

DEC - 1 2015

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 053303	LIC# SAN DIEGO (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/28/2015
NAME OF PROVIDER OR SUPPLIER Rady Children's Hospital - San Diego		STREET ADDRESS, CITY, STATE, ZIP CODE 3020 Childrens Way, San Diego, CA 92123-4223 SAN DIEGO COUNTY		
(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
	<p>The following reflects the findings of the Department of Public Health during a complaint/breach event visit:</p> <p>Complaint Intake Number: CA00402445, CA00403287, CA00401886, CA00403150 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 28183, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1280.15(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.</p> <p>The investigation was limited to the specific self-reported events investigated and does not</p>		<p><i>The following is submitted pursuant to California Health and Safety Code § 1280(b) that requires a Plan of Correction and is not an admission of liability for any alleged acts or omissions.</i></p> <p><i>a. How the correction will be accomplished, both temporarily and permanently and the plan for continued compliance and the description of the monitoring process to prevent recurrence of the deficiency:</i></p> <p>Incident #1 was the result of a leader who inadvertently attached a patient source file to an email when creating a tool to test job applicants.</p> <p><u>Immediate Actions Taken As a Result of Incident #1:</u></p> <p>Leaders from RCHSD telephoned each of the 14,121 families involved in the disclosure and personally spoke to everyone who had a working phone number.</p> <p>Letters were subsequently mailed on June 16, 2014, and identity protection services were extended to all of the patients involved.</p> <p>RCHSD reported this disclosure to CDPH.</p> <p>Upon learning of incident #1, RCHSD immediately contacted the four individuals who received the emails. RCHSD immediately secured the data by asking the</p>	<p>6/14/2014 through 6/16/2014</p> <p>6/16/2014</p> <p>6/12/2014</p> <p>6/10/2014</p>

Event ID: LZG911

11/24/2015

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

 EVP/CAO 12/1/15

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 6

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

Acceptable POC 12/3/15
JWain HFEN

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	<p>represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 1279.1 (c)</p> <p>(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.</p> <p>The CDPH verified that the facility informed the patients or the parties responsible for the adverse event by the time the report was made.</p> <p>Title 22, Division 5, Chapter 1, Article 7</p> <p>70751(b) The medical record, including X-ray films, is the property of the hospital and is maintained for the benefit of the patient, the medical staff and the hospital. The hospital shall safeguard the information in the record against loss, defacement, tampering or use by unauthorized persons.</p> <p>This RULE: is not met as evidenced by:</p> <p>The facility failed to protect patients' medical record information from unauthorized access by potential job applicants. As a result, confidential medical information for 20,421 patients was compromised.</p> <p>Findings:</p>		<p>four individuals to delete the email and the attached Excel report from their email inbox.</p> <p>RCHSD conducted follow-up phone interviews with the four individuals and learned that one of the candidates forwarded the email to two other people. Of the six individuals who received the email and the Excel spreadsheet, two confirmed in writing that they were not able to open the file.</p> <p>RCHSD hired an independent information security firm to conduct remote scans of the recipients' computers to confirm that the email and its attachment had been removed from each individual's personal computer. The security firm was successful in contacting five of the six recipients and performing a remote scan to confirm that the email and attachment was either removed or not found on the individuals' personal computers.</p> <p>RCHSD worked diligently to attempt to obtain signed attestations from the individuals involved in incident # 1 confirming they had destroyed or deleted the email and attachment. One candidate sent an email confirming that the email and its attachment had been deleted, however, despite our efforts, that individual has refused to allow the security firm to complete this remote scan, and the individual has refused to sign an attestation. However, this individual is one of the two</p>	<p>6/11/2014</p> <p>6/11/2014</p> <p>6/11/2014 through 6/25/2014</p>

