California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000034	A. BUILDING _____ B. WING _____	C 09/26/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHILDRENS HOSP OF LOS ANGELES	4650 SUNSET BLVD LOS ANGELES, CA 90027

(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 Los Angeles County Department of Public Health during the investigation of an entity reported event. Intake Number: CA00281069 Representing the Department of Public Health: [redacted] Pharm.D., Pharmaceutical Consultant The inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility. 1280.1(c) Health and Safety Code Section For purposes to this section, "Immediate Jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused or likely to cause, serious injury or death to the patient.	A 000	Corrective actions for deficiencies noted have been implemented and completed.	
A 334	CCR TITLE 22 DIV5 CH1 ART3 -70263(c) Pharmaceutical Service General Requirements (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. (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	A 334		

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A 334	Continued From page 1 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. (2) The committee shall be responsible for the development and maintenance of a formulary of drugs for use throughout the hospital. This Statute is not met as evidenced by: Based on review of the facility and clinical records, and interview with staff, the facility failed to protect Patient 1 from an adverse medication consequence. The facility failed to consistently implement and establish policies and procedures for the safe and effective use of an antifungal agent, amphotericin B (for treatment of severe systemic fungal infection). The facility failed to ensure the correct medication dosage form and strength were ordered, prepared, and administered for Patient 1. On [redacted] 2011, at 8:29 a.m., the prescribing physician, Physician 1, ordered "amphotericin B, conventional" (generic for Fungizone, also called amphotericin B injection, it has a maximum limit for a single daily dose of 1.5 milligrams [mg] per kilogram [kg] of patient's weight) 375 mg for Patient 1. Based on the patient's weight, 74.4 kg, the physician's order required Patient 1 to receive approximately 5 mg per kg of the medication mentioned above, which would be more than three times over the maximum dosage limit. The pharmacy staff failed to recognize the dosing irregularity and the administering nurse failed to verify safe dose calculation. The patient received 375mg at 10:15 a.m., subsequently experienced a cardiac arrest and expired at 1:15 p.m. A review of Patient 1's death certificate revealed	A 334	The first deficiency cited states that the facility failed to protect Patient 1 from an adverse medication consequence. In response to this deficiency, the facility has eliminated the ability to order amphotericin B conventional for intravenous use in our Computerized Provider Order Entry (CPOE) System. This was completed on 7/28/2011 by the Director of Pharmacy. The second deficiency cited states that the facility failed to consistently implement and establish policies and procedures for the safe and effective use of an antifungal agent, amphotericin B. As stated above, the ability to order amphotericin B conventional for intravenous use in our Computerized Provider Order Entry (CPOE) System is no longer an option. This was completed on 7/28/2011 by the Director of Pharmacy. Additionally, Amphotericin B liposome is now the first medication to be seen in CPOE ordering pick list. This was completed on 08/09/11 by the Director of Pharmacy.	

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A 334	Continued From page 2 the immediate cause of death as cardiac arrest. Findings: On September 15, 2011, an investigation was conducted of an entity reported incident involving a medication error that resulted in an adverse medication consequence. A review of the clinical records revealed Patient 1 was admitted on [redacted] 2011, for a bone marrow transplant. Patient 1's diagnoses included, but were not limited to, acute myeloblastic leukemia (a cancer of the blood and bone marrow) and pulmonary aspergilloma (a mass caused by a fungal infection that grows in the lung cavity). A review of the electronic physician order dated [redacted] 2011, at 8:29 a.m., indicated "amphotericin B, conventional" (generic for Fungizone, it has a maximum limit for a single daily dose of 1.5 mg per kg of patient's weight) 375 mg IV (intravenous) Q24H (every 24 hours) was ordered by physician 1 for Patient 1. Based on the patient's weight on record, 74.4 kg, the physician's order required Patient 1 to receive approximately 5 mg per kg of the medication, which would be more than three times over the maximum dosage limit. According to the director of pharmacy (DOP), a communication box, titled "black box warnings" would pop up during the prescription ordering process for amphotericin B, conventional. A review of the "pop-up" communication screen shot, provided by the DOP during the investigation, prompted the prescriber to "verify that the dose does not exceed 1.5mg/kg." A review of Patient 1's electronic pharmacy record, under "Patient Note," dated [redacted] 2011,	A 334		

