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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY DEPARTMENT OF PUBLIC HEALTH

	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPF IDENTIFICATION 050348			(X2) MULTIP A. BULDING B. INING	LECONSTRUCTION	(X3) DATE SU COMPLE	
	NAME OF PROVIDER OR SUPPLIER University of California Irvine Medical Center		STREET ADDRESS. 101 The City Dr S		PCODE 92868-3201 ORANGE COUNTY		
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Event ID:	The following reflects the of Public Health during Complaint Intake Number CA00562668 - Substant Representing the Department of Interest of Public Health: Surveyor ID#3 The inspection was limited event investigated and findings of a full inspect Health and Safety Code purposes of this section means a situation in who noncompliance with one licensure has caused, of injury or death to the particular or death to the particular shall inform the presponsible for the patient of the particular or the party respadverse event by the time. Health and Safety Code this section, "immediate in which the licensee's immore requirements of licelikely to cause, serious in Health and Safety Code (VO3611).	an inspection visit: per: tiated artment of Public (043, HFEN) ted to the specific fact does not represent to the facility. a Section 1280.3(9): It immediate jeopard (ich the licensee's er or more requirement is likely to cause, so tient. a Section 1279.1 (c): patient or the party ent of the adverse evalue. the facility informed consible for the patient er the report was made (a 1280.3 (g): For purply jeopardy" means a sonocompliance with a consure has caused, injury or to the patien	cility he For y" Ints of perious The ment by the nt of the pade. Doses of situation one or or is t.	2:58	:31PM		2018 OCT 18 PN 5: 05

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

.00.011 101

TITLE Chief Executive Officer (X6) DATE 10/18/2018

By signing this document I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 21.

Any deficiency statement ending with an asterisk (") denotes a deficiency which the institution may be excused from correcting providingt is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 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 disclosable 14 days following the date these documents are made available to the facility. If deficiencies are ded, an approved plan of correction is requisite to continued program participation.

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ATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER. 050348			(X2) MULTIPLE CONSTRUCTION A BUILDING B WING		COMPLE	(X3) DATE SURVEY COMPLETED		
NAME OF PROVIDER OF SURPLIES			02/06/2018					
NAME OF PROVIDER OR SUPPLIER University of California Irvine Media	cal Center	A CONTRACTOR SERVICES	ADDRESS CITY STATE,ZIP CODE					
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this section, "adverse (4) Care management following: A patient death or send a medication error, inderror involving the wrowning patient, the wrowning preparation, or administration, excluded clinical judgment on description of the assigned responsibility (A)(2) Developing, man written policies and proof the appropriate heal administration. Policies governing body. Proceethe administration and appropriate. T22 DIV5 CH1 ART 3 (a) A registered nurse is (2) The planning, supe evaluation of the nursing patient. The implement delegated by the regist the patient to other lices assigned to unlicensed limitations of their licensions validated competency, (b) The planning and deflect all elements of the assessment, nursing displacements.	t events, including the tevents, including the ious disability associateding, but not limite on drug, the wrong of the wrong route of ing reasonable differ rug selection and dos 70203 (a)(2) medical staff shall be for: intaining and implemoredures in consultath professionals and its shall be approved to dures shall be approved to dures shall be approved to reasonable differ rug selection, implementating care provided to eation of nursing care ered nurse responsilensed nursing staff, of staff, subject to any sure, certification, levand/or regulation.	ated with d to, an dose, the rate, the rences in se. renting tion with by the by the such is rence be and by such is				2010 OCT 18 PN 5: 05		
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	ND PLAN OF CORRECTION IDENTIFICATION NUMBER:		LTIPLE CONSTRUCTION	(X3) DATESU COMPLE			
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MYZMEIDFECH-DAS) XFEFF	TEVENT CFDEFICIENCIES ALSTBEPRECEEDED BY PLUL CIDENTIFYINGINFORVATION	ID FREETIX TAG	FROMDERS PLANCEON (EACHOCRRECTIME ACTIONS) FEFERENCED TO THE APPROP	CULDEECROSS.	(XS) COMPLETE DATE		
intervention, evaluation require, patient advocace registered nurse at the total test and the committee of equivalent established. The committee of her readministrator or his representation on the committee shall procedures for establish systems for procurement dispensing, and use of depharmacist in consultation health professionals and responsible for the developmentations of proceapproved by the governing be approved by the governing be approved by the administration of a prescribe or furnish. This administration of aerosol therapists. The order shall drug, the dosage and the administration, the route than oral, and the date, till prescriber or furnisher. Owritten or transmitted by the committee of the control of t	ry, and shall be initiated ime of admission. c)(1) rapeutics committee, or composition, shall be tee shall consist of atle macist, the director of presentative and the esentative. develop written policies ment of safe and effect at, storage, distribution trugs and chemicals. To my with other approprial administration shall be elopment and edures. Policies shall be reduced by Procedures sinistration and medicals ate. g)(2) rinistered except by prized to administer drug berson lawfully authorizes shall not preclude the drugs by respiratory all include the name of the frequency of of administration, if other and signature of the orders for drugs should be drugs s	a ast and ove ne e nall staff	Pharmacist Verification: 1. As of 11/17/17, pharmacise ducation regarding the correverification technique as desipolicy "MM: Medication Veri Processing and Dispensing." I were instructed to use the "of EPIC at ALL TIMES. Pharmacists we to NOT use the "summary vie Monitoring: IV room and Infusion Center Perform 10 random audits of order verification/month/site rate will be reported to Medi Committee, P&T, Quality & S Committee, Medical Executivand Governing Body until 100 is achieved for 6 months. 2. The policy "MM: Medication Order Processing and Dispensive verification or the Pharmacian Therapeutics Committee on a Monitoring: Audits to ensure policy compas described above.	ect order cribed in UCI fication, Order Pharmacists letailed view" in ere instructed ew." Supervisors will medication e. Compliance cation Safety afety Oversight e Committee D% compliance on Verification, sing" was tion practice. It cy & 2/6/18.	3/6/18 20-3/6/18 3/6/18 		