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	<p>On 6/12/14 at 3:15 P.M. the facility reported a breach of confidentiality of patients' medical information to the Department. On 6/13/14 at 10 A.M. a joint interview was conducted with administrative staff, including the Director of Risk Management (DRM), the Chief Privacy and Compliance Officer (PCO) and the Chief Operating Officer (COO). According to administrative staff, on 6/6/14 the Director of Decision Support (DDS) sent an email with an attached file to a Human Resources Recruiter (HRR) related to conducting a search to hire a Decision Support Analyst. The DDS requested that the HRR send the file to four job candidates to use in an exercise to assess the candidates' data analysis and software skills. The HRR then sent the email with the data file to each of the four job candidates (JC1, JC2, JC3, and JC4). The file had two tabs; one tab with scrambled data and a second tab, inadvertently, included, which contained confidential medical information for 14,121 patients admitted between 7/1/12 and 6/30/13. The confidential medical information included: the patients' names, dates of birth, age, diagnoses, admit/discharge dates, medical record numbers and insurance details.</p> <p>The facility was made aware of the disclosure on 6/10/15 when JC1 contacted the HRR to report that confidential medical information was in the spreadsheet file which the facility emailed to him. The facility initiated an investigation, and found that JC1 had forwarded the data file to two other individuals (F1, F2).</p> <p>On 6/17/15 at 2:58 P.M., the COO called the</p>		<p>who confirmed in writing on 6/11/2014 that they were unable to open the email attachment as it had gone directly to their spam folder.</p> <p>RCHSD immediately prohibited the use of patient data to test job candidates. Department leadership was instructed that they are prohibited from creating department specific testing materials. All testing will be conducted through the RCHSD Human Resources Department. All RCHSD leaders were notified of this prohibition on June 24, 2014 during the Management All Staff Meeting when training and educational materials were presented and distributed to leaders for them to present at their own departmental meetings. The recruiters were retrained regarding appropriate job applicant testing tools. RCHSD's Recruitment and Selection policy (PPM 202) was updated to clearly outline the process for selecting and coordinating the use of approved purchased testing materials to test job candidate competency.</p> <p>Human Resources and Management took appropriate corrective action with the individuals who were involved in the disclosure, up to and including termination of one individual.</p> <p><u>Permanent Corrections as a Result of Incident #1:</u></p> <p>RCHSD has committed to using only commercially available and validated</p>	<p>6/24/2014</p> <p>7/11/2014 and 8/13/2014</p> <p>6/30/2014</p>

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	<p>Department to report another breach that was discovered during the facility's investigation of the first incident. According to the COO, in August, November, and December of 2012 an employee emailed a training exercise to test three job applicants. An additional six job applicants came to the facility's campus to take the test on a facility computer; however, the job applicants had no ability to save, store or send the data. The file contained confidential medical information for 6,293 patients who were registered for inpatient or outpatient treatment between 6/30/09 and 6/30/10. Information disclosed included: patients' names, discharge dates, the location where patients were seen, and account information such as the payors' names and balances.</p> <p>On 6/23/15 at 5:26 P.M. the Privacy Compliance Manager (PCM) reported to the Department a third incident. According to the PCM, the Financial Department created a tool to test job applicants' knowledge and use of appropriate billing codes. Between April 2012 and June 2013 (on six different dates) seven job applicants were onsite and were given printed test materials that included portions of confidential medical information for six patients. The patients' names and medical record numbers were "blacked out" on some pages before they were given to the applicants, but information was not completely removed from all of the pages. The job applicants had no ability to save, store, or personally use or send the confidential medical information, and the documents were retrieved when the tests were completed. Information disclosed included: the patients' names, medical</p>		<p>testing programs to evaluate job applicants. IBM <i>Prove It</i> is an office assessment tool that was previously in place and will continue to be utilized by the RCHSD Human Resources recruiters.</p> <p>RCHSD continues to use its standard e-mail filter through Zix Corp which quarantines outbound emails that may contain potential protected health information (PHI) or other sensitive information. The only way these quarantined emails are released is through encryption, or through review and release by the Compliance Department. Since implementation of the email quarantine system, the volume of quarantined emails has been significantly reduced from approximately 1,500 emails per month to 400 emails per month (this represents approximately .0007 % of RCHSD's total outbound email volume each month). The reduction is a result of workforce member awareness and appropriate use of email encryption.</p> <p>In 2015, RCHSD approved the purchase of a Data Loss Prevention (DLP) System that further secures RCHSD data. Implementation date 1/30/2016.</p> <p>The Information Technology Department continues to work with key RCHSD business entities and providers to build more secure email tunnels (TLS) to ensure that email conversations that contain PHI or other proprietary information are protected and sent securely.</p>	<p>6/30/2014</p> <p>Pending for 1/30/2016</p> <p>6/10/2014</p>

