

go POC accepted 11/28/11

PRINTED: 11/15/2011
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(01) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA000014385	(02) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(03) DATE SURVEY COMPLETED C 01/24/2011
NAME OF PROVIDER OR SUPPLIER DOWNEY REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 11500 BROOKSHIRE AVENUE DOWNEY, CA 90241	

(04) 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)	(05) COMPLETE DATE
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A 000 Initial Comment

The following reflects an Amended findings of the Department of Public Health during the investigation of an entity reported incident.

Entity reported incident number CA00281578 - Substantiated

Representing the Department:
Shielah Craus, RN, HFEN

The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.

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A 017 1280.16(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

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The following plan of correction includes:

How the correction (s) will be accomplished, both temporarily and permanently.

Temporary correction of the facility's failure to prevent unlawful or unauthorized access included:

- Immediate restriction of access to Patient 1's radiologic exam in the electronic medical record (PACS system) was performed by the Director of Radiology.
- Immediate restriction to Patient 1's paper medical record was performed by the Director of Health Information.

Licensing and Certification Division

Kathy Foster RN
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Vice President TITLE
Emilia de Risk "Quality"
11/23/11 (05) DATE

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA000014385	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 01/24/2011
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A 017	<p>Continued From page 1</p> <p>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.</p> <p>This Statute is not met as evidenced by: Based on record review and interview, the facility failed to maintain the privacy and confidentiality of Patient 1's medical record. Two hospital employees (Employee A and Employee B), inappropriately accessed Patient 1's electronic medical records without the authorization of the patient.</p> <p>Findings:</p> <p>On January 24, 2011, an unannounced visit was made at the facility to investigate a facility reported incident regarding a breach in patient health information on [REDACTED], 2010. The facility letter to the Department dated December 6, 2010, indicated that there was an improper access to Patient 1's computed tomography (CT Scan) (imaging method that uses x-rays to create cross-sectional pictures of the body) results by two staff members.</p> <p>Patient 1's clinical record was reviewed on January 24, 2011, at 1:25 p.m. The Admission Face Sheet indicated Patient 1 was admitted to the facility on [REDACTED] 2010.</p> <p>The facility document titled "Conditions of Services to Downey Regional Medical Center," signed and dated by Patient 1 on [REDACTED]</p>	A 017	<ul style="list-style-type: none"> • Presentation to Department Managers on Federal and State regulations regarding protected patient information was provided on Dec. 2, 2010. • Employee A was interviewed and disciplined on Dec. 10, 2010. Employee A completed the corrective action as requested by the hospital on Jan. 14, 2011. • Employee B was interviewed and disciplined on Dec. 13, 2010. Employee B completed the corrective action as requested by the hospital on Dec. 23rd and Dec. 24th. • All employees were required to sign the revised Employee Nondisclosure Agreement. • All employees were required to complete the mandatory education on HIPAA and Health and Safety Code Section 1280.15 by June 30, 2011. <p>Permanent correction of the facility's failure to prevent unlawful or unauthorized access includes:</p> <ul style="list-style-type: none"> • All employees are required to sign the Employee Nondisclosure Agreement during their annual employee evaluation. • All employees are required to complete the mandatory education on HIPAA and