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	Verbal orders for drugs person lawfully authoriz shall be recorded promedical record, noting the verbal order and threceiving the order. The countersign the order of the verbal order and the receiving the order of the verbal order and the receiving the order of the verbal order and the receiving the order of the verbal order of the verbal order of the administered as ordered as prior to the administration and administered administered administration trathecal [IT] etoposid administered directly in between the thin layers brain)] to Patient A as each of the verbal or eview all element or eview and the verbal or	red to prescribe or further many when Pharma of the space of tissue that cover is evidenced by: Tech 1) failed to follow uring the preparation macist 2 failed to identification of the prescribe of the prescribe of the cover is evidenced by: Tech 1) failed to identification of the order for insure the preparation and the preparation of the cover is evidenced by: Tech 1) failed to follow uring the preparation macist 2 failed to identification of the etoposide of the etoposide of the etoposide of the preparation macist 2 failed to identify compounded whiten of the etoposide 2 as correct for	rnish and I's congiving dividual hershall nent s, edication ce the with an e acist 1 the v the n of ntify the nen the		3. As of 1/4/18, all pharmacists, we ambulatory Infusion Centers component Chemotherapy Workflow. Compete confirmed their understanding of the fost of safety, order verification principals the tools and resources available pharmacy staff. Monitoring: Results of annual competency for all Infusion Center pharmacists will be to Medication Safety Committee, Mexecutive Committee and the Governation of actives to pharmacists and 100% pass rate is for 2 consecutive years. Pharmacy Technician: 1. As of 12/1/18, EPIC (EHR) produce were revised for all medications the compounding to ensure the correcting volume, and relevant preparation are displayed correctly. Monitoring: Ongoing. EPIC drug preparations a reviewed, added, and revised base practice changes. IV Room and Infusion Center Supe perform 10 random audits/month, ensure active use and accuracy of Labels. Compliance rate will be reported.	eleted a ency, which the culture eles, as well e to Ambulatory e reported P&T, Quality edical erning Body staff achieved ction labels eat require et drug dose, e, total instructions re regularly ed on clinical rvisors will /site to Production ported to	3/6/18
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	2. RN (registered nurse) 2 failed to review and evaluate the dose of etoposide was correct by failing to review the initial order when RN 2 released the etoposide 100 mg order for dispensing by the hospital's outpatient infusion center pharmacy. 3. RN 2 failed to recognize the high dose of etoposide IT during the time out process (a brief suspension of ongoing activity to ensure safe care was provided) prior to the medication administration to Patient A. In addition, the hospital's P&P (policy and procedure) addressing administration of chemotherapy drugs failed to show guidance for a consistent and standardized method of performing a timeout procedure immediately prior to the administration of IT medications, such as etoposide IT for Patient A, as a means to identify errors and prevent or identify the occurrence of a medication error.			Medication Safety Committee, P&T, Quality & Safety Oversight Committee, Medical Executive Committee and Governing Body until 100% compliance is achieved for 6 months. 2. As of 1/29/18, pharmacy technicians successfully received education regarding the use of PRODUCTION labels as references for compounding recipes during preparation. Monitoring: IV Room and Infusion Center Supervisors will perform 10 random audits/month/site to ensure active use and accuracy of Production Labels. Compliance rate will be reported to Medication Safety Committee, P&T, Quality & Safety Oversight Committee, Medical Executive Committee and Governing Body until 100% compliance is achieved for 6 months.		3/6/18	
	The cumulative effects of these failures resulted in Patient A receiving 200 times the prescribed dose of etoposide, administered IT on 11/14/17, during an outpatient treatment at the hospital. The patient experienced an immediate adverse reaction after the administration of etoposide IT. Patient A was hospitalized in the intensive care unit and had a rapid progressive decline in neurological status. The patient was deemed to have a poor chance of recovery in association with the patient's present diagnosis of recurrent medulloblastoma (a type of brain cancer).				3. As of 1/4/18, pharmacy Leadersh reinforced the use of a Master Formation Verify recipes and preparation instruction IV room staff. Monitoring: IV Room and Infusion Center Superperform 10 random audits/month/ensure active use and accuracy of Flabels. Compliance rate will be rep Medication Safety Committee, P&T & Safety Oversight Committee, Me Executive Committee and Governing until 100% compliance is achieved months.	visors will site to Production orted to Quality dical	18 DCT 18 PH 5: 0
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University of California Irvine MedicalCenter 101 The City Dr S, Orange, CA 92868-3201 ORANGE COUNTY (X4) D SUMMARY STATEMENT OF DEFICIENCIES PREFIX (EACH DEFICIENCY MUST BE PREGEDED BY FULL PREFIX CORRECTIVE ACTION SHOULD BE CROSS- COMPLE			050348		B.WING		02/0	6/2018
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On 11/28/17, the Department received a written complaint that Patient A received a chemotherapy medication at wice the amount intended to be prescribed while being a patient in the hospital's outpatient infusion center on 11/14/17 at approximately 1130 hours. Patient A reacted with immediate nauses and extreme pain after the administration of the drug and experienced progressive neurological decline. Patient A was agimitted to the hospital on 11/14/17. The patient was unable to breathe on her own or feed herself and subsequently placed on a ventilator (mechanical assistance in breathing) and a feeding tube (a medical device used to provide nutrition to people who cannot obtain furtifion by mouth, are unable to swallow safely, or need nutritional supplementation) was inserted. The patient's level of consciousness had declined from lethargy (sluggish) to non-responsiveness over a period of 14 days. The Patient didal several months later but did not regain consciousness. Patient A's medical record was reviewed beginning on 12/12/17. Patient A had a history of recurring medulloblastoms and was undergoing oncology treatment by MD 2 for cancer as an outpatient in the hospital's outpatient infusion center. Review of the Ambulatory Follow-Up Note dated 9/29/17 at 1138 hours, showed Patient A would begin a course of etoposide IT via an Omaya reservoir (a catheter placed in the brain to access the cerebrospinal fillid). The review of systems showed Patient A was alert and oriented with a fund 4. This is now included in Pharmacy Orientation training for all new staff. The policy "Sterile Compounding – General Principles: Aseptic Technique and Professional Conduct in Controlled Area" was revised to reflect this practice. This policy was reviewed to reflect this practice. This policy was reviewed to reflect this practice. This policy was reviewed to manife the administration of the Ambulatory of recurring in the Ambulatory of the Ambulatory of the Ambulatory of recurring medulloblastoms and was undergoing oncology treatm	complemedic prescription outpat approximmed admining progress admitting a sassisting assisting as a sassisting a sassistin	complaint that Patient needication at twice the rescribed while being utpatient infusion cent pproximately 1130 hours and distributed to the hospital as unable to breather and subsequently places is sistance in breathing needical device used to the cannot obtain nutries as inserted. The patient died several monsciousness. The table to breather and declined from leth on-responsiveness of attent died several monsciousness. The table t	A received a chemoth amount intended to a patient in the hospiter on 11/14/17 at ours. Patient A reacted extreme pain after thrug and experienced hal decline. Patient A alon 11/14/17. The paragraph of the don a ventilator (merginal and a feeding tube or provide nutrition to provide nutrition to provide nutrition by mouth, are und nutritional supplement's level of conscious argy (sluggish) to over a period of 14 day on the later but did not cord was reviewed behad a history of recurs was undergoing on concancer as an outpatient of the later but did not consider the later but did not consider the later but did not consider an outpatient and a history of recurs and outpatient and a history of recurs and outpatient and a history of recurs and outpatient and an outpatient and the later but did not consider an outpatient and on the later but did not consider an outpatient and on the later but did not consider the later but	nerapy be ital's d with he was atient erself echanical (a beople hable to entation) esness ays. The ot regain ginning rring logy ent in the dated rould /a ccess ems h a	2.	Orientation training for all new stapolicy "Sterile Compounding – Ger Principles: Aseptic Technique and I Conduct in Controlled Area" was reflect this practice. This policy waby Pharmacy & Therapeutics Comm 2/6/18. Monitoring: IV Room and Infusion Center Supeperform 10 random audits/month, ensure active use and accuracy of Labels. Compliance rate will be rep Medication Safety Committee, P& & Safety Oversight Committee, P& Executive Committee and Governiuntil 100% compliance is achieved months. Registered Nurse: 1. As of 1/4/18, a hyperlink in the pMAR and Medication Order Screen was created to provide easy access physicians, nurses, and pharmacist reference for intrathecal dosing gu Completed and ongoing.	off. The neral Professional evised to sapproved mittee on rvisors will /site to Production forted to T, Quality edical ng Body for 6	