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	<p>record numbers, dates of birth, visit dates, chief complaints, diagnoses, medications, History and Physicals, treatment plans, and discharge instructions.</p> <p>On 6/25/15 at 8:30 A.M., the PCM reported a fourth incident to the Department. According to the PCM, the Financial Department created a tool to test job applicants' knowledge and use of appropriate billing codes in 2010. The one page testing tool included portions of health information on one patient, which was viewed on a facility's computer screen by four job applicants, on each of the following dates: 2/26/10, 4/12/10, 4/23/10 and 6/18/10. Information disclosed included: the patients' home addresses, dates of birth, dates of service, locations of service, physician names, billing codes, health plan names, health plan ID numbers, quantity and code type for medications dispensed, total amount billed for medications dispensed, gender, dates of onset of illness, initial treatment dates, and related hospital admission dates. The applicants did not have the ability to keep, save, copy, forward or personally use the information.</p> <p>The facility failed to prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information in violation of Health and Safety Code Section 1280.5, subdivision (a). The facility failed to ensure the confidential medical information for patients was maintained in a secure environment and not accessible to unauthorized persons when patients' medical information was released to various job applicants over a period of four years. During that time, the confidential</p>		<p><u>Ongoing Monitoring:</u></p> <p>The Compliance Department is copied on all quarantined emails. The Compliance Department conducts daily sampling of the quarantined emails and communicates with individuals or department leadership, as appropriate, regarding the content of the quarantined email. The Chief Compliance and Privacy Officer (CCO) conducts monthly trending and analysis to identify areas or individuals that may need additional education and to identify opportunities to establish TLS secure tunnels with new business partners. These reports are reviewed on a monthly basis by the CCO. Any negative trends identified are escalated as appropriate to the Executive Compliance Committee that meets monthly for review and resolution. None of the quarantined emails have resulted in a privacy incident as the emails are unable to leave the network without encryption or further intervention.</p> <p><u>Incident #2</u></p> <p>After the first disclosure, leadership investigated and identified other uses of patient data in the applicant testing process. Three more incidents were then discovered. Incidents #2, 3 and 4 involved the inadvertent use of patient data for applicant testing in 2010, 2012 and 2013. RCHSD found no other current use of patient data for testing purposes.</p> <p>Upon learning of incident #2, leaders from RCHSD phoned families who were involved in both the first and second disclosures.</p>	<p>6/30/2014</p> <p>6/16/2014</p> <p>6/20/2014</p>

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	medical information for 20,421 patients was compromised.		<p>Letters for the second incident were sent to the involved patients on June 23, 2014 and identity protection services were extended to this group of patients as well.</p> <p><u>Immediate Actions Taken as a Result of Incident #2:</u></p> <p>RCHSD immediately secured the data. RCHSD hired an independent information security firm to conduct remote scans of the three recipients' computers who had received the email and test document. The security firm was successful in conducting remote scans of the computer systems of two of the three recipients. In addition, two of the three individuals signed attestations confirming that the information had been removed from their computer. The remaining individual allowed the security firm to conduct the remote scan of their computer, but has not responded to our numerous requests to get a signed attestation.</p> <p>Corrective action was taken with the involved employee by Human Resources and Management.</p> <p>The CCO conducted HIPAA/ Privacy refresher training for 130 employees in the Patient Financial Services (PFS) Department on July 9, 2014. (This was the department involved in privacy incident #2.) A follow up training session was held for PFS on February 25, 2015.</p> <p>The CCO held thirty minute coaching and counseling meetings with the involved employee twice a month for five months, through November 6, 2014.</p>	<p>6/23/2014</p> <p>6/19/2014</p> <p>7/16/2014</p> <p>7/9/2014</p> <p>2/25/2015</p> <p>7/23/2014 through 11/6/2014</p>

