POC accepted 8/7/09 cn

PRINTED: 06/11/2009
FORM APPROVED

California Department of Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000912	A. BUILDING _____ B. WING _____	05/29/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
USC UNIVERSITY HOSPITAL	1500 SAN PABLO ST LOS ANGELES, CA 90033

(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
E 000	Initial Comments	E 000	The incident cited in the Statement of Deficiencies occurred in September 2007 when the hospital was licensed to and operated by a subsidiary of Tenet Healthcare Corporation. The incident was corrected by the prior licensee on January 2008, before the initial survey visit.	Jan 2008
	The following reflects the findings of the Department of Public Health during a Complaint Investigation.			
	Complaint Intake Number CA00143480			
	Inspection was limited to the specific complaint investigated, and does not represent the findings of a full inspection of the facility.		The incident arose almost two years ago, and was followed by immediate corrective action. There has been no occurrence of any similar incident since phase one of the plans of correction was completed more than 20 months ago, in October 2007.	Oct 2007
	Representing the Department of Public Health: [redacted] Health Facilities Evaluator, Nursing			
	1280.1(c) Health & Safety Code Section 1280 For purposes of this section, "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.		The hospital is now under new ownership, the University of Southern California (USC), and has continued the monitoring plan in order to prevent recurrence of the incident.	
E 430	T22 DIV5 CH3 ART3-70243(f)(5) Clinical Laboratory Service General Requireme	E 430	The following is the plan of correction that CDPH has requested, for the notice dated June 11, 2009 for facility license number 930000459.	6-11-09
	(f) The director of the clinical laboratory shall assure that:			
	(5) A communications system to provide efficient information exchange between the laboratory and related areas of the hospital is established.			
	This RULE is not met as evidenced by: Based on interviews, review of administrative documents, and examination of a patient's medical records, the facility failed to ensure th			

[redacted] 6/24/09

LABORATORY DIRECTOR'S OR PROVIDER/SUPPL[redacted]'S SIGNATURE | TITLE | (X6) DATE

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E 430	Continued From Page 1	E 430	**How was the correction accomplished?**	

physician of record was alerted when it was discovered that an incorrect diagnostic pathology report was attached to the wrong patient and a new report with the corrected diagnosis had been submitted.

Patient 1 was being treated for infections and other complications of a fracture in the left leg. Preparing to implement another proposed course of treatment, tissue from Patient 1's left leg was collected and sent to the hospital's pathology laboratory for biopsy on 8/6/07. The results of that analysis identified the presence of an infection.

The pathology report for a biopsy performed on tissue from Patient 2's extremity was read and verified on 8/8/07. Patient 2's biopsy results diagnosed the presence of B-cell lymphoma. On 8/8/07, Patient 2's diagnosis of cancer was erroneously entered into Patient 1's medical record, and submitted to related areas of the facility via the laboratory's electronic system at 10:37 a.m. The error was discovered and Patient 1's correct diagnosis was re-submitted through the laboratory's electronic system at 10:49 a.m.

An examination of Patient 1's medical record on 7/28/08 produced no evidence the patient's physician, or other involved parties, were specifically made aware of the error and subsequent corrected diagnosis from the pathology lab.

Influenced by the diagnosis of cancer, Patient 1 elected to undergo a below-the-knee amputation of the left leg on 9/24/07. A post-surgical diagnostic pathology examination revealed "no malignancy" was present in the amputated leg.

The facility failed to ensure that a corrected

The plan of correction was initiated following the incident (September 2007), and required a technical fix to the hospital information reporting systems. The initial phase of the plan was completed in October 2007 in order to insure that corrected reports would appear first in the patient's medical record per policy #SP-127. — Oct 2007

The second phase of the plan of correction, including the revision of hospital policies and inservice education, was completed in January 2008. The cold feed function of the computer system-Cerner to EPF (electronic patient file) was discontinued as of January 15, 2008. A hard copy print out of Cerner pathology reports is now printed in HIM (Health Information Management) and is manually scanned, by HIM personnel, into the EPF system as part of the patient's permanent record. — Jan 2008

(Continued on Page 3)

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E 430	Continued From Page 2 biopsy report for Patient 1 was communicated in a manner that enabled the patient to make an informed decision about treatment versus amputation of the leg, based upon accurate information. The failure to ensure corrected laboratory test results were effectively communicated between the laboratory and related areas of the hospital resulted in amputation of Patient 1's leg. Findings: A review of the medical record of Patient 1 on 7/28/08 revealed a laboratory report indicating that on 8/7/07, at 8:02 a.m., a diagnostic analysis of tissue obtained from Patient 1's leg determined the patient had an "infection of lt. tibia." Employee E stated during an interview on 7/28/08, at 9:15 a.m., that a pathologist inadvertently entered Patient 2's biopsy results in Patient 1's record. The diagnosis of Patient 2's tissue collected on 8/1/07 identified the presence of cancer. On 8/8/07, at 10:37 a.m., Patient 1's verified pathology report reflected the diagnosis, "multiple myeloma...B-cell lymphoma." Employee A declared on 7/28/08, at 11:10 a.m., "Within minutes" the error was discovered, and Patient 1's accurate diagnosis of "infection of lt. tibia" was entered into the laboratory's electronic system on 8/8/07, at 10:49 a.m. Patient 2's diagnostic report had not been affected, and no correction was needed. On 7/28/08, at 11:50 a.m., Employee C disclosed the facility's computerized chart system documents in reverse chronological order (the newest report goes to the bottom), so the "oldest	E 430	When Pathology issues a corrected report, Pathology notifies HIM so that HIM personnel can remove the original report from EPF, HIM stamps original report with large "ERROR PLEASE DISREGARD. SEE CORRECTED REPORT", then HIM rescans the report with the proper subtitle. The corrected report is then signed by the Pathologist, a hard copy prints in HIM, and the HIM staff scans the revised report into the EPF system. These reports will now be getting inserted into their document\subtitle list, first to be seen. Please refer to attached policy number, SP-127, dated January 14, 2008. Education was completed for HIM and Pathology personnel when the policy was finalized on January 14, 2008.	1-14-08