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	of knowledge and atten has stored in memory a things). Patient A's specranial nerves (the nerver from or enter the skull) comprehension and full strength. However, Pation the finger-nose asset to the nose) and was ur (where the toes of the both the front foot at each stern the foot at each stern the front foot at each stern the foot at each stern the front foot at each stern the foot	bout people, places ech was clear and fluces of the brain, which intact. Patient A had upper and lower bount A had discoording the mable to walk in tanderack foot touch the heap). 's order dated 9/25/1/2 ordered etoposide to be given every two food 20 doses) starting of the medication Guidelines datecal or IT chemotheractered by MD 2, a clean specialized in contract of the medication, and a nurse and a physical every the medication, and a nurse and a physical even with: the patient of the medication of the medication at the cal route), medical swell as to verify the and the medication lateraction and the medicat	and uentwith shemerge normal dy motor nation efinger em eel of 17 at 10.5 mg weeks on ted rapy n the cancer on, the The sician name, ation ee pelat		2. As of 2/6/18, all Infusion Center were educated to verify with Uptoo link within EPIC EHR) when unsure medication dosing/dose ranges. In the Uptodate resource, the nurses educated with respect to the range additional unit based resources avaithem: Charge Nurse, Pharmacist, O Physician, Infusion Center Nurse Procumentation of education profice entered into the personnel file of elinfusion Center manager will perform andom audits per month until 100 compliance is achieved for 3 month nurses will demonstrate where the in the patient's MAR and Medicationscreen in EPIC regarding intrathecal guidelines. 3. The Infusion Center Orientation/Competency Validation was revised as of 2/6/18 to require orientation/education/competency Medication Administration: Intrathelipection under the Care of the Patic Requiring Medication and IV Therage Complete and ongoing 4. As of 2/6/18, the Annual Skills Da Infusion Center Nurse will incorporated action on intrathecal administration chemotherapy. Completed and will be ongoing. Time-Out Process: 1. The Time Out (Procedural/Surgical Verification) policy was revised as or require a time out when any chemoagent is administered intrathecally.	date (click of proper addition to were addition to were a of ailable to ordering actitioner. Siency was ach nurse. It is a constant of a const	3/6/18 3/6/18 23 3/6/18 3/6/18	
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					out process was expanded to inclu				
	Review of Patient A's A	ssessment dated 11	/14/17		appropriate, (e.g. intrathecal chem	otherapy)			
	at 1000 hours, RN 2 do	cumented Patient A	was		verification of correct medication,				
	within defined limits (VV				dose, medication route and docum	entation in			
	assessment, and the Ri				the EHR.				
	Scale [RASS (measure	34			Monitoring:				
	agitation)] showed Pati				The Infusion Center Manager will p	erform 10			
	Patient A's respiratory (random audits per month of time of				
	gastrointestinal (digest		,		until 100% compliance is achieved				
	musculoskeletal asses		In		months. Once completed results to	be			
	addition, Patient A's skir		727		reported to Regulatory Affairs.		0/5/40		
	psychosocial assessme	ents were also WDL.					3/6/18		
					2. As of 2/5/18, all Infusion Center	nurses			
	Review of the Action Su	mmary showed			were educated to the policy revision	ns.			
	etoposide 100 mg in a v	olume of 5 ml (millili	ters)		Education included the fact that th				
	via the IT route was adr	ministered to Patient	A by		process is considered a "no interru				
	MD 2 on 11/14/17at 125				event. A "TIME OUT IN PROCESS/D	O NOT			
					INTERRUPT" sign will be placed on				
	Review of the Interdiscip	olinary Notes dated 1	1/14/17		patient's room door prior to comm				
	at 0930 hours [the time i				time out. The time out, led by the F				
	was first created in the e				will be completed with no interrupt	tions, with			
	record) and later filed (til	me unknown)] showe	ed		no one leaving the room. In the eve	ent there is			
	immediately after the inf				an interruption, the time out will be	e restarted.			
	Patient A became diaph				No nurse will be assigned a patient	receiving			
	complained of extreme h		ea and		intrathecal chemotherapy unless th	iere is	**		
	vomiting. Patient A was				documented evidence of their educ	cation to	>>		
	hospital's Emergency De	epartment (ED) for			the policy.		5-2 5-1		
	assessment.		39		Monitoring:		5		
			1		The Infusion Center Manager will p		→ 		
	Review of the ED to Hos	5			random audits per month of this tir		et-creat		
	11/14/17, showed Patier				process until 100% compliance is ac		50		
	11/14/17 at 1521 hours,		san		3 months. Once completed results t	1.	U		
	inpatient to the hospital a	at 1745 hours.			reported to Regulatory Affairs		D/1		
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1	On 1/4/18 at 1150 hours,	, MD 1,the Director of	of			K	5		
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	Neurocritical Care (Neupatients with severe net primary physician overs interviewed. MD I state Patient I was "not doing Patient I was "not doing Patient I was "awake a had since "slowly deteriunresponsiveness." ME for Patient I was "not go On 2/2/18 at 1557 hour with RN 4, the primary rin bed with both eyes pwas on a ventilator mabreathing) which was cotracheostomy (tube to feeding tube inserted the abdominal wall was in pafeeding pump (a macinal liquid form through stated Patient A was notal assistance with head order into the eHR, and follow the compounding incorrect medication dos Review of the hospital's Management: Medicatic and Dispensing dated 2 When a medication ord pharmacist shall review appropriateness and co	rvous system issues) leeing Patient 1's car led on arrival to the Ni g very good." MD 1 s and interactive" initially orated" to "complete of 1 stated the overall bood." Is, Patient A was obs aurise. Patient A was artially closed. Patie chine (machine to as annected by a tube to help with breathing) brough an incision in lace andwas connect hine which infuses in the feeding tube). onresponsive and re ar needs. I Tech 1 failed to prop recipe, creating the se. I Tech 2 failed Medicati on Verification, Prepa 2/17 showed in part: er is received, the or the order for	care for and the e, was euro ICU stated /, but outlook erved s lying nt A ssist o her and a the cted to utrition RN4 equired the perly on ration, " 1.	TAG	3. As of 2/6/18, the time-out proce added to the Annual Skills Day for Center nurse. Completed and on-going. Electronic Health Record (EHR): 1. As of 12/1/17, UCI has removed electronic order items in EPIC that intraTHECAL and intraVENOUS roupptions to prevent confusion. Completed and on-going. 2. As of 12/1/17, seven stand-along intraTHECAL electronic order items with suffix "intraTHECAL chemo injurer created to help users differer intraTHECAL route from intravenous infusions and other routes of admit The word "intrathecal" was added wording of the medication name a administration instructions to make intrathecal orders stand out and be obvious to pharmacists during medical order verification. Completed and on-going.	ess will be the Infusion de the Infusion de the the the the the the the the the th	3/6/18 3/6/18
	confirming the order in tl	ne computer system	. 2.				
