

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  03/29/2012
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: CA00281816 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25093, Pharmaceutical Consultant II</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>T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements</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</p>		<p>The statements made on this Plan of Correction are not an admission and do not constitute agreement with the alleged deficiencies herein. This Plan of Correction constitutes UCSF Medical Center's written credible allegation of compliance for the deficiencies noted.</p> <p>Plan of Correction: Institute electronic health record enhancements to reduce the opportunity to give live vaccines to potentially immune compromised patients. On June 27, 2011, an electronic health record (EHR) was implemented in the UCSF Teen Clinic that replaced the paper records that were in use prior to that date. Since then, three significant and related EHR projects have been completed to improve the safety of live vaccine administration and to reduce the risk that an immune compromised patient might get a live vaccine. The first of the three had multiple components. Starting in December 2011, providers and staff were trained on the best approach to use existing functionality to document live vaccine contraindications. Hovering over "allergies" on the patient banner was enhanced to show all allergies and medication/immunization contraindications for the patient. All live vaccine orders were modified to include "Live Vaccine" in their display name as a reminder to the ordering providers to consider the risks of ordering a live vaccine.</p>	<p>6/2011</p> <p>12/2011</p>

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

*Kathryn Radius* Regulatory Manager

TITLE (X6) DATE

10/20/14

By signing this document, I am acknowledging receipt of the entire citation packet, *Enacted 1 thru 10*

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 discloseable 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 discloseable 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.

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	<p>such is appropriate.</p> <p>This Statute is not met as evidenced by:</p> <p>Based on interview and record review, the hospital failed to develop policy and procedures on the safe and effective use of vaccines to ensure patient safety. Patient 1 was administered varicella (chicken pox) vaccine, a live virus vaccine, on [redacted]/11 in the presence of clinical contraindications as indicated by the manufacturer and CDC (the Centers for Disease Control and Prevention) including immunodeficiency, concurrent intravenous immunoglobulin therapy and chronic prednisone (a corticosteroid immunosuppressant) therapy. The inappropriate use of varicella vaccine caused Patient 1 to contract varicella infection of both eyes which required hospitalization and multiple eye surgeries and resulted in loss of vision (blindness) of the right eye and retinitis (inflammation of the retina, the innermost coat of the posterior part of the eyeball that receives the image produced by the lens) of the left eye.</p> <p>Findings:</p> <p>A review of Patient 1's clinical record showed that the patient had a complex medical history including Common Variable Immune Deficiency (CVID) which was managed with intravenous immunoglobulin (IVIG) therapy and inflammatory bowel disease which was</p>		<p>Once the contraindications were documented, any future attempt at ordering a live vaccine for an immune compromised patient triggered both an alert to the ordering provider and to the nurse who would be tasked to administer the vaccine. The second project focused on further enhancing the BHR so that any provider who attempted to order a live vaccine for a patient with a known diagnosis or medication use that could compromise their immune system would get a live vaccine contraindication alert even if the contraindication wasn't manually documented in the allergy and contraindication activity in the BHR.</p> <p>UCSF partnered with a medication information vendor First Data Bank to create and implement that system. The work started in the fall of 2011 and was fully implemented on May 20, 2013. And finally, the BHR was enhanced to remind providers and patients of their need for preventive care measures including vaccines. In order to avoid an inappropriate reminder for a live vaccine, a procedure was implemented with the reminder system to first manually and then systematically to exclude immune compromised patients and their providers from seeing or receiving reminders for contraindicated live vaccines. Training documents were used for the training to support the first BHR project to improve the safety of live vaccine administration. The strategy was developed by the Live Vaccines in APoX Committee which completed its recommendations on October 11, 2011.</p>	<p>10/2011 05/2013  10/2011</p>