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			<p>The Customer Service Department mailed follow up letters to 51 patients/ families who had additional questions regarding the disclosures.</p> <p>The Compliance Department sent out second copies of the patient notice letters to 216 patients/ families who had notified us of an updated address for incident #1 and incident #2.</p> <p><u>Permanent Corrections as a Result of Incident #2:</u></p> <p>All applicant testing is conducted on site using the IBM <i>Prove It</i> assessment tool.</p> <p>The facility continues to utilize the Zix email quarantine system to prevent any inadvertent release of unencrypted emails leaving RCHSD that contain PHI or other sensitive information.</p> <p><u>Ongoing Monitoring Following Incident #2:</u></p> <p>RCHSD Compliance Department continues with its daily review of quarantined emails. Trend reports are reviewed monthly by the CCO and any negative trends identified are escalated as appropriate to the Executive Compliance Committee that meets monthly for review and resolution.</p> <p><u>Incidents #3 and #4</u></p> <p>Our ongoing investigation identified incident #3 and #4. Letters for the third incident were sent to the involved patients on June 23, 2014. The letter for the fourth</p>	<p>8/15/2014</p> <p>9/10/2014</p> <p>6/10/2014</p> <p>6/30/2014</p> <p>6/30/2014</p> <p>6/23/2014 and 6/27/2014</p>	

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			<p>Incident was sent to the involved patient on June 27, 2014.</p> <p>Incidents #3 and #4 involved use of patient data for applicant testing in 2010, 2012 and 2013. RCHSD found no other current use of patient data for testing purposes.</p> <p><u>Immediate Actions Taken as a Result of Incidents #3 and #4:</u></p> <p>RCHSD secured the patient data by removing the applicant test documents from the department.</p> <p>RCHSD immediately prohibited the use of patient data to test job applicants. Department leadership was instructed that they cannot create department specific testing materials. All testing will be conducted through the RCHSD Human Resources Department. All RCHSD leaders were notified of this prohibition on June 24, 2014 during the Management All Staff Meeting and the recruiters were retrained regarding appropriate job applicant testing tools.</p> <p>Human Resources and management took corrective action with the individuals involved.</p> <p>The RCHSD Privacy Compliance Manager conducted one on one privacy training with the individual involved in incident #3 on August 7, 2014.</p> <p>The individual involved in incident #4 is the</p>	<p>6/23/2014</p> <p>6/24/2014</p> <p>7/21/2014</p> <p>8/7/2014</p> <p>7/23/2014 through 11/6/2014</p>

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			<p>same individual involved in #2. The CCO met twice monthly with this individual following these incidents to provide coaching and counseling.</p> <p><u>Permanent Corrective Actions for Incidents #3 and #4:</u></p> <p>As summarized in incidents #1 and #2 above, actions include implementation of the Zix quarantine system, an update to RCHSD Personnel Policy (PPM 202) Recruitment and Selection, and education for department leadership on the prohibition on use of department created testing tools to test job applicant proficiency.</p> <p><u>Ongoing Monitoring for Incidents #3 and #4:</u></p> <p>All of the previously noted monitoring activities continue.</p> <p><u>As a result of these four incidents, Rady Children's has also implemented the following permanent actions:</u></p> <p>RCHSD leadership is using these incidents to reinforce our policies concerning protection of patient information and to strengthen our training programs.</p> <p>The annual mandatory education and new employee orientation modules were further enhanced to include information on appropriate use of the RCHSD email systems. Additional emphasis was placed on the appropriate use of PHI.</p>	<p>6/24/2014 and 6/30/2014</p> <p>6/30/2014</p> <p>6/10/2014</p> <p>10/2/2014</p>	