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Appropriate Route of Administration & [and] Dosage Standard formulations or recipes for all compounded pharmacelutions. Will be assessed through visable employed to reduce the frequency of errors associated with the use of high risk full fugs The policy listed chemotherapy agents as high risk medications. The representation The preparation "On 1/4/18 at 0940 hours, the Director of Pharmacy, and Assistant Director of Pharmacy, were interviewed. The stiff stated on 11/4/17, the hospital transition does not interest the chemotherapy depends on the preparation "On 1/4/18 at 0940 hours, the Director of Pharmacy, and Assistant Director of Pharmacy, were interviewed. The stiff stated on 11/4/17, the hospital transition of the preparation "In employment of the members, and Assistant Director of Pharmacy, were interviewed. The stiff stated on 11/4/17, the hospital transition of the preparation" The medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by the physician. The medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by the physician. The medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by the physician. The medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by the physician. The medication orders would then be verified by two	7 (40 m) 16 (17 (47 (47 (47 (47 (47 (47 (47 (47 (47 (4	OF DEFDIENCIES F CORRECTION	(X1) PROMDER/SUPPLIER/CUA IDENTIFICATION NUMBER	(X2)MU		(X3) DATESURVEY COMPLETED	
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University of California Irvine Medical Center 101 The City Dr S, Orange, CA 92868-3201 ORANGE COUNTY CALID SUMMARY STATEMENT OF DEFICIENCIES D PROVIDER'S PLANOF CORRECTION SOULDIE CROSS REFERENCED TO TITLEAPROPHIATE DEFICIENCY COMPLETE REGULATORY ON LSC DENIFTING INFOBANTON SECRET TAKE PROVIDER'S PLANOF CORRECTION SHOULDIE CROSS REFERENCED TO TITLEAPROPHIATE DEFICIENCY COMPLETE REGULATORY ON LSC DENIFTING INFOBANTON SECRET TAKE PROVIDER'S PLANOF CORRECTION SHOULDIE CROSS REFERENCED TO TITLEAPROPHIATE DEFICIENCY COMPLETE REPRESENCED TO TITLEAPROPHIATE DEFICIENCY COMPLET REPRESENCED TO TITLEAPROPHIATE DEFICIENCY COMPLETE REPRESENCE	NAME OF PR	OVIDER OR SUPPLIER	STREET ADDRES	S. CITY, STA	TE ZIP CODE] 52,0	30/2010
The general categories for which pharmacists will concurrently review medication regimens are Appropriate Route of Administration & [and] Dosaga Standard formulations or recipes for all compounded pharmaceuticals, along with appropriate references for those recipes will be maintained The integrity of prepared medications will be assessed through visual observation A pharmacist will always verify technician work prior to dispensing" Review of the hospital's P&P titled Medication Mgmt [Management]. High Risk Medications dated 3/17 showed in parti Drug specific strategies will be employed to reduce the frequency of errors associated with the use of high risk drugs" The policy listed chemotherapy agents as high risk medications. The Reduction Strategies for High Risk Medications included the following precautions for the preparation, dispensing, and labeling: "Dispensed with high alert sticker "Chemo" (chemotherapy)," and "Double check (pharmacy)" and "Double check by R.X (pharmacy) of final preparation." On 14/18 at 0940 hours, the Director of Risk and Regulatory Affairs, Director of Pharmacy, and Assistant Director of Pharmacy were interviewed. The staff stated on 11/4/17, the hospital transitioned to a different electronic health record (eHR) system. During this transition, the previous medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by thephysician. The medication orders would then be verified by two	University	of California Irvine Medica	al Center 101 The City Dr	S, Orange	CA 92868-3201 ORANGE COUNTY		
The general categories for which pharmacists will concurrently review medication regimens are Appropriate Route of Administration & [and] Dosaga Standard formulations or recipes for all compounded pharmaceuticals, along with appropriate references for those recipes will be maintained The integrity of prepared medications will be assessed through visual observation A pharmacist will always verify technician work prior to dispensing" Review of the hospital's P&P titled Medication Mgmt [Management]. High Risk Medications dated 3/17 showed in parti Drug specific strategies will be employed to reduce the frequency of errors associated with the use of high risk drugs" The policy listed chemotherapy agents as high risk medications. The Reduction Strategies for High Risk Medications included the following precautions for the preparation, dispensing, and labeling: "Dispensed with high alert sticker "Chemo" (chemotherapy)," and "Double check (pharmacy)" and "Double check by R.X (pharmacy) of final preparation." On 14/18 at 0940 hours, the Director of Risk and Regulatory Affairs, Director of Pharmacy, and Assistant Director of Pharmacy were interviewed. The staff stated on 11/4/17, the hospital transitioned to a different electronic health record (eHR) system. During this transition, the previous medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by thephysician. The medication orders would then be verified by two							
The general categories for which pharmacists will concurrently review medication regimens are Appropriate Route of Administration & [and] Dosaga Standard formulations or recipes for all compounded pharmaceuticals, along with appropriate references for those recipes will be maintained The integrity of prepared medications will be assessed through visual observation A pharmacist will always verify technician work prior to dispensing" Review of the hospital's P&P titled Medication Mgmt [Management]. High Risk Medications dated 3/17 showed in parti Drug specific strategies will be employed to reduce the frequency of errors associated with the use of high risk drugs" The policy listed chemotherapy agents as high risk medications. The Reduction Strategies for High Risk Medications included the following precautions for the preparation, dispensing, and labeling: "Dispensed with high alert sticker "Chemo" (chemotherapy)," and "Double check (pharmacy)," and "Double check by R.X (pharmacy) of final preparation." On 14/18 at 0940 hours, the Director of Risk and Regulatory Affairs, Director of Pharmacy, and Assistant Director of Pharmacy, were interviewed. The staff stated on 11/4/17, the hospital transitioned to a different electronic health record (eHR) system. During this transition, the previous medication orders for chemotherapy were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by thephysician. The medication orders would then be verified by two							
The general categories for which pharmacists will concurrently review medication regimens are Appropriate Route of Administration & [and] Dosage Standard formulations or recipes for all compounded pharmaceuticals, along with appropriate references for those recipes will be maintained The integrity of prepared medications will be assessed through visual observation A pharmacist will always verify technician work prior to dispensing" Review of the hospital's P&P titled Medication Mgmt [Management]: High Risk Medications dated 3/17 showed in part." Drug specific strategies will be employed to reduce the frequency of errors associated with the use of high risk drugs" The policy listed chemotherapy agents as high risk medications. The Reduction Strategies for High Risk Medications included the following precautions for the preparation, dispensing, and labeling: "Dispensed with high alert sticker "Chemo" [chemotherapy]." "Independent double check (pharmacy)," and "Double check by R.X [pharmacy] of final preparation." On 1/4/16 at 0940 hours, the Director of Risk and Regulatory Affairs, Director of Pharmacy, and Assistant Director of Pharmacy, wand Assistant Director of Pharmacy, wand Assistant Director of Pharmacy, were transcribed by a pharmacist into the new system, then they were reviewed and signed electronically by the physician. The medication orders would then be verified by two	PREFIX	(EACH DEFICIENCY	MUST BE PRECEEDED BY FULL	PREFIX	(EACH CORRECTIVEACTION SHOULD	BE CROSS.	COMPLETE
