.NT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION N OF CORRECTION COMPLETED **IDENTIFICATION NUMBER:** A. BUILDING C B. WING CA070001349 12/20/2010 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 725 WELCH ROAD LUCILE SALTER PACKARD CHILDREN'S HSP PALO ALTO, CA 94304 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 000 E 000: Initial Comments The following reflects the findings of the California Department of Public Health during investigation of an entity reported incident completed on 12/20/10. CALIFORNIA DEPARTMENT For entity reported incident CA00247777 OF PUBLIC HEALTH regarding a Medication Error, state deficiencies were identified (see California Code of AUG 2 4 2011 Regulations, Title 22, Sections 72015(b). 70263(g)(2), and California Health and Safety L & C DIVISION Code, Section 1280.1(c)). SAN JOSE Inspection was limited to the specific entity reported incident and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health: 09714. Health Facilities Evaluator Nurse. E 294 E 294 T22 DIV5 CH1 ART3-70215(b) Planning and COMPLETE CORRECTIVE ACTIONS FOR PATIENT DATE Implementing Patient Care /10 Patient seizures ceased Patient continued on anticonvulsant (b) The planning and delivery of patient care shall medications. reflect all elements of the nursing process: Seizure precautions implemented for patient. assessment, nursing diagnosis, planning, CORRECTIVE ACTIONS FOR OTHER intervention, evaluation and, as circumstances POTENTIAL PATIENTS require, patient advocacy, and shall be initiated Nurse Manager/CNS reviewing with 90% of 11/24/2010 by a registered nurse at the time of admission. CVICU RN's during education huddles the need for updating care plans as patient clinical condition changes or at least every 24 hours. This Statute is not met as evidenced by: Changes include seizures, abnormal test results Based on interviews and record review, the or values as well as clinical condition. nursing staff failed to revise the care plan for one sampled patient (1) who developed abnormal electrolytes and seizures. Findings: Record review on 12/15/10 indicated Patient 1 was a newborn admitted to the hospital on '10. The patient had surgery on 110 to repair a congenital heart defect. On 710 at Licensing and Certification Division (X6) DATE DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE STATE FORM Q2P411

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CL IDENTIFICATION NUMBER CA070001349			(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED C 12/20/2010		
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E 294	3:30 a.m., the paticindicated a low chl milliequivalents/lite 96-106 mEq/L. The ammonium chlorid be given every two abnormal level of a condicated the first is ammonium chlorid about 2:35 p.m. To indicated the paticinated the paticinated the start of the chloride. The infunctional continued to have indicated a second chloride was infus. On 100 micromoles newborn is 100-20 a.m. the ammonial liter. The nursing inflow sheets on seizures at 2:47 period developed to addrabnormal laborated to have additional ordered anticonvolutional ord	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) ontinued From page 1 30 a.m., the patient's laboratory results idicated a low chloride level of 88 illiliequivalents/liter (mEq/L.) Normal range is 6-106 mEq/L. The physician ordered 5 mEq of mmonium chloride at 12:14 p.m. on 1/10 to be given every twelve hours to treat the patient's bnormal level of chloride in the blood. The medication administration record (MAR) indicated the first intravenous (IV) dose of mmonium chloride was infused on 1/10 at bout 2:35 p.m. The nursing note on 1/10 at bout 2:35 p.m. The nursing note on 1/10 indicated the patient had a seizure 15 minutes fiter the start of the first dose of ammonium chloride. The infusion was stopped. The patient ontinued to have additional seizures. The MAR indicated a second IV dose of ammonium chloride was infused on 1/10 at 11:30 p.m. In 1/10 at 3:25 a.m., laboratory results indicated Patient 1's ammonia level was over 000 micromoles per liter. Normal range for a ewborn is 100-200 micromoles per liter. At 7:30 m. the ammonia level was 538 micromoles per leter. The nursing notes and the intensive care		E 294	IMMEDIATE MEASURES AND SYSTEMIC CHANGES TO MITTIREOCCURRENCE Identified improvements lead to the actions taken: Nurse Manager/CNS conducted wee plan tracers for 5 weeks reviewing of for 4 RN's each week to validate corwith updating care plans every 24 houpdating as patient clinical condition Results reported to Nurse Manager a organization wide Regulatory Overs Readiness Committee and Chapter I Group with monthly reporting to VP Committee. PERFORMANCE MONITORING PROCESS Nurse Manager/CNS conducted wee plan for tracer for 5 weeks reviewing for 4 RN's each week to validate cowith updating care plans every 24 houpdating as patient clinical condition Nursing Care Plan tracers occurring 2011, performed by Quality. Results reported to Nurse Manager organization wide Regulatory Overs Readiness Committee and Chapter I Group with monthly reporting to VI Committee. PERSON RESPONSIBLE FOR MONITORING AND HOW RES WILL BE REPORTED OUT Nurse Manager/CNS conducted we plan tracer; Quality performing monplan tracer. Results reported out to Director of I VP/CNO of Nursing. Results reported to organization with Regulatory Oversight Readiness Coand Chapter Leader Group with monter Leader Group with monter Porting to VP Operations Commit Regulatory Oversight Readiness Coand Chapter Leader Group with monter Porting to VP Operations Commit Reporting to VP Operations Commit Reported to Operations Commit Reporting to VP Operations Commit Reported to Operations Commit Reporting to VP Operations Commit Reported to Operations Commit Reported to Operations Commit Reported to Operations Commit Reported to Operations Commit Reported	kly care are plans impliance ours and in changes. Indicate of the properations of the properation	11/24/2010
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ş t	frequency of updat than every 24 hour	ing the care plan mo	re often				1	
E 485				E 485	CORRECTIVE ACTIONS FOR PATIENT		COMPLETE DATE	
	Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. (2) Medications and treatments shall be administered as ordered.		ept by ister awfully shall not drugs by nclude the requency ration, if signature or drugs prescriber all be ed to led d, noting al order iving the		Patient seizures ceased Patient continued on anticonvulsant medications. Laboratory results followed for abnormal levels. CORRECTIVE ACTIONS FOR OTHER POTENTIAL PATIENTS 1. Computer-generated patient label was changed to more clearly specify "Dilution" on 10/26/10. 2. Products compounded by dilution are recorded on a dilution log implemented on 10/28/10. 3. Procedure was reviewed to remind staff that a technician must check the drug name and concentration and compare this to the patient label prior to preparing doses, completed by 11/2/10. 4. Competency training implemented to validate that all staff know how to prepare and verify that the correct druproduct is compounded, completed by 12/31/10. 5. Log initiated on 11/15/10 to record all products prepared in the IV room. Log will include patient identification, and		All corrective actions identified implemented by 12/31/10	
	HSC 1280.1(c) Fo "Immediate Jeopa the licensee's non requirements of licensee"	t met as evidenced by purposes of this se or purposes of this se ordy" means a situation compliance with one censure has caused, injury or death to the	or more or is likely		manufacturer, and lot num 6. Use of cell phones, intern during work hours will be work-related issues only, on 10/28/10.	et, and e-mail restricted to		