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	<p>managed with prednisone, a steroid anti-inflammatory medication. Common Variable Immune Deficiency (CVID), also known as hypogammaglobulinemia, is an immune system disorder in which an individual has low levels immunoglobulins (antibodies) that help to fight infections. Intravenous immunoglobulin (IVIG) therapy is indicated for the management of patients with primary immunodeficiency such as common variable immunodeficiency (CVID). IVIG is a sterile preparation of concentrated antibodies extracted from healthy donors to be administered intravenously (into a vein). Patient 1's immunization record showed positive serologic test on [REDACTED]/09 for varicella antibodies which indicated the patient already had immunity against varicella virus at that time.</p> <p>A copy of an electronic mail (email) dated [REDACTED]/09 by Physician 2, a pediatric rheumatology physician, was found in Patient 1's clinical record which showed the following:</p> <p>" He (Patient 1) should get all his killed virus vaccines only."</p> <p>Varivax® is a live varicella virus vaccine. According to the Centers for Disease Control and Prevention (CDC) publication " Epidemiology and Prevention of Vaccine-Preventable Diseases ", live vaccines are derived from " wild, " or disease-causing, viruses or bacteria. These wild viruses or bacteria are attenuated, or weakened, in a</p>		<p>The EHR build and training documents were completed in November 2011 and during the month of December, they were used to train the primary care EHR super user groups, used for regular training updates including "Knowledge at Noon" sessions, used in practices that administer vaccines and in practices that care for patients who are immune compromised, and were incorporated into all standard EHR training for new clinical staff and providers. No new training was required for the second and third EHR projects to improve live vaccine administration safety because they are part of the basic training received to use the EHR.</p> <p>Monitoring:</p> <p>A medication alert audit, which included the live vaccine alert, was conducted in December 2013 by Pharmacy and reported to Chief Medical Information Officer and his leadership team of physician informaticists, the Office of the CMIO (OCMIO). In July 2014 an audit of medication alerts, which included the live vaccine alert was completed and will be reported to the Chief Medical Information Officer and OCMIO in October 2014.</p> <p>Responsible Party: Medical Director of Ambulatory Informatics, Director of Medication Outcomes Center, Chief Pharmacy Officer</p>	<p>10/2011</p> <p>12/2013</p> <p>07/2014</p> <p>10/2014</p>

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	<p>laboratory, usually by repeated culturing. To produce an immune response, live attenuated vaccines must replicate (grow) in the vaccinated person. A relatively small dose of virus or bacteria is administered, which replicates in the body and creates enough of the organism to stimulate an immune response. Live attenuated vaccines may cause severe or fatal reactions in immunosuppressed persons due to uncontrolled replication (growth) of the vaccine virus. Persons receiving larger doses of corticosteroids should not receive live vaccines including persons receiving 20 milligrams or more of prednisone daily or 2 or more milligrams of prednisone per kilogram of body weight per day for 14 days or longer. Screening for contraindications and precautions is key to preventing serious adverse reactions to vaccines. Every provider who administers vaccines should screen every patient before giving a vaccine dose. Laboratory evidence of immunity or laboratory confirmation of disease is an evidence of immunity to varicella. A contraindication is a condition in a recipient that increases the chance of a serious adverse reaction.</p> <p>A review of the prescribing information of Varivax® by Merck indicated the following:</p> <p>1. Contraindications:</p> <p>- Do not administer Varivax® to immunosuppressed or immunodeficient</p>		<p>Plan of Correction:</p> <p>The Vaccine Administration Policy was revised in April 2012 to include screening process by providers including allergies, contraindications, and vaccination eligibility based upon established criteria; providers must order appropriate vaccines or document the reason for not ordering required vaccines; storage and dispensing of vaccines according to manufacturer requirements and in compliance with federal and state regulations.</p> <p>Monitoring:</p> <p>To monitor ambulatory compliance, a vaccine administration audit was done by ambulatory clinic leadership during the 4/2012 - 6/2012 timeframe and reported to the Ambulatory Patient Care Director on 4/24/12, 5/15/12 and 7/16/12. An additional compliance audit has been planned for fourth quarter 2014; the results will be reported to the Patient Safety Committee.</p> <p>Responsible Party: Executive Director, Ambulatory Services &amp; Chief Pharmacy Officer</p>	<p>04/2012</p> <p>04/2012-06/2012</p> <p>04/2012, 05/2012, 07/2012</p> <p>4th qtr 2014</p>

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	<p>individuals, including those with a history of primary or acquired immunodeficiency states.</p> <ul style="list-style-type: none"> <li>- Do not administer Varivax® to individuals receiving immunosuppressive therapy, including individuals receiving immunosuppressive doses of corticosteroids.</li> </ul> <p>Varivax® is a live, attenuated varicella-zoster vaccine (VZV) and may cause an extensive vaccine-associated rash or disseminated disease in individuals who are immunosuppressed or immunodeficient.</p> <p>2. Immune Globulins and Transfusions</p> <ul style="list-style-type: none"> <li>- Immunoglobulins should not be given concomitantly with Varivax®. Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin.</li> <li>- Following administration of Varivax®, immune globulin(s) should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination.</li> </ul> <p>Prednisone is a corticosteroid anti-inflammatory medication. The American Hospital Formulary Service (AHFS) Drug information, a comprehensive evidence-based source of drug information published by the American Society of Health-System Pharmacists (ASHP), indicates that prednisone is indicated for the treatment of a wide variety of diseases and conditions and is used</p>		<p>Plan of Correction:</p> <p>In October of 2011, a Vaccine Annual Review Training tool was created by ambulatory clinical leadership and distributed to all ambulatory nursing staff, Registered Nurses and Licensed Vocational Nurses, who administered vaccines. All ambulatory nursing staff, Registered Nurses and Licensed Vocational Nurses, who administer vaccines, were required to successfully complete the training and post-test. Compliance was tracked by Ambulatory Administration.</p> <p>In April of 2012, the Vaccine Training tool was fully integrated into the online Ambulatory Annual Review module that is completed by all ambulatory nursing staff annually.</p> <p>Monitoring:</p> <p>Compliance with the successful completion of the training and post-test is monitored on a monthly basis by Ambulatory Administration and reported out to the Ambulatory Patient Care Director. Status reports were presented to the Patient Safety Committee on 10/31/11, 12/13/11 and 4/23/12.</p> <p>Responsible Party: Executive Director, Ambulatory Services</p>	<p>10/2011</p> <p>04/2012</p> <p>12/2012 &amp; Ongoing</p> <p>10/31/11, 12/13/11, 4/23/12</p>