10/3/2010 2.30.3 [P]VI		concurrently review me Appropriate Route of Act Dosage Standard form compounded pharmace appropriate references maintained The integri medications will be as observation A pharmatechnician work prior to Review of the hospital's [Management]: High Ris showed in part:"Drug employed to reduce the associated with the use policy listed chemotheramedications. The Reduct Risk Medications include for the preparation, disp "Dispensed with high ale [chemotherapy]." "Indep (pharmacy)," and "Doubl of final preparation." On 1/4/18 at 0940 hours Regulatory Affairs, Direct Assistant Director of Phathe staff stated on 11/4/transitioned to a different (eHR) system. During this medication orders for chetranscribed by a pharmathen they were reviewed by the physician. The medic property is the physician. The medic property is the physician. The medic property is the physician in the property is the physician.	dication regimens are dministration & [and] mulations or recipes for all mulations or recipes for all mulations or recipes will be dity of prepared disessed through visual moderation will always verify dispensing" P&P titled Medication Mgmt disk Medications dated 3/17 dispecific strategies will be frequency of errors of high risk drugs" The dipy agents as high risk dition Strategies for High died the following precautions densing, and labeling: densing and labeling: densing the titcker "Chemo" dendent double check densing check by RX [pharmacy] In the Director of Risk and ditor of Pharmacy, and dirmacy were interviewed. 17, the hospital delectronic health record distransition, the previous demotherapy were distinto the new system, and signed electronically dication orders would then		stop limits for all intrathecal cheinjections. Users are not able orders if doses exceed establish Specifically, the hard stop for etoposide does not allow proenter dosages greater than 0.5 mg as standard daily dose, or 2 the maximum single dose. Completed and ongoing. 4. As of 1/4/18, twenty-one intrath treatment plans with standardized doses pre-configured were built to efficiency and decrease the risk of error. Completed and ongoing. 5. As of 2/28/18, safety parameter been made more robust for other chemotherapy) drugs that are provintrathecally (e.g. baclofen, morph antibiotics, etc.); by ensuring the fosteps are taken. 1) Completely sepentry for intrathecal, 2) Removal o intrathecal option for drugs rarely administered intrathecally (e.g. nal botox). Completed and ongoing	motherapy to submit ned limits. intrathecal viders to 2.25 mg as necal lintrathecal vincrease order entry s have (non- vided ine, bllowing arate drug f an oxone,	3/6/18
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	STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OFCORRECTION IDENTIFICATION NUMBER.			(X2) MULTIPLE CONSTRUCTION (X3) DATE SU COMPLE A. BUILDING			
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	OMDER OR SUPPLIER of California Irvine Medica	al Center	STREET ADDRESS . (I 101The City Dr S, (ZIP CODE CA 92868-3201 ORANGE COUNTY		
(X4)1D PREFIX TAG	(EACH DEFICIENCY I	TEMENT OF DEFICIENCIES MUST BE PRECEEDED BY F SC IDENTIFYING INFORMAT	FULL	ID PREFIX TAG	PROVIDER'S PLAN OFCORREC' (EACH CORRECTIVE ACTION SHOULD B REFERENCED TO THE APPROPRIATE D	BECROSS.	(XS) COMPLETE DATE
	pharmacists prior to preparation. The medications would be prepared by a pharmacy technician and checked by a pharmacist prior to dispensing. However, the conversion to the new eHR did not include the ability to order etoposide with an ITroute				MD Verification: 1. As of 1/4/18, a hyperlink in the period medication administration record (Medication Order Screen in EPIC we to provide ready access for physicial	(MAR) and as created	3/6/18
	and so a work-around v		ALVER THE RESERVE THE PROPERTY OF THE PERTY		reference for intrathecal dosing gu Completed and ongoing.	idelines.	
	Review of the transcribed order for Patient A in the new eHR dated 11/13/17 at 1554 hours, showed etoposide 100 mg chemo infusion instead of the ordered etoposide 0.5 mg IT, which was 200 times the ordered dose. Further review of the transcribed order showed MD 2 electronically verified thisorder as correct on 11/13/17 at 1720 hours. Review of the medication dispensed to Patient 1 by Pharmacist 1showed the medication was labeled as etoposide 100 mg in 5 ml of normal saline (solution to dilute the medication) andwas prepared by Technician (Tech) I and checked by Pharmacist 2. The label also showed the administration route was "intrathecal," and not IT as ordered.			W.	2. The organization's Medical Committee (MEC) received a writte for a formal corrective action into the action(s) by the Attending from the Chief Medical Officer Submitted 1/17/18). The MEC inversely, and the referral of this review, are consistent with oculture. Per Medical Staff bylaws,	en request vestigation Physician (<u>Referral</u> estigative is case for our safety a request	3/6/18
	On 1/4/18 at 1025 hours Supervising Pharmacist treatment) area and one involved in the verification order was interviewed. I etoposide 0.5 mg in 5 m dispensed; instead, the etoposide 100 mg in 5 m did not note that the addintrathecal during the route was IVPB (intrave medication diluted in a sand	in the Oncology (ca e of the two pharmac on of Patient A's med Pharmacist 1 stated I should have been pharmacy dispense nl. Pharmacist 1 state ministration route wa verification and assu nous piggy back -	d ded he s medthe		for a formal corrective action invequires formation of an investigatory committee of the Staff, which then conducts a separ to examine the episode of care ir (in this case the intrathecal overdose which occurred on Nov. to determine whether or not the scare/quality expected at UC Irvine sufficiently achieved and sustained Completed.	ad hoc e Medical ate review n question etoposide 14, 2017) tandard of e has been	2018 007 18
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	STATEMENT OF DEFICIENCES (X1) PROVIDER/SUPPLIER/CUA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:			(X2) MU A. BUILD		(X3) DATE SU COMPLET				
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	infused into the vein over Pharmacist 1 stated 100 IVPB etoposide, but no done through the intratt further stated both he as summary review of the order details in the eHF where the administration correctly as IT. Pharmal stocked and used by the preparation. The medic by the manufacturer was Pharmacist 1 confirmed dispensed in the same by the manufacturer and prior to administering to Review of the compount containing the ingredient prepare the medication) (IVPB) with Pharmacist be diluted in 500 ml nor The preparation instruct compounding recipe for were as follows: "DILUT 30 ml vial, add 0.5 ml mg per ml or 10 mg per saline] 19.5 ml forfinal of 20 ml or 0.5 mg per ml] Calculate the volume [of Withdraw this amount from 1/4/18 at 1440 hours Tech 1 stated he had the	omg was the usual of the total the IT administration and pharmacist 2 use order instead of ope and the total the tot	lose for ation sist 1 d the ining the iffication shown product poside supplied suted in the ining the ining the iffication shown product poside supplied in the ining the initial in		Pharmacist Medication Compound The following changes to the pharm verification process for intravenou intrathecal compounded medication been implemented: 1. As of 11/17/17, a distraction-free created in compounding areas. Uni phone calls to the IV room are mini allowing the staff to focus on quali Nursing began using the "Dispense function in EPIC to minimize status phone calls to pharmacy. Completed and ongoing. 2. As of 1/4/18, laminated intrathe guidelines are posted at each biosa cabinet for dosing reference when This is to ensure that mandatory gu that define allowable dosages for in medications are readily available. Completed and ongoing. 3. As of 1/4/18, a hyperlink in the p medication administration record (the Medication Order Screen in EPI created to provide easy access for p nurses, and pharmacists to a refere intrathecal dosing guidelines. Completed and ongoing.	macy s and ons have e zone was necessary imized, ty checks. Track" check cal dosing afety needed. uidelines ntrathecal patient MAR) and IC was ohysicians, ence for	3/6/18			
E VOIR ID. VVC	KVU 1		10/0/2010	2.3	JU.J.F IVI		ĆÜ			