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Based of for Patinhospital pharmal chloride The supaccurate according Californ according dilution Recording was a repair a physicial ammore	ENCY CON RDY on interviewent 1 was not a pharmacy and a per manufacture of the horizontal properties of ammoniant review on a pewborn and the post a congenital an ordered	v and record review, not administered as of technician failed to it rechnician failed to it refor dilution of amifacturer's recommentarmacist failed to versital's policy to use f Pharmacy standard ospital pharmacy projum chloride. Finding 12/15/10 indicated Filmitted to the hospitatient had surgery on I heart defect. On 5 mEq (milliequivaled at 12:14 p.m. to be	medication ordered. A implement monium ndations erify medications e the distant distant and occurrent for gs: Patient 1 al on /10 to /10 the ents) of		 Dose Edge, workflow manager software has received hospital funding approval as of 10/29/10 and will be implemented in the IV room. This system promotes best-practice workflow in the IV and integrates drug verification, dose and dilution calculations, and provides an audit trail of doses prepared and checked. Ammonium Chloride supply labeled in RED with instructions: "MUST BE DILUTED", implemented on 11/2/10. In-service education for all pharmacists staffing inpatient pharmacy on the treatment of hypochloremic alkalosis including staff involved in occurrence, implemented on 12/23/10 and continues in 2011. Pharmacy newsletter to all staff on the use of Ammonium Chloride distributed in December 2010. Re-evaluate work flow and location of label printers occurred in December 2010. IMMEDIATE MEASURES AND 		
director been not drug she-mail with pharma reporte substitut hypoch alkalos card hall V roon. On 12/director	of the pha brified by the cortage of a was sent or acists and to d ammonia loremia (lor is. The e-ras been man."	a.m., during an intervarmacy stated the home manufacturer there arginine hydrochloride in/10 to inform echnicians. The e-rum chloride would be jinine hydrochloride two chloride levels) and also stated "a neade and will be available a.m. during an intervarmacy stated on technician and a please are stated on technician and a please macy stated on technician and a please macy stated to	spital had re was a e. An the nail e to treat ad metabolic ew dilution able in the		was changed to specify "Dilution 2. Products composed are recorded on implemented of 3. Procedure was remind staff the must check the concentration at the patient labeled doses, implemented to implemented to	rated patient label more clearly on on 10/26/10. Sounded by dilution a dilution log, in 10/28/10. The reviewed to at a technician drug name and and compare this to bel prior to preparing the ented by 12/31/10. Saining to validate that all to prepare and	12/31/10

