

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 060454	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/18/2011
NAME OF PROVIDER OR SUPPLIER UCSF MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 505 Parnassus Ave, San Francisco, Ca 94143-2204 SAN FRANCISCO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00253999 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25730, 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 1280.1(c): 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.</p> <p>1279 1(b)(4)(A) Medication Error</p> <p>(b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following: (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.</p>		<p>The statements made in this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein.</p> <p>This Plan of Correction constitutes UCSF Medical Center's written credible allegation of compliance for the deficiencies noted.</p> <p>Corrective Action:</p> <p>On 12/10/10, the Hematology Blood and Marrow Transplant (HBMT) Manager counseled and re-educated in accordance with medical center policy the Nurse Practitioner (NP) about the requirements and process for allergy verification prior to ordering medications.</p> <p>On 12/15/10, the HBMT Manager counseled and re-educated the medical assistant involved in the incident on the correct method of verification of patient allergy.</p>	<p>12/10/10</p> <p>12/15/10</p>

CA DEPT OF PUBLIC HEALTH
APR 12 2012
L&C DIVISION
SAN FRANCISCO

Event ID: E2DJ11

3/12/2012

11:18:42AM

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

TITLE

(X6) DATE

John Caragay, RN MS Director Regulatory Affairs 4/9/12

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Spencer 4/12/12

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	<p>Continued From page 1</p> <p>T22 DIV5 CH1 ART3 - 70263 Pharmaceutical Service General Requirements</p> <p>(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative.</p> <p>T22 DIV5 CH1 ART3-70263(c)(1)</p> <p>(1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>These regulations were not met as evidenced by:</p> <p>Based on interview, observation, and record review, the hospital failed to check Patient 1's list of known allergies before prescribing an antibiotic for Patient 1, which resulted in Patient 1 suffering a severe anaphylactic reaction (allergic reaction) with prolonged hospitalization and inability to perform activities of daily living (ADLs).</p> <p>Findings:</p>		<p>Beginning in December 2010 and implemented in January 2011, the patient case load for NPs working in the clinic was modified and now consists of no more than 15 patients per 10 hour day and no more than 12 patients per 8 hour day. Also, the HBMT faculty added additional clinic days and hired more mid-level providers, including a physician assistant, to accommodate the change in the NP case loads.</p> <p>On 1/12/11, the HBMT manager gave a presentation to the clinic staff about the event, the practice issues that lead to the medication error and the changes made to the NP patient case load. Additionally, the manager re-educated the clinic staff and all providers about the correct use of electronic "Summary Time Oriented Record" (STOR) where allergy information is noted. STOR is an outpatient electronic health record.</p> <p>On 3/8/11, the Medical Director for Ambulatory Quality and Patient Safety presented the results of a survey conducted by UCSF Medical Center Patient Safety Program in the ambulatory practices using the Agency for Healthcare Research and Quality tool "Medical Office Survey on Patient Safety Culture". Following the presentation, the director met with clinic staff to reinforce concepts of patient safety.</p>	<p>12/2010 1/2011</p> <p>1/12/11</p> <p>3/8/11</p>

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	<p>Continued From page 2</p> <p>On 1/12/11 at 1:15 PM, the Licensing & Certification Coordinator (LCC) stated Patient 1 was a primarily Chinese-speaking woman being treated at the hospital's Hematology/Oncology Clinic for chronic leukemia. On [REDACTED] 10, the patient was examined in the Clinic by a Nurse Practitioner (NP) who gave Patient 1 a prescription for the antibiotic Amoxicillin and told Patient 1 that if she continued to have symptoms of an upper respiratory infection, Patient 1 should have the prescription filled and start taking the antibiotic as directed. The LCC stated that on [REDACTED] 10, Patient 1 was brought to the hospital's Emergency Room (ED) with symptoms of an anaphylactic reaction (difficulty breathing and loss of consciousness). Patient 1 was treated in the Intensive Care Unit (ICU) for several days on a ventilator and acute hemodialysis. Patient 1 was stabilized in the ICU and was then treated on an inpatient unit for approximately 21 days. Patient 1 was independent in all of her activities of daily living (ADLs - bathing, ambulating, toileting, dressing, etc.) prior to the anaphylactic reaction. The LCC stated that at the end of her inpatient stay, Patient 1 had not achieved this same level of independence so she was transferred to a skilled nursing facility (SNF) for additional rehabilitation.</p> <p>The LCC stated that during an interview with the Nurse Practitioner (NP) who prescribed the amoxicillin, NP stated she did not check the record for Patient 1's allergies before prescribing the amoxicillin. The LCC said the record indicated Patient 1 was allergic to ampicillin, an antibiotic in</p>		<p>In October 2011, during the transition to the new UCSF Medical Center electronic health record system known as "APeX" (which stands for Advancing Patient-centered Excellence), the pharmacy APeX team implemented a warning alert for allergies that displays when a provider attempts to prescribe a drug for which the patient has a documented allergy. The HBMt clinic will go-live with APeX in September 2012.</p> <p>Monitoring:</p> <p>On 4/6/11, the HBMt Manager completed an audit from the prior 4 month period of compliance with checking allergy information prior to ordering medications. The results of the audits were reported to Patient Safety Committee on 4/6/11.</p> <p>Compliance with allergy verification process with a focus on patient safety is a standing agenda item every other month for the Bone Marrow Transplant Team meetings.</p> <p>The HBMt Manager regularly reviews the NP patient case load to ensure compliance with the modified patient assignments.</p> <p>Responsible Party: Director of Nursing and Director of Pharmacy</p>	<p>10/2011</p> <p>4/6/11</p> <p>Ongoing</p> <p>4/6/11 and Ongoing</p>