1	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER:	(X2)MUI	TIPLECONSTRUCTION	(X3) DATE SUP	
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- CASSA AL AND	UNDER UB ZITIBBITER	N 120 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ESS, CITY, STATE			
University	of California Irvine Medic	al Center 101 The City	Dr S, Orange,	CA 92868-3201 ORANGE COUNTY		
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(X4) ID	SUMMARY ST	ATEMENT OF DEFICIENCIES	ID	PROVDER'S PLAN OF CORRECT	ON	
PREFIX	(EACH DEFICIENCY	MUST BE PRECEEDED BY FULL	PREFIX	(EACH CORRECTIVE ACTION SHOULD		
TAG	REGULATORY OR L	SC IDENTIFYING INFORMATION)	TAG	REFERENCED TO THE APPROPRIATE DE	EFICIENCY)	
			1.	4.4.52/20/62		
	TOPOLOGIC CONTROL OF THE PARTY OF	prepared the medications for		4. As of 2/28/18, a skills-based		3/6/18
		th 1 stated this was his first edication; however, the tech		competency on the compound		1,7,20
	The same of the sa	able" preparing it and did not		check process was developed f pharmacists to integrate into t		
	use any reference (suc			workflow. This competency will	11/20/2005	
	recipe) to guide him wit	th the preparation.		focused upon, but not limited t	re market	
	The madication lab at 5	. He was the second of the sec		following aspects:	o) the	
		or the medication dispensed yed with Tech 1. The label		a. Ability to retrieve patient		
		components required for this		information from EHR to valida	te	
	preparation: etoposide	100 mg and normal saline		dosing and regimen appropriat		
		did not use normal saline for		based on information available	on	
	the preparation and did of the solution on the I	not question the presence		the medication label.		
		uations before and was told it		b. Ability to visually identify inc	orrect	
		presence of the solution on		Information on the medication		
	the label.		A S	label: (dose, route, infusion rate erroneous administration	е,	
				information).		
		1/4/18 at 1440 hours, the		c. Ability to identify incorrect		
	use the compounding re	rated she expected Tech 1to		dilution/compounding technique	ies	
	intrathecal, especially w			performed by technicians via ca	ise	
	preparing the medicatio	n.		scenarios.		
				d. Ability to consult appropriate		
		ied Tech 1's compounded		resources when unsure of medi	200 (100 C) (0.00 (0.00 C) (0.00 C)	
	interview.	nsing, was not available for		doses presented on compoundi	ng	
				labels.	E-	
	On 1/4/18 at 1125, the E			Monitoring:		
		harmacy, and the Assistant		Results of annual skills-based comp for IV Room and Infusion		
		ere interviewed. The staff		pharmacists will be reporte		
	acknowledged the pharr	side should have checked		Medication Safety Committee,	P&T, CO	
		dministration and caught the		Quality & Safety Oversight Com-		
1	error, but he did not.			Medical Executive Committee ar		
				Governing Body.	Ç	
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STATEMEN DEFICIENC CORRECTION	IES AND PLANOF	(X1) PROVIDER/SUPPLIE IDENTIFICATION NU 050348		A. BUILD		(X3) DATE SU COMPLE 02/0	
Universit	ROVIDER ORSUPPLIER y of California Irvine Medica	The state of the s			E ZIP CODE CA 92868-3201 ORANGE COUNTY		
(X4)ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEEDED BY F SCIDENTIFYING INFORMATI	FULL	D PREFIX TAG	PROVIDER'S PLAN OF CORRECTIVE ACTION SHOULD REFERENCED TO THE APPROPRIATE	BE CROSS.	(XS) COMPLETE DATE
	On 1/4/18 at 1400 hour Director of Risk and Rep Pharmacy, and the Ass was conducted. The staverification training for temphasize the important [to see all relevant infor 2. MD 2 failed to identify was incorrect when MD transcribed order in the Review of the Medical subsection 3 dated 11/2 responsibility of a medical by the Medical Staff Byl Regulations, and allothe and rules of the medical Review of the hospital's Management: Medication and Documentation date providers administering her best judgement to at and route are consistent and history. Discrepanci resolved before the medical On 12/12/17 at 1031 hour concurrent review of the conducted with MD 2. M Computerized Physician etoposide 0.5 mg IT for Fhours, in the old eHR systransition to the new eHF	gulatory, Director of place of sistant Director of Phace of acknowledged the the pharmacists did rece of using the order mation] as it should. If the dose of etoposic of a cathenticated the new eHR. Staff Bylaws section 28/16, showed the cal staff member is to laws, Rules and er lawfulstandards, potenter. P&P titled Medication of Administration, Moded 11/17 showed car medications will use some the medications will use some the medication with the patient's context with the p	armacy e order not ardetails de IT 3, abide policies, n nitoring e his or , dose, ndition pe ed s was d a of for at 1718 pital's		MD Verification: 1. As of 1/4/18, a hyperlink in the medication administration record Medication Order Screen in EPIC value to provide ready access for physic reference for intrathecal dosing grouplete and ongoing 2. As of 12/1/17, UCI implemented limits for all intraTHECAL chemo in Physicians will not be able to submorders if doses exceed established Specifically, the hard stop for intratosages greater than 0.5 mg as stadose, or 2.25 mg as the maximum Complete and ongoing 3. As of 1/4/18, twenty-one intraTtreatment plans with standardized intraTHECAL doses pre-configured to increase efficiency and decreasorder entry error. Complete and o	(MAR) and was created ians to a uidelines. d hard-stop njections. nit or verify I limits. athecal is to enter andard daily single dose. HECAL I were built e risk of	3/6/18
Event ID:W	Q3611	:*:	10/3/2018	2.5	58:31PM	. c	
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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CUA AND PLAN OF CORRECTION IDENTIFICATION NUMBER: 050348			A, BUILDING		100 W	MPLETED 02/06/2018	
NAME OF PRO	DVIDER ORSUPPLIER	197.00	STREET ADDRESS O	LITY STATE	ZIP CODE		
NAME OF PROVIDER OR SUPPLIER University of California Irvine Medical Center 101 The City Dr.S, Orange, CA 92868-3201 ORANGE COUNTY							
300-010-03-17-15-00-01- 3			l ar me ony or o,	orango, o			
(X4) ID PREFIX TAG	(EACH DEFICIENCY	NTEMENT OF DEFICIENCIES MUST BE PRECEEDED BY SC IDENTIFYING INFORMA	FULL	ID FREIK TAG	FRONDERSPLANGFOOTECT	ECFCE6	(XS) COMPLETE DATE
	Review of the Transcrit dated 11/13/17 at 1554 100 mg chemo infusion IT). The order was elect 11/13/17 at 1720 hours identify the discrepancy the medication when he transcribed.	hours, showed etop (instead of etoposic ronically verified by . MD 2 stated he did in the dosage and r	le 0.5 mg MD 2 on not route of		MD Verification: 1. As of 1/4/18, a hyperlink in the medication administration record and Medication Order Screen in Electrotects to provide ready access for physicians to a reference for intrated dosing guidelines. Complete and or	(MAR) PIC was or thecal	3/6/18
	Review of the Action Summary showed Patient A received 100 mg of etoposide in 5 ml of chemo infusion on 11/14/17 at 1253 hours, with the comment "Administered by" MD2. MD 2 stated he did "not catch" the medication error prior to administering the medication to Patient A. MD 2 stated the medication label appeared different from the medication labels used prior to the eHR transition; the label had a smaller type print and the label was difficult to read. MD 2 acknowledged he				2. As of 12/1/17, UCI implemented stop limits for all intraTHECAL cher injections. Physicians will not be all submit or verify orders if doses excestablished limits. Specifically, the stop for intrathecal etoposide does allow providers to enter dosages g than 0.5 mg as standard daily dose 2.25 mg as the maximum single do Complete and ongoing	mo ble to ceed hard s not reater c, or	3/6/18
	missed the chance to ide was incorrect for the IT re "not verified" by him prio administration to Patient	oute when the dose or to the medication			3. As of 1/4/18, twenty-one intraThetreatment plans with standardized intraTHECAL doses pre-configured built to increase efficiency and decible of and an anti-process.	were	3/6/18
	3. RN (registered nurse) evaluate the dose of eto to review the initial order released the etoposide 1 by the hospital's outpaties pharmacy. Review of the hospital's Management: Medication and Documentation date	poside was correct k in the eHR when Rt 00 mg order for disp nt infusion center P&P titled Medication n Administration, Mo	oyfailing N 2 Pensing		risk of order entry error. Complete ongoing	and Coll UCT	
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	vider or supplier of California Irvine Medica	al Center	STREET ADDRESS 101 The City Dr		IP CODE A 92868-3201 ORANGE COUN	ТҮ	
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEEDED BY I SC IDENTIFYING INFORMAT	20. 1771 accessor	ID PREFIX TAG	FROVIDERS PLAN OF C (EACH CORRECTIVE ACTION S REFERENCEDTO THE APPROP	HOULD BECROSS-	(XS) COMPLETE DATE
I i i i i i i i i i i i i i i i i i i i	providers administering her best judgement to a and route are consistent and history. Discrepand resolved before the medication to be given to the motherapy order should be fore the medication to be given in the eHR. On 2/2/18 at 1103 hours conducted with RN 3 and Manager. When asked a preparing a patient for our stated the list of patient reatments were reviewed ach patient and the me purpopriateness. If a menusual in some way, sin an online medication ospital and notified the coalso stated she looked before coefficients with the properiate of the motherapy to purpopriate, RN 3 releases the menusual of the process the menusual of the process where the process were not proposed to the process where the process were the process were the process where the process where the process where the process where the process were the process where the pr	assure the medication of with the patient's considered or questions will dication is administer. P&P titled Medication is P&P titled Medication is administer. P&P titled Medication in the process of the initiated the could review and valid with what had been on the initiated the process of the initiated the medication cyclication orders for the initiated the medication cyclication orders for the initiated the initiated the initiated the initiated the order to the initiated the patient arriable to receive ager verified RN 3's swerecorrect.	n, dose, ondition be red. on dated date the ordered rapy, RN ive orning. clesfor for lication ne D. RN the the r was ived			28 CCT 8 PH 5: U3	
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STATEMENT OF DEICIENCIES (X1) AND PLAN OF CORRECTION PROVIDER/SUPPLIES A IDENTIFICATION				ULTIPLE CONSTRUCTION DING	(X3) DATE SURVEY COMPLETED		
		NUMBER.		B. WING	9	02/0	06/2018
NAME OF PE	ROVIDER ORSUPPLIER	300 W 300 W-	STREET ADDRESS,C	CITY, STA	TE.ZIPCODE		
University	y of California Irvine Medica	al Center	101 The City Dr S,	Orange,	CA 92868-3201 ORANGE COUNTY		
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Approved 2/6/18 #3043

