior to go-live date. **Monitoring performance to ensure corrections are achieved and sustained** 1. Department specific new hire privacy training occurs during department orientation with a signed attestation document. This training is monitored by the	Ongoing

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A017		A017	pharmacy managers on a quarterly basis.	
			2. All completed Database Query Request Forms are monitored and reviewed by pharmacy managers on a quarterly basis.	Ongoing
			3. IT Security Chief Information Officer will monitor downloads of patient data to unencrypted USB drives on a quarterly basis.	Ongoing
			4. While the provider, as part of its security/privacy program, has proactively reviewed and enhanced security over the two years since this potential incident occurred, the provider will submit a quarterly report of the monitoring results to the Privacy Governance Council for a period of one year from the date of this POC submission.	3/2015

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