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			<p>The RCHSD CCO provides monthly trend reports to the Executive Compliance Committee and the Operational Compliance Committee regarding quarantined emails.</p> <p>The Privacy and Security Advisory Council created a comprehensive Privacy Assessment Survey Tool that was sent to all departments. The survey responses helped us to identify areas where policy clarification and/or re-education is needed.</p> <p>Continued use of the Zix email quarantine system.</p> <p>Ongoing training for Rady Children's workforce members to include annual mandatory education, new employee orientation and focused training for targeted areas.</p> <p>Continued use of purchased testing materials through IBM <i>Prove It</i> to test job applicant knowledge and proficiency.</p> <p>The Rady Children's plan for continued compliance and ongoing monitoring includes:</p> <p>Information Technology Department implementation of a Data Loss Prevention (DLP) solution that will allow RCHSD to effectively discover, monitor, control, and secure sensitive data, whether on the network, in use on desktops or laptops, at rest on end-user devices and network servers, or stored in the cloud. Implementation and start up by January 30, 2016.</p>	<p>EFFECTIVE:</p> <p>6/30/2014</p> <p>10/24/2014</p> <p>6/30/2014</p> <p>6/10/2014</p> <p>6/10/2014</p> <p>Pending for 1/30/2016</p>

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NAME OF PROVIDER OR SUPPLIER Rady Children's Hospital - San Diego			STREET ADDRESS, CITY, STATE, ZIP CODE 3020 Childrens Way, San Diego, CA 92123-4223 SAN DIEGO COUNTY		
(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	
			Continued use of the RCHSD Safety Reporting System (SRS) for workforce members to report potential privacy incidents. Documentation and follow up is also included in this system. Compliance Department reviews track and trend reports that are generated on a monthly basis from the SRS system. These reports are used to identify departments or individuals that may need support or re-education.	<u>EFFECTIVE:</u> 6/10/2014	
			Ongoing use and promotion of the Compliance Hotline for workforce members to report concerns confidentially and anonymously.	6/10/2014	
			<u>Ongoing Monitoring Activities Include:</u> Compliance Department conducts a monthly review of privacy incidents by location and by type of incident to identify trends/ focus areas.	6/10/2014	
			On an annual basis, the RCHSD CCO and the Chief Information Security Officer (CISO) review and update the RCHSD training materials for Workforce Members.	10/2/2014	
			Compliance Department and departmental leadership conduct an ongoing assessment of staff comprehension of privacy and security requirements through the testing that accompanies the annual mandatory education modules.	6/10/2014	
			The Compliance Department conducts monthly audits of the RCHSD clinical	6/10/2014	

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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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			<p>information systems to ensure that access to patient information is consistent with RCHSD policies.</p> <p>System-wide use of Break the Glass (BTG) in the electronic medical record to add extra privacy protection for sensitive patients. Compliance Department monthly monitoring of the BTG audit reports to ensure appropriate access to patient information.</p> <p>CCO and CISO review and update the RCHSD privacy and security related policies as needed or at least every three years, whichever is sooner.</p> <p>Compliance Department and/or Quality Management monthly rounding to proactively identify opportunities to enhance our privacy protections.</p> <p>Reports regarding this monitoring activity will be presented on a monthly basis to the Operational Compliance Committee and the Executive Compliance Committee to evaluate outcome of audits, respond to concerns, and make recommendations for improvement, as appropriate.</p> <p><u>Persons responsible for implementing this Plan of Correction:</u> Chief Compliance and Privacy Officer Chief Information Security Officer</p>	<p>6/10/2014</p> <p>6/10/2014</p> <p>8/1/2014</p> <p>6/10/2014</p>	

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