CORRECTIVE ACTION PLAN

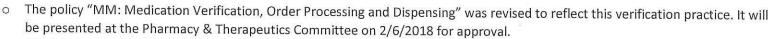
IMMEDIATE JEOPARDY: 02/02/2018

Complaint #CA00562668

IMMEDIATE CORRECTIVE ACTIONS

- 1. The Pharmacist verified the order without reviewing all the elements of the order to ensure it was appropriate.
 - Electronic Health Record (EHR, EPIC)
 - UCI removed electronic order items in EPIC that had both intraTHECAL and intraVENOUS route options to prevent confusion.
 Completed: 12/1/2017.
 - Seven stand-alone IntraTHECAL electronic order items in EPIC with suffix "intraTHECAL chemo injection" were created to help users differentiate intraTHECAL route from intravenous infusions and other routes of administration. The word "intrathecal" was added to the wording of the medication name and in the administration instructions to make intrathecal orders stand out and be more obvious to pharmacists during medication order verification. (See screenshot #1). Completed: 12/1/2017.
 - UCI implemented hard-stop limits for <u>all</u> intraTHECAL chemo injections. Users will not be able to submit orders if doses exceed established limits. Specifically, the hard stop for intrathecal etoposide does not allow providers to enter dosages greater than 0.5 mg as standard daily dose, or 2.25 mg as the maximum single dose. (See screenshot #2 and #3). Completed: 12/1/2017.
 - Twenty-one intraTHECAL treatment plans with standardized intraTHECAL doses pre-configured were built to increase efficiency and decrease the risk of order entry error. (See screenshot #4). Completed: 1/4/2018.
 - O Safety parameters have also been made more robust for other (non-chemotherapy) drugs that are provided intrathecally (e.g. baclofen, morphine, antibiotics, etc.) by ensuring the following steps are taken. 1) Completely separate drug entry for intrathecal; 2) Removal of an intrathecal option for drugs rarely administered intrathecally (e.g. naloxone, botox, amongst others). This has already been requested of our combined UCSD-UCI EPIC Governance Team. Will be completed Feb 28, 2018.
 - Pharmacist Verification
 - Pharmacists received education regarding the correct order verification technique as described in UCI policy "MM: Medication Verification, Order Processing and Dispensing." Pharmacists were instructed to use the "detailed view" in EPIC at ALL TIMES.
 Pharmacists were instructed to NOT use the "summary view." Completed: 11/17/2017.

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- All pharmacists, working in the ambulatory Infusion Centers successfully completed a Chemotherapy Workflow Competency, which confirmed their understanding of the culture of safety, order verification principles, as well as the tools and resources available to pharmacy staff. <u>Completed: 1/4/2018.</u>
- The "Culture of Safety" is reinforced at every team meeting. It is stressed that safety supersedes speed and is essential for quality of care.