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	<p>principally as an anti-inflammatory and immunosuppressant agent. Concurrent administration of live or live, attenuated vaccines in patients receiving immunosuppressive doses of corticosteroids is contraindicated. The immunosuppressive effect of prednisone may cause an increase in susceptibility to infections secondary to glucocorticoid-induced immunosuppression. Certain infections (e.g. varicella, measles) can have a more serious or even fatal outcome in such patients.</p> <p>Patient 1 was seen by Physician 1 and Physician 3 at the hospital adolescent and young adult clinic on [REDACTED] 1. The progress note written by Physician 1 and Physician 3 indicated that Patient 1's maintenance medications included IVIG (intravenous immunoglobulin) therapy every 2 weeks and Prednisone 50 mg (milligrams) daily. Varicella vaccine (Varivax), a live virus vaccine, was ordered by Physician 1 and was administered and documented on Patient 1's vaccine order sheet on the same day. There was no documented clinical rationale for the order of the vaccine in the presence of multiple clinical contraindications and documented laboratory evidence of immunity to varicella from [REDACTED] 09. The ordering of a live vaccine also contradicted Physician 2's note dated [REDACTED] /09 which indicated that Patient 1 should only receive killed virus vaccines. In addition, there was no documentation addressing how Patient</p>		<p>Plan of Correction:</p> <p>In October of 2011, the vaccine administration process was revised and the Vaccine Information Statement (VIS), which is provided to patients/families, was handed to patients/families as the patient was roomed to ensure that patient/parent had ample time to review the VIS prior to any vaccine being administered.</p> <p>Monitoring:</p> <p>To monitor compliance, a Vaccine Administration audit was done by Ambulatory clinic leadership during the 4/2012 - 6/2012 timeframe and reported to the Ambulatory Patient Care Director on 4/24/12, 5/15/12 and 7/16/12. Status reports were presented to the Patient Safety Committee on 10/31/11, 12/13/11 and 4/23/12 and 7/20/12.</p> <p>In 2014, from 1/2014 through 4/2014 the Regulatory Department conducted an audit of Pediatric Clinics to monitor compliance with the process of providing the Vaccine information Statement to patients/families at patient rooming. The results were presented to the Patient Safety Committee on 06/04/14.</p> <p>Responsible Party: Executive Director, Ambulatory Services.</p>	<p>10/2011</p> <p>04/2012-06/2012</p> <p>04/2012, 05/2012, 07/2012</p> <p>10/2011, 04/2012, 07/2012</p> <p>01/2014-04/2014</p> <p>06/2014</p>

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	<p>1's chronic IVIG therapy may affect the effectiveness of the varicella vaccine.</p> <p>Patient 1 developed redness in eyes which progressed to blurred visions and foreign object sensation in [REDACTED] 2011 and was referred to the hospital on [REDACTED] for possible viral conjunctivitis (infection of the membrane lining the eyelids) Iritis (swelling and irritation of the uvea, the middle layer of the eye) with retinal involvement. During the hospital course, Patient 1 was diagnosed with bilateral (both side) varicella zoster virus retinitis (inflammation of the retina in the eye) and progressive outer retinal necrosis (the death of cells in living tissue) with bilateral increased intraocular (inside the eye) pressure. Patient 1's viral eye infection was treated with laser therapy for retinal detachment, antiviral implant in the right eye, injection of antiviral medications into the eyes and intravenous (into the vein) antiviral medications. Patient 1 also underwent multiple eye surgeries of both eyes.</p> <p>A laboratory report by the Division of Viral Diseases of the Centers for Disease Control and Prevention (CDC) dated [REDACTED]/11 indicated that the results of Patient 1's vitreous culture (a culture of the clear gel that fills the space between the lens and the retina of the eyeball) was positive for varicella zoster virus DNA (genetic material) by PCR (polymerase chain reaction, a biological technology). The report further indicated that the zoster virus (VZV) DNA detected in Patient 1's specimen was</p>		<p>Plan of Correction:</p> <p>The Immunization Patient Screening Questionnaire, which identifies possible contraindications for vaccine administration, and is used by nurses to screen patients on nurse only visits. A nurse only visit is a visit where the patient receives a provider ordered vaccine but sees the nurse for the vaccine administration visit. The questionnaire was revised in October 2011 with a plan to implement the tool into the electronic medical record. Nurse training on utilizing the Immunization Patient Screening Questionnaire in the electronic medical record was conducted in March 2012. The education consisted of a video to provide training to the nursing staff on documenting vaccines in ApeX and a tip sheet. On 4/23/2012 the Immunization Patient Screening Questionnaire questions went live in ApeX.</p> <p>Monitoring:</p> <p>To monitor compliance, a Vaccine Administration audit was done by Ambulatory clinic leadership during the 4/2012 - 6/2012 timeframe and reported to the Ambulatory Patient Care Director on 4/24/12, 5/15/12 and 7/16/12. Status reports were presented to the Patient Safety Committee on 10/31/11, 12/13/11 and 4/23/12 and 7/20/12.</p> <p>Responsible Party: Executive Director, Ambulatory Services</p>	<p>10/2011</p> <p>03/2012</p> <p>04/2012</p> <p>04/2012-06/2012</p> <p>04/2012</p> <p>05/2012</p> <p>07/2012</p> <p>10/2011, 12/2011, 04/2012, 07/2012</p>