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A 334	Continued From page 3 at 8:36 a.m., disclosed Pharmacist 1 noted Ambisome (brand name for the liposomal preparation of amphotericin B, which has a normal dosage range of 3 to 5 mg per kg, [http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f7be6506-4d20-401e-a0ff-02ad7c33158a]) was approved by one of the infectious disease specialists (ID). The same record, under "Inquire intermittent order" (according to the DOP, this would be the screen the verifying pharmacist uses during order verification and obtaining approval from the ID), revealed amphotericin B conventional was being processed. The screen print revealed notations of "equiv. to Fungizone" and "amphotericin B". During an interview, on September 15, 2011, at 1:30 p.m., the DOP agreed the pharmacists missed opportunities to correct the medication error during the verification process. The pharmacist failed to notice the medication order being processed was not for the Ambisome as approved by the ID. A review of the facility's policy and procedure, numbered "PHARM-43.0", titled "Compounding Sterile Products," dated April 2009, under "Procedure" item III. 7., revealed "all finished [compounded sterile products] must be checked by a pharmacist prior to dispensing ..." Under item III 8.2.1., the policy stipulated "the pharmacist must ensure that the drug, dose, concentration and volume are correct." A review of Patient 1's clinical record, titled "medication details," documented, the registered nurse administered the amphotericin B (conventional) 375 mg on [redacted] 2011, at 10:15 a.m.	A 334	The third deficiency cited states that the facility failed to ensure the correct medication dosage form and strength were ordered, prepared and administered for Patient 1. In response to this deficiency the facility feels that the changes made to the CPOE system on 7/28/2011 and 8/9/2011 correct the cited deficiencies. The fourth deficiency cited states that the pharmacy staff failed to recognize the dosing irregularity and the administering nurse failed to verify safe dose calculation. Amphotericin B Conventional is a formulation rarely used intravenously. The pharmacist was unfamiliar with the different formulations of Amphotericin B. The terms "Amphotericin B" and "AmBisome" are commonly used without distinction in conversation, leading to the misperception that they are interchangeable. Education provided to all pharmacists and pharmacy technicians regarding safe medication dispensing practices which included information on the different formulations, toxicities, dosing and administration of	

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A 334	Continued From page 4 During an interview, on September 15, 2011, at 12:15 p.m., the bone marrow specialist, who was part of the team for the care of Patient 1, stated Physician 1 intended to order Ambisome. She also stated physicians at the facility often refer to Ambisome as amphotericin B. During an interview, at 1:50 p.m., Physician 2 and the pediatric residency program director confirmed all resident physicians, including Physician 1, received training on the electronic prescription ordering system, including the ordering process and black box warnings. However, the system did not require acknowledgement or documentation of acknowledgement for such warnings. The system also did not log alerts. The pop-up communication box for any warnings would disappear upon hitting the "enter" button on the keyboard. A review of the facility's policy, PHARM-46.0, titled "High alert medication (including LASA and black box warnings medications)", dated July 2008, under item G. 3. i.," <BLKBOX> ...indicate the drug has a black box warning." Also, the policy, under "definition" , indicated "Black box warnings are FDA (Food and Drug Administration) warnings for healthcare providers of potentially life-threatening complications associated with specific medications ... " Under Table 1 of the same policy, it stipulated "orderable search restricts the selection of amphotericin B to conventional amphotericin. Ambisome and Abelcet have to be ordered by their brand name." During a telephone interview on September 26, 2011, at 4:30 p.m., RN 1, the registered nurse who administered the amphotericin B to Patient 1,	A 334	Amphotericin B and the recent changes made within CPOE system beginning 08/29/11 through 09/02/11 by the Director of Pharmacy. With regards to the administering nurse failing to verify safe dose calculation, education regarding safe practices for medication administration and the "Five Rights" was provided to nursing staff on 8/5/11, 8/30/11 by the Chief Nursing Officer and the Director of Pharmacy. Additionally, three Patient Care Services (PCS) "Grand Rounds" were held throughout the months of October and November regarding the importance of "Five Rights". The fifth deficiency cited states that the pharmacist failed to notice the medication order being processed was not for AmBisome as approved by ID. As stated previously, Amphotericin B and AmBisome are commonly used interchangeably, leading to this misunderstanding. The education provided to the pharmacy staff from 8/29/11 through 9/2/11 by the Director of Pharmacy addresses this deficiency. Additionally, a computer was placed in the IV room where the pharmacist was working to ensure that staff can verify the correct information. This was completed on 7/29/11 by the Director of Pharmacy.	

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A 334	Continued From page 5 stated she was not aware of the difference between the conventional form and liposomal form of amphotericin B. She also stated she did not double check the dose because of Patient 1's critical condition and urgent situation. Furthermore, she stated she later learned that the dose given was approximately 3 times higher than recommended. A review of the facility's policy and procedure, numbered "CC-193.0" , titled "Administration of intravenous fluids and continuous medications," item 2.E. stipulated "the RN must verify safe and therapeutic dose calculation before administration and be aware of the rationale for the medication." Under item 2.M.3., the procedure stipulated "verification of orders for IV fluids and medications to be carried out by RN include to check the following: ... safe and therapeutic dose for weight/BSA (body surface area) of the patients." According to Dailymed, (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a0a54943-9ce4-4f3e-b681-a1a9144c16ce#nlm34066-1), amphotericin B (conventional) "should not be given in doses greater than 1.5 mg/kg ...exercise caution to prevent inadvertent over dosage, which may result in potentially fatal cardiac or cardiopulmonary arrest." The facility's failure to ensure consistent implementation and establishment of current policies and procedures for the safe and effective use of amphotericin B, 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.	A 334	Additional and ongoing education has been provided to the pediatric residents. On 9/14/11, under the direction of the Director of Pharmacy and the Medical Director of the Residency Program, an ongoing educational initiative was started between the pediatric residents and the Pharmacy. Pharmacy meets weekly with pediatric residents to review errors with medication orders. Additionally, three times per year all house staff will participate in a medication error awareness workshop with Pharmacy. This workshop will include ordering protocols and common medication error orders. The Director of Pharmacy will be ultimately responsible for implementation of all corrective actions and ongoing monitoring of compliance.	