The technician compounded the medication without using the recipe and ignored the elements on the label

- EPIC (EHR) production labels were revised for all medications that require compounding to ensure the correct drug dose, drug volume, base solution volume, total volume, and relevant preparation instructions are displayed correctly. (See Screen Shot #5). Completed: 12/1/2017.
- Pharmacy technicians successfully received education regarding the use of PRODUCTION labels as references for compounding recipes during preparation. Completed: 1/29/2018.
- Medication compounding in IV rooms will not occur until ALL of the following criteria are met:
 - Compounding recipe is added to the Master Formula and reviewed and signed off by either the Pharmacy Supervisor or two pharmacists.
 - Production label in EPIC is validated to have clear and correct information for technicians to follow.
 - New addition to the Master Formula is reviewed with pharmacy staff who have the required education documented.
 - These expectations were added to the policy "MM: Medication Verification, Order Processing and Dispensing" to ensure expectations are clear. This policy will be reviewed at Pharmacy & Therapeutics Committee for approval on 2/6/2018.
- Pharmacy Leadership reinforced the use of a Master Formula to verify recipes and preparation instructions by IV room staff.
 (Completed: 1/4/2018 for current staff). This is now included in Pharmacy Orientation training for all new staff. The policy "Sterile Compounding General Principles: Aseptic Technique and Professional Conduct in Controlled Area" was revised to reflect this practice. This policy will be reviewed at Pharmacy & Therapeutics Committee for approval on 2/6/2018.

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3. The Pharmacist checked the compounded medication without verifying for appropriateness

- The following changes to the pharmacy verification process for intravenous and intrathecal compounded medications were made:
 - Pharmacist Quality Check:
 - i. A distraction-free zone was created in compounding areas (Completed: 11/17/2017)
 - a. Unnecessary phone calls to the IV room are minimized, allowing the staff to focus on quality checks.
 - b. Nursing began using the "Dispense Track" function in EPIC to minimize status check phone calls to pharmacy.
 - ii. Laminated intrathecal dosing guidelines are posted at each biosafety cabinet for dosing reference when needed. This is to ensure that mandatory guidelines that define allowable dosages for intrathecal medications are readily available. (See screenshot #7). Completed: 1/4/2018.
 - iii. A hyperlink in the patient medication administration record (MAR) and the Medication Order Screen in EPIC was created to provide easy access for physicians, nurses, and pharmacists to a reference for intrathecal dosing guidelines (See screenshot #6). Completed: 1/4/2018.
 - iv. A skills-based competency on the compounding final check process will be developed and assessed annually for pharmacists, who perform this activity in their daily workflow. This competency will be focused upon, but not limited to, the following aspects:
 - a. Ability to retrieve patient information from the EHR to validate dosing and regimen appropriateness based on information available on medication label.
 - b. Ability to visually identify incorrect information on the medication label (dose, route, infusion rate, erroneous administration information).
 - c. Ability to identify incorrect dilution/compounding techniques performed by technicians via case scenarios.
 - d. Ability to consult appropriate resources when unsure of medication doses presented on compounding labels.
 - e. Note: the first skills-based competency on compounding will be administered to all pharmacists by February 28, 2018.
- 4. The time-out process failed to catch the medication error. There is no guidance to staff and providers on verifying the correct medication and dose of medication during the time-out as a means to capture a medication error.
 - The Time Out (Procedural/Surgical Verification) policy and accompanying Attachment C were revised to require a time out when
 any chemotherapy agent is administered intrathecally. The time out process was expanded to include, when appropriate (e.g.
 intrathecal chemotherapy) verification of correct medication, medication dose, medication route and documentation in the EHR
 (Completed: 2/5/18)

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- All Infusion Center nurses were successfully educated to the policy revisions. Education included the fact that the time out process
 is considered a "no interruption" event. A "TIME OUT IN PROCESS/DO NOT INTERRUPT" sign will be placed on the patient's room
 door prior to commencing the time out. The time out, led by the Physician, will be completed with no interruptions, with no one
 leaving the room. In the event there is an interruption, the time out will be restarted. No nurse will be assigned to a patient
 receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. (Completed: 2/5/18)
- The Time Out process will be added to the Annual Skills Day for the Infusion Center nurse. A date for Skills Day will be identified on 2/6/18.

5. The MD verified the incorrect order when e-signing the transcribed medication, and prior to administration.

- Electronic Health Record (EHR, EPIC)
 - i. UCI implemented hard-stop limits for <u>all</u> intraTHECAL chemo injections. Physicians will not be able to submit or verify orders if doses exceed established limits. Specifically, the hard stop for intrathecal etoposide does not allow providers to enter dosages greater than 0.5 mg as standard daily dose, or 2.25 mg as the maximum single dose. (See screenshot #2 and #3). Completed: 12/1/2017.
 - ii. Twenty-one intraTHECAL treatment plans with standardized intraTHECAL doses pre-configured were built to increase efficiency and decrease risk of order entry error. (See screenshot #4). Completed: 1/4/2018.
- A hyperlink in the patient medication administration record (MAR) and Medication Order Screen in EPIC was created to provide ready access for physicians to a reference for intrathecal dosing guidelines (See screenshot #6). Completed: 1/4/18.
- The organization's Medical Executive Committee (MEC) received a written request for a formal corrective action investigation into the action(s) by the Attending Physician from the Chief Medical Officer (Referral Submitted 1/17/18). The MEC investigative processes, and the referral of this case for review, are consistent with our safety culture. Per Medical Staff bylaws, a request for a formal corrective action investigation requires formation of an ad hoc investigatory committee of the Medical Staff, which then conducts a separate review to examine the episode of care in question (in this case the intrathecal etoposide overdose which occurred on Nov. 14, 2017) to determine whether or not the standard of care/quality expected at UC Irvine has been sufficiently achieved and sustained. Note that in completing this investigative work, the MEC ad hoc committee may solicit input from outside experts as deemed necessary. Once the MEC investigation is complete, relevant sanctions will be levied on the Attending Physician, as deemed appropriate, and within the scope of the Medical Staff Bylaws; and, consistent with the laws of the State of California.



- 6. The RN failed to recognize the high dose of medication when releasing the medication and prior to the MD administering the medication.
 - A hyperlink in the patient MAR and Medication Order Screen in EPIC was created to provide easy access for physicians, nurses, and pharmacists to a reference for intrathecal dosing guidelines (See screenshot #6). Completed: 1/4/2018.
 - All Infusion Center nurses currently on staff will be successfully educated to verify with Uptodate (click link within EPIC EHR) when unsure of proper medication dosing/dose ranges. In addition to the Uptodate resource, the nurses will be successfully educated with respect to the range of additional unit based resources available to them: Charge Nurse, Pharmacist, Ordering Physician, Infusion Center Nurse Practitioner. Documentation of education proficiency will be placed in the personnel file of each nurse currently on work status (To Be Completed 2/6/18). Nurses on FMLA, vacation, or not scheduled, will be educated the first date of return to work and prior to being given a patient care assignment.
 - The Infusion Center Orientation/Competency Validation Record will be revised to require orientation/education/competency in Medication Administration: Intrathecal Injection under the Care of the Patient Requiring Medication and IV Therapy category (To Be Completed 2/6/18)
 - The Infusion Center Nurses' Annual Skills Day will incorporate education on intrathecal administration of chemotherapy. A date for Skills Day will be identified on 2/6/18.

Plan Approved Date: February 4, 2018

Richard J. Gannotta, Chief Operating Officer

Willie C. Wil Md

William C. Wilson, MD, Chief Medical Officer

Pat Patton, RN, Chief Nursing Officer