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report stays on top." Employee D acknowledged at 11:55 a.m., on 7/28/08, that their system had no notification process that would alert medical personnel to the presence of additional lab results

A review of Patient 1's medical record, on 7/28/08, produced no evidence that facility staff were alerted to the erroneous, and subsequently corrected, diagnoses. The lab report itself did not contain notification that identified it as a revised or corrected report. Furthermore, there was no indication that any verbal or other communication was made to the physician of record, or to interested parties, alerting them to the change in diagnosis.

Both the erroneous and the corrected laboratory reports were processed through the facility's electronic system and entered automatically in Patient 1's record. All new chart entries were filed in reverse chronological order, with the most recent placed on the bottom. There was no system to specifically alert either the physician or any related parties of the presence of a corrected or new laboratory report.

When asked about the procedure for processing corrected reports, Employee F stated during an interview at 1:20 p.m. on 7/28/08, "We just send them through [the electronic system]; I figure it goes to Medical Records and filed as usual." Employee B added at 1:25 p.m. on 7/28/08, "We didn't have an actual process [for corrected pathology reports]."

Unaware that the diagnosis of cancer had been revised, Patient 1 signed a consent agreeing to a below the knee amputation (BKA) for "treatment of multiple myeloma and infection." That same day, on 9/24/07, Patient 1 underwent surgery for

The title or person responsible for the correction?

Director, Health Information Management (HIM)

A description of the monitoring process to prevent further recurrence of the deficiency:

As part of the weekly quality check on ten (10) randomly selected medical records (six inpatient and four outpatient), one of our quality indicators is the compliance with policy #SP-127-"Corrected Reports in Cerner Millenium and EPF," which is the policy that was implemented to address this issue. This audit is performed under the supervision of the HIM Supervisors, and is logged in a binder in the HIM Supervisor's office.

Date of Plan Completion:

Phase 1: October 2007.
Phase 2: January, 2008.

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the amputation of her left leg below the knee.

Further review of Patient 1's medical record revealed a biopsy report of the surgically excised limb, "fresh from surgery," on 9/24/07, yielded negative findings for cancer. The pathology report dated 10/2/07, verified at 8:26 a.m., there was "no malignancy seen" in the excised limb. It further confirmed the initial diagnosis of "infection of left tibia."

During an interview on 9/30/08, at 2:30 p.m., Patient 1 declared, "My doctor told me my leg infection was 'limb threatening', and I was doing everything to avoid that." The patient added, "I always fought amputation by doing every alternate treatment they suggested."

An examination of the patient's records supported evidence that Patient 1 repeatedly opted for treatments for the infected leg. Further review of the medical record showed one consultative report outlining the options of treatment versus a below the knee amputation, which Physician AA discussed with Patient 1 in October 2006, at that time Patient 1 "elected to proceed with limb salvage." Following the erroneous diagnosis of cancer, a physician's progress note documented on 8/15/07, "Patient has chosen to do trial of antibiotic treatment before opting for amputation..."

On 10/16/07, during an office visit, Physician AA informed Patient 1 of the error.

During an interview on 9/30/08, at 2:40 p.m., Patient 1 stated the diagnosis of lymphoma was "the motivating factor to decide on amputation."

Employee A disclosed in an interview on 5/25/09, that the physicians decided the amputation was a

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"good choice anyway," because Patient 1 had multiple left lower extremity infections since 2006.

The facility's policy and procedure entitled, "Critical Diagnoses (Critical Values) in Anatomic Pathology" (#SP-152), provided on 5/29/09, stipulated, "...occasional diagnoses in surgical pathology and cytology require urgent contact of the physician to facilitate rapid intervention or treatment." The policy established a process to identify diagnoses that "qualify as critical," and which required immediate communication to the clinician of record. None of the cases/diagnoses on the list addressed erroneous reports, such as what had occurred with Patient 1.

The facility failed to provide a process to ensure the efficient exchange of information whereby changes, addenda, or corrections of laboratory reports were effectively communicated to all related parties. This failure to ensure corrected laboratory test results were effectively communicated between the laboratory and related areas of the hospital resulted in amputation of Patient 1's leg.