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E 485	failed to dilute amm before preparing do administration for Fachnician A received medication according to the patient of the prepared the patient following the hospit medication according A 20 ml vial contains chloride was not distect the patient administration when measuring to verify the dosest technician were dilliphysician before the patient administration medicated the first in ammonium chloridal a syringe pump stanursing note indicated the first in ammonium chloridal a syringe pump stanursing note indicated the first in ammonium chloridal the MAR indicated chloride was infused physician ordered including Ativan ar seizures. The patient the patient of t	STREET ADD. 725 WELC PALO ALTI SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 4 alled to dilute ammonium chloride as required efore preparing doses for intravenous dministration for Patient 1. Pharmacy echnician A received the physician's order and 0 ml (milliliter) vials of ammonium chloride from Pharmacist B. The pharmacy technician according to the drug's dilution card. The pharmacy echnician without collowing the hospital procedure to dilute the nedication according to the drug's dilution card. The pharmacy echnician withdrew 12.5 cc (cubic centimeters) from the 20 ml vial. One cc is equivalent to one of the medication were diluted as prescribed by the pharmacy echnician were diluted as prescribed by the subscian before the medication was sent out for patient administration. Each dose contained 62.5 an Eq of ammonium chloride was infused on the survinge pump starting at about 2:35 p.m. The intravenous (IV) dose of the medicated the patient had a seizure 5 minutes after the start of the first dose of memonium chloride. The infusion was stopped. The MAR indicated a second dose of ammonium chloride was infused on more seizures. The obspician ordered anticonvulsant medications including Ativan and phenobarbital to prevent the seizures. The patient had not required these medications prior to the overdose of ammonium checitical continued to have more seizures. The patient had not required these medications prior to the overdose of ammonium checitical continued to have more seizures. The patient had not required these medications prior to the overdose of ammonium checitical continued to have more seizures of ammonium checitical continued to have more		E 485	5. Log initiated on 10/2 record all products provided and products provided and product provided and provided and integrates drug valued and provided and integrates drug valued and provided and integrates drug valued and provided and integrated a	repared in the include patient tient dose, ation, at number. Internet, and ours will be ated issues in 10/29/10. It manager if hospital of 10/29/10 inted in the IV promotes ow in the IV promotes ow in the IV promotes of trail of hecked. It is supply instructions: ED", 23/10. If or all the treatment of the costs including the	
On/10 at 3:25 a.m. laboratory results indicated Patient 1's ammonia level was over 1000 micromoles per liter. Normal range for a newborn is 100-200 micromoles per liter. At 7:30							

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	liter. According to dated 110, Pamental status chars several days follow. The director of phareviewed Patient 1 morning of 17	m. the ammonia level was 538 micromoles per er. According to the IP Discharge Summary ted 10, Patient 1 had seizures and ental status changes requiring intubation for veral days following the medication error. The director of pharmacy stated a pharmacist viewed Patient 1's laboratory results the prining of 10, saw the elevated ammonia rel, and initiated an investigation. The			Audits performed for compliance process by Director of Pharmacy. 30/30 doses logged appropriately from12/1/10 – 12/30/10 None reported for Ammonium C from 1/1/11 thru 2/28/11, when do longer available Daily monitoring of Quantros for reporting by Director of Pharmacy. PERSON RESPONSIBLE FOR MONITORING AND HOW R	hloride lrug no error ey.	12/30/2010
	pharmacist discovidoses of ammonius physician. The host the error occurred the pharmacy tech pharmacy procedulispensing of medical pharmacy and medical pharmacy procedulispensing of medical pharmacist discovery.	rered the patient receum chloride than order spital's investigation of because the pharmanician failed to follow ure established to endications. The dilution e-mail sent to staff ware	ived higher ered by the determined acist and v the sure safe a card		WILL BE REPORTED OUT Director of Pharmacy responsible for monitoring and reporting results monthly to Medication Management Steering Committee, reporting to Patient Safety Committee which reports to Quality Improvement Committee. Drug not available after 2/28/11		1/11/11
	On 12/15/10 when asked to review the policies and procedures for medication preparation, the associate director of pharmacy stated the pharmacists followed standards of practice determined by the Board of Pharmacy Regulations. The policies provided referred only to procedures to follow during drug shortages (March 2010) and for safe medication administration (October 2010) at the patient's bedside. There were no policies or procedures provided specific to compounding medications. The director of pharmacy described the pharmacy procedure which required the pharmacist to obtain the medication as supplied by the manufacturer, then provide the pharmacy technician with the medication and the physician order. The dilution card was kept in the IV pharmacy. The technician was to read the card, dilute the medication according to the instructions				CALIFORNIA DEPA OF PUBLIC HE AUG 2 4 L & C DIVIS SAN JOS	2011 SION	
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for medication diluted syringes with the purpose medication. The Board of Phare Code of Regulation states the pharmack compounding is repreparation, labeling compounded drug. The pharmacist fair chloride was diluted developed by the purpose medication resulted administered to Paphysician. Patient following administer required treatment medications which discharge home. Tadminister medications	tion, and fill the indivi- rescribed amount of macy Regulations (Cons. Title 16, Section of the properties of the medication of the medication of the medication of the medication of the facilition as ordered by the or is likely to cause,	california 1735.2) pervising, per very of the nium rocedure dilute the medication by the eizures on and r				

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