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	<p>Continued From page 4 [REDACTED] 10/08.</p> <p>Record review indicated Patient 1 was transferred out of the ICU on [REDACTED] 11. On [REDACTED] 11 a Physical Therapy Initial Evaluation indicated Patient 1's previous level of activity was independent at home. She could ambulate one block independently with a single point cane or a front wheeled walker depending on how she was feeling. Patient 1 was able to climb and descend the twenty stairs to her apartment where she lived with her elderly husband.</p> <p>The Physical Therapy Evaluation determined Patient 1 had "impaired functional mobility 2/2 (secondary to) decreased strength, balance and endurance." This evaluation showed that on [REDACTED] 10 Patient 1 needed the moderate assistance of one person to go from lying down to sitting and then standing. She needed moderate assist of one person to transfer from bed to a chair. Patient 1's ability to walk or climb stairs was not tested at that time. The evaluation recommended Patient 1 be transferred to a Skilled Nursing Facility (SNF) for further mobility training prior to her discharge to home with her husband.</p> <p>Patient 1 received Physical Therapy (PT) treatments until [REDACTED] 10. The PT note of [REDACTED] 10 indicated Patient 1 was making steady progress but she still needed transfer to a SNF for continued PT. Patient 1 was discharged to a SNF on [REDACTED] 10.</p> <p>On 1/19/11 at 9:00 AM Patient 1 was wheeled, by the Nurse Manager (NM), from the dining room to her bedroom in a wheelchair with no foot rests.</p>	[REDACTED] 10/08.	<p>CA DEPT OF PUBLIC HEALTH</p> <p>APR 12 2012</p> <p>L&C DIVISION SAN FRANCISCO</p>	
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	<p>Continued From page 6</p> <p>The son stated the ambulance took Patient 1 to the facility's ED where they told him they thought his mother had an allergic reaction to the medicine (amoxicillin).</p> <p>Patient 1's son said his mother spent a week in the ICU and "went through a lot of pain and suffering." The son said they even put two holes in Patient 1's neck and gave her round-the-clock dialysis. The son said the specialists who came all commented the rash was the worst they had ever seen. The son said the rash was gone now so his mother doesn't itch all over anymore. He added that he doesn't think he would have survived everything his mother went through.</p> <p>The son confirmed his mother's assessment of her pre-hospital functional abilities and he thought she was close to that except she now needed a walker instead of a cane.</p> <p>Patient 1's son stated that her anticipated discharge date to home was 1/25/11, more than two months after taking the medication.</p> <p>In an interview on 1/19/11 at 9:45 AM, the Certified Nursing Assistant (CNA) caring for Patient 1 stated she (CNA) had regularly cared for Patient 1 since her admission to the SNF. The CNA stated that on admission Patient 1 needed help to stand and she could not walk to the bathroom (approximately 10 feet). The CNA stated Patient 1 now stands and walks to the bathroom independently. The CNA said Patient 1 bathes, dresses, and feeds herself</p>				

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	<p>Continued From page 7</p> <p>independently which she could not do on admission.</p> <p>Record review of Patient 1's Minimum Data Set (MDS) assessment dated 1/19/11 indicated Patient 1 still required limited assistance of one person to perform all of the areas of activities of daily living except eating which was supervision only, and locomotion on and off the unit which required more extensive assistance.</p> <p>In an interview on 9/9/11 at 8:30 AM, the Nurse Practitioner (NP) who prescribed the amoxicillin for Patient 1 stated she thought the medical assistant who had prepared the chart had checked the box for "No known allergies". The NP stated she usually asked patients if they had allergies before prescribing any new medications but the NP said she could not remember if she had asked Patient 1 about her allergies.</p> <p>Record review of Patient 1's [REDACTED]10 clinic visit indicated that on page 1 the section for allergies was marked "NKDA" (No known drug allergies). The medication list on page 4 of the clinic record indicated that Patient 1 was allergic to penicillin and amoxicillin. Both of those allergies were last updated on 2/21/07. The NP signed and dated page 4 on [REDACTED]10.</p> <p>The facility policy and procedure "Allergy Identification and Documentation" dated 11/07, stated "Medical staff (including Nurse Practitioners) must review patient records for allergy documentation prior to writing an order." This</p>			
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	<p>Continued From page 8</p> <p>policy also indicated that for outpatients, the documentation of allergies could be found on the medication list.</p> <p>The facility failed to thoroughly check Patient 1's record for medication allergies prior to prescribing a medication which was known to cause her to have an allergic reaction. As a result, Patient 1 suffered a severe anaphylactic reaction and she was forced to endure the pain and discomfort of multiple invasive medical interventions including intubation, a ventilator, acute hemodialysis, and wrist restraints to prevent her from discontinuing all of these tubes. This allergic reaction required two months of medical treatment and rehabilitation, leaving Patient 1 with some permanent functional deficits in her ability to walk.</p> <p>The facility's failure to follow its policy and procedure on Allergy Identification and Documentation, is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1.</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).</p>			

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