

PRINTED: 08/12/2016
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA050000020	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED C 08/12/2016
NAME OF PROVIDER OR SUPPLIER LOS ROBLES HOSPITAL & MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 215 W JANSS RD THOUSAND OAKS, CA 91360		
(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 a breach investigation: Complaint intake number: 391015 Representing the California Department of Public Health: HFEN's 22363, 9666 and 32971. The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.	A 000		
A 001	Informed Medical Breach Health and Safety Code Section 1280.15(b)(2) Subject to subdivision (c), a clinic, health facility, home health 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, or by an alternative means or at an alternative location as specified by the patient or the patient's representative in writing pursuant to Section 164.522(b) of Title 45 of the Code of Federal Regulations, no later than 15 business days after the unlawful or unauthorized access, use, or disclosure has been detected by the clinic, health facility, home health agency, or hospice. Notice may be provided by email only if the patient has previously agreed in writing to electronic notice by email. 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		
A 100	1280.15(a) Health & Safety Code 1280.15	A 100		

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

Quinn Holoff
TITLE Facility Privacy official

(X6) DATE 8-24-1

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A 100 Continued From page 1

(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 facility failed to safeguard the medical records of 133 patients and this failure placed an additional 2,390 patients at risk of having their medical information accessed by unlawful means or by unauthorized persons.

Findings:
The Director of Risk Management (DRM), the

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2016 AUG 25 AM 7:34
LICENSING & CERTIFICATION
VENTURA DISTRICT OFFICE
CALIFORNIA DEPT OF PUBLIC HEALTH

Complaint Number CA00391015

Notified DPH 3/12/14

RE: Courier transport of medical records out of State of California for scanning at Regional office in Nevada. 133 records missing upon receipt at Nevada business office. 2390 other medical records may have been accessed. To date, no criminal activity reported.

a.)The patients were notified regarding the incident on 3-12-14. Patients were provided with a toll-free number to find out if they were affected by the breach. Patients were offered one year of free online credit monitoring. Media notice was provided in a local newspaper on 4-16-14. To date, no criminal activity has been reported.

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Continued From page 2
 Privacy Officer (PO), Director of Medical Records (DMR), Director of Health Information Management (DHIM) and the Chief Nursing Officer (CNO) were interviewed on 4/16/14, from 12:20 to 2:00 p.m. The PO advised during the interview that on or about July 2012, medical records were transferred by a third party courier service (Vendor A) to an out of state scanning center (Scanning Center X), for electronic storage. The PO also indicated that 200 or more medical records from the facility could be transported at one time. Review of facility correspondence dated 10/5/12 revealed an approval of this process was granted by the Department (California Department of Public Health Licensing and Certification) and addressed to the facility Administrator with stipulations to include, "Records will be protected against loss during transit by being packaged in tamper-resistant containers and closed with tamper evident seals." The DMR explained that the records were transported in plastic bins secured with "Zip ties," but that the facility failed to ensure the seals were tamper-resistant or tamper evident.
 Further review of the CDPH program flex dated October 5, 2012 indicated the facility was to ensure each individual that handled patient medical records would either be a hospital employee or the employee of a vendor that had executed a confidentiality agreement with the hospital or parent company. The DMR confirmed the facility had a confidentiality agreement with Scanning Center X.
 The process of transporting the medical records was reviewed with the DHIM, DRM, PO, DMR and CNO during the interview. According to the DMR, the medical records were picked up from the facility by Courier A. Courier A met another subcontracted Courier (Courier B) and

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b.) All patients that were affected by the incident were accounted for and notified of the incident. Since then, all matters raised by this breach have been resolved through voluntary compliance actions of Los Robles Hospital and Medical Center (LRHMC).
 c.) LRHMC terminated its previous courier services and kept all records on site during the initial investigation.
 LRHMC thoroughly reviewed the transporting process as well as its business associate's policies and procedures.
 LRHMC hired a new courier service which started on May 15, 2014.
 LRHMC revised and implemented the process of transferring medical records from hospital to courier and scanning center. The facility also replaced plastic security devices on bins with metal combination locks. The couriers do not have access to the combinations at any time.
 The facility has a forms committee which reviews and authorizes any new forms. Forms with social security numbers are not permitted.
 d.) Hospital Corporation of America (HCA) has implemented a monitoring program to ensure that records delivered from the hospitals to the Scan Center in Nevada are all received. Any outliers are discussed with the DHIM by the following day.