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A 017	<p>Continued From page 2</p> <p>2010 at 4:30 p.m., indicated the facility was committed to protecting the medical information about the patient. The facility would obtain the patient's written authorization to release information or other than basic information concerning the patient.</p> <p>The facility's statement of event dated December 8, 2010, indicated that two individuals had accessed the computed tomography (CT) exam (an imaging method that uses x-rays to create cross-sectional pictures of the body) of Patient 1 on [REDACTED] 2010 to confirm that Patient 1 had a CT exam done at the facility. The staff had accessed electronically the result of the CT scan of Patient 1.</p> <p>The Employee file for Employee A, a registered nurse (RN) was reviewed at 1:50 p.m. The "Employee Nondisclosure Agreement" dated July 4, 2010, was signed by Employee A. The document indicated "I will not access, review or view patient information without a direct need for that information in order to perform my job duties. I must have a "need to know the protected information" to obtain the information." A revised version of the form was signed by Employee A on December 8, 2010.</p> <p>A "Memorandum" dated December 10, 2010, was issued to, and acknowledged by, Employee A. The Memorandum indicated that Employee A was one of the staff members who opened the medical record of Patient 1, violating the facility's strict compliance policies with respect to the patient's privacy. The document indicated that as a healthcare professional, access to a patient's medical record should be within the course and scope of her job duties.</p>	A 017	<p>Health and Safety Code Section 1280.15 on an annual basis by June 30th.</p> <ul style="list-style-type: none"> • Director of Health Information/Privacy Officer provides information on HIPAA, DRMC's Patient Privacy Practices, and Health and Safety Code Section 1280.15 at new employee orientation and has employees sign the Employee Non-disclosure Agreement. • Director of Health Information/Privacy Officer provides high risk areas with HIPAA, DRMC's Patient Privacy Practices, and Health and Safety Code Section 1280.15 information at their departmental meetings. <p>A description of the monitoring process to prevent recurrence of the deficiency. Compliance will be monitored through systems and record audit as part of the Radiology Department's Performance Improvement program beginning on November 1, 2011.</p> <ul style="list-style-type: none"> • The Director of Radiology will analyze and oversee the audit results. • The monitoring measures include the following: <ol style="list-style-type: none"> 1. Review of access to Radiology PACS (Picture Archiving Communication System) by users and departments. 2. Purpose of the access to individual records. 	
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A 017	<p>Continued From page 3</p> <p>The Employee file for Employee B, radiology technologist, was reviewed at 2:33 p.m. The "Employee Non-disclosure Agreement" dated January 6, 2009, was signed by Employee B. The document indicated "I will not access, review or view patient information without a direct need for that information in order to perform my job duties. I must have a "need to know the protected information" to obtain the information." A revised version of the form was signed by Employee B on December 2, 2010.</p> <p>A "Memorandum" dated December 10, 2010, was issued to, and acknowledged by, Employee B. The Memorandum indicated that Employee A was one of the staff members who opened the medical record of Patient 1, violating the facility's strict compliance policies with respect to the patient's privacy. The document indicated that as a healthcare professional, access to a patient's medical record should be within the course and scope of her job duties.</p> <p>Employee C, was interviewed on January 24, 2011, at 2:20 p.m. He stated that he had asked a staff member to possibly change Patient 1's name on the hospital's computer as "also known as (AKA)" to protect Patient 1's identity. He was notified that Patient 1's radiology result was accessed by 2 employees without authorization. Employee C stated that during his interview with Employee A and Employee B, the reason given by both employees to the unauthorized access of the radiology result was "just to establish" that Patient 1 was at the facility.</p> <p>A letter sent by the facility to Patient 1, dated December 1, 2010, indicated the facility was informing Patient 1 that "two members of our facility staff accessed your medical record without</p>	A 017	<ul style="list-style-type: none"> Identified non-compliance with hospital policy and procedures will be immediately reported to the HIPAA Privacy and Security Officers for investigation and reporting. The audit results will be reported quarterly to appropriate medical staff and Quality Management System meetings. Monitoring will continue through December 31, 2012.

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A 017	<p>Continued From page 4</p> <p>authorization." The letter disclosed that the access was to Patient 1's radiologic exam in the electronic medical record at the hospital.</p> <p>The facility policy and procedure titled "Confidential Information" revised on January 6, 2011, indicated that the facility provides protection of patient confidential information as required by law. The discussion and/or release of confidential patient information must be limited to that which is necessary to conduct normal hospital business. The employees sign an Employee Non-Disclosure Agreement indicating the employee will not access, review or view patient information without a direct need for that information in order to perform his/her job duties.</p> <p>The facility policy and procedure titled "Privacy Practices" dated January 7, 2010, indicated the patients have the right to privacy and protected health information.</p> <p>Based on the findings, the facility's failure to prevent unlawful or unauthorized access to Patient 1's medical information and abide by the facility's "Confidential Information" and "Privacy Practices" policy and procedures is a violation of Health and Safety Code section 1280.15. subdivision (a).</p>	A 017		
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