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	<p>identified as the vaccino strain which indicated that the varicella zoster virus that Patient 1 contracted was the same strain that was in the varicella vaccine.</p> <p>Patient 1 was discharged from the hospital on [REDACTED]/11. Patient 1's discharge medications included intravenous acyclovir (an antiviral medication) and 6 new eye drops which the patient was not on prior to contracting the infection including brimonidine (an eye drop for the management of open-angle glaucoma, a condition of increased pressure inside the eye), Cosopt ( a combination eye drop for the management of increased pressure inside the eye), homatropine (eye drop for the management of uveitis), prednisolone (an anti-inflammatory eye drop), Polytrim (an antibiotic eye drop) and Xalatan (an eye drop for the management of increased pressure inside the eye) for the management of the patient's clinical condition.</p> <p>A document of a consultation with Ophthalmologist 1 dated [REDACTED] 12 indicated that Ophthalmologist confirmed that Patient 1 had retinitis in the left eye and loss of vision in the right eye as a result of the varicella zoster virus infection. Ophthalmologist 1 also stated that it was possible that Patient 1 might develop a glaucoma condition (increase in ocular pressure which may lead to damage to the optic nerve) and might require cataract surgeries sooner than otherwise had the patient not developed the infection.</p>			

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	<p>During an interview at approximately 12:05 p.m. on 9/9/11, Administrative Staff 2 stated that laboratory test results confirmed that Patient 1 developed varicella secondary to the varicella vaccine administered in 2011. It was not a community acquired varicella infection.</p> <p>During an interview at approximately 10:10 a.m. on 9/20/11 in the presence of Administrative Staff 2, Physician 1 stated that he was not aware of Patient 1's positive varicella immunity test dated 2009 when he ordered the varicella vaccine on 2011. Physician 1 also stated that the decision to vaccinate Patient 1 with varicella vaccine appeared to be a wrong decision when he retrospectively reviewed Patient 1's clinical record.</p> <p>During an interview at approximately 10:30 a.m. on 9/20/11, Administrative Staff 1 stated that the hospital did not have a written policy and procedures on the administration of vaccines in clinics. Administrative Staff 1 added that unlike medication orders in the hospitals, vaccine orders in clinic were not required to be reviewed for appropriateness by a pharmacist prior to administration.</p> <p>During an interview at approximately 10:00 a.m. on 3/27/12, Licensed Vocational Nurse 1 (LVN 1) of the adolescent and young adult clinic stated that a patient screening</p>			

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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		
(K4) 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)	(K5) COMPLETE DATE	
	<p>questionnaire was developed and implemented effective 8/26/11 to screen patients for any contraindications to vaccination. LVN 1 added that prior to the implementation of the questionnaire, LVNs were not required to screen patients for contraindications prior to vaccine administration. LVN 1 also stated that she was not aware of any hospital policy and procedures on patient screening prior to vaccine administration and she was not familiar with the effect of immunodeficiency on vaccine administration prior to Patient 1's incident.</p> <p>The failure of the hospital to develop and implement policies and procedures to ensure the safe and effective use of vaccines resulted in Patient 1 contracting varicella infection and suffered loss of vision due to the administration of varicella vaccine while clinically contraindicated. The violation of licensing requirement had caused serious injury to the patient, and therefore constituted 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>				

Event ID: 8QMY11

9/28/2014

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DEPARTMENT OF PUBLIC HEALTH