James Heloah FPO, 8-24-16

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A 100	<p>Continued From page 3</p> <p>transferred the records to Courier B. Courier B then met with another subcontracted Courier (Courier C) and transferred records to Courier C, who in turn met with a fourth subcontracted Courier (Courier D). Courier C would transfer the records to Courier D, and subsequently, Courier D would deliver the medical records to Scanning Company X. The DRM stated in the interview that the facility representatives were unaware if each courier checked the zip ties, or if a security breach could be identified between the multiple couriers.</p> <p>During the interview on 4/16/14, the DMR explained that on 2/18/14, she was notified by the Director of Document Imaging (DDI) there was a discrepancy between the number of records leaving the facility and the number of records arriving at Scanning Center X. The DDI reported ten medical records were missing from 2/14/14. The DMR recreated the records but did not report to anyone. The DDI contacted the DMR again on 3/4/14 about a discrepancy between the number of medical records leaving the facility and the number arriving at Scanning Center X, this time the DDI reported there were 16 missing medical records from 2/26/14, and 18 medical records missing from 2/28/14. The DMR stated she investigated, monitored the procedure for transfer of medical records and reported the incident to her boss, the Regional Medical Director (RMD), indicating her investigation was inconclusive. The DMR further advised during her interview on 4/16/14 that on 3/5/14, the DDI contacted the DMR again about more missing medical records, specifically 34 medical records on 3/3/14 and 26 missing medical records on 3/4/14. The DMR and the PO met with their "Team" and decided to put "Black dots" on the zip ties to see if, when the records arrived at Scanning Center X, that the same zip ties were on the plastic bins.</p>	A 100	<p>The facility's policies and procedures were thoroughly reviewed to ensure that all associated policies were accurate and compliant.</p> <p>The process for hiring and screening of courier employees includes background checks, drug screens and compliance with vendor credentialing practices.</p> <p>The process for pick-up of records has been revised to include additional monitoring with a person-to-person handoff and a log of record transfer of the records between the hospital and the courier service and the courier scanning center. The process to secure the bins during transport has been enhanced by the use of metal combination locks to replace the prior plastic security devices. These system changes and monitors will be continued on an on-going basis for all current and future medical records.</p> <p>e.) The systems and monitoring revisions began in March, 2014 and were completed by LRHMC in May, 2014. The systems and monitoring will be permanent and ongoing.</p>	

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A 100	<p>Continued From page 4</p> <p>On 3/6/14, the DDI notified the DMR and PO that 29 records were missing from 3/5/14, there were no "Black dots" on the zip ties, and in fact the zip ties were different than the ones applied at the facility. At this point a total of 133 medical records were reported to the facility as missing. It was unknown at what point and with which courier service the breach had occurred. The facility identified the following missing records upon delivery to Scanning Center X: On 2/14/14 there were 10 patient records missing. On 2/26/14 there were 16 records missing. On 2/28/14 there were 18 records missing. On 3/3/14 there were 34 missing records. On 3/4/14 there were 26 missing records On 3/5/14 there were 29 missing records, for a total of 133 missing patient records. The DMR further explained during the interview on 4/16/14 that the facility Emergency Department (ED) staff had implemented a new process for entering patient data into the computer system. For ease of entry, the ED staff created and had implemented a patient form for data input. The ED patients would fill out this new form, which now included the patient's social security numbers. The form was not authorized by the facility, and was not intended to be part of the patient medical record but had inadvertently been added to the medical records being transferred out of state in the plastic bins for 123 of the 133 breached medical records. The facility failed to provide appropriate and adequate safeguards to protect the confidentiality of patients' medical information, and failed to maintain the confidentiality of patients' medical information, during transport of patient medical records, which resulted in unlawful and unauthorized access, use and disclosure of confidential medical information of multiple</p>	A 100	<p style="text-align: center;">RECEIVED 2016 AUG 25 AM 7:34 SCANNING & CERTIFICATION VENTURA DISTRICT OFFICE</p>	<p style="text-align: center;">RECEIVED 2016 AUG 25 AM 7:34 SCANNING & CERTIFICATION VENTURA DISTRICT OFFICE</p>

Janice Hoboff FPO

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CA DEPT OF PUBLIC HEALTH
 2016 AUG 25 AM 7:34
 CENTRAL DISTRICT OFFICE

J. Holoff FPO 8-24-16