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CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050348	A. BUILDING _____ B. WING _____	02/06/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
University of California Irvine Medical Center	101 The City Dr S, Orange, CA 92868-3201 ORANGE COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00562668 - Substantiated Representing the Department of Public Health: Surveyor ID# 3043, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.3(9): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Health and Safety Code Section 1279.1 (c): The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made. The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code 1280.3 (g): For purposes of this section, "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or to the patient. Health and Safety Code 1279.1(b): For purposes of			2018 OCT 18 PM 5:02

Event ID: WQ3611 10/3/2018 2:58:31PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
	Chief Executive Officer	10/18/2018

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

Approved 10/18/18 #36703

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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	this section, "adverse event" includes the following: (4) Care management events, including the following: A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose. T22 DIV5 CH1 ART 3 70203 (a)(2) (a) A committee of the medical staff shall be assigned responsibility for: (A)(2) Developing, maintaining and implementing written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. T22 DIV5 CH1 ART 3 70215 (a)(b) (a)A registered nurse shall directly provide: (2) The planning, supervision, implementation, and evaluation of the nursing care provided to each patient. The implementation of nursing care may be delegated by the registered nurse responsible for the patient to other licensed nursing staff, or may be assigned to unlicensed staff, subject to any limitations of their licensure, certification, level of validated competency, and/or regulation. (b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning,			

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	intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission. T22 DIVS CHI 3 70263 (c)(1) (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 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. T22 DIVS CHI 3 70263 (g)(2) (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.		**Pharmacist Verification:** **1.** As of 11/17/17, 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." Monitoring: IV room and Infusion Center Supervisors will Perform 10 random audits of medication order verification/month/site. 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. **2.** The policy "MM: Medication Verification, Order Processing and Dispensing" was revised to reflect this verification practice. It was approved by the Pharmacy & Therapeutics Committee on 2/6/18. Monitoring: Audits to ensure policy compliance will occur as described above.	3/6/18 3/6/18

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	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. Based on observation, interview, and document review, the hospital failed to develop and implement an effective and safe system of checks and balances to ensure the safe distribution and administration of the chemotherapy agents (medications to treat cancer), considered as high risk medications, prior to the administration of an intrathecal [IT] etoposide [chemotherapy medication administered directly into the fluid-filled space between the thin layers of tissue that *cover* the brain)] to Patient A as evidenced by: 1. Systems of safe distribution of etoposide with an IT (Intrathecal) route were not followed in the outpatient infusion pharmacy when Pharmacist 1 failed to review all elements of the order for the etoposide prior to verifying the order. The pharmacy technician (Tech 1) failed to follow the compounding recipe during the preparation of etoposide. Then Pharmacist 2 failed to identify the medication was incorrectly compounded when the incorrect dose and dilution of the etoposide was verified by Pharmacist 2 as correct for administration to Patient A.		**3.** As of 1/4/18, all pharmacists, working in the ambulatory Infusion Centers 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. Monitoring: Results of annual competency for Ambulatory Infusion Center pharmacists will be reported to Medication Safety Committee, P&T, Quality & Safety Oversight Committee, Medical Executive Committee and the Governing Body until 100% participation of active staff pharmacists and 100% pass rate is achieved for 2 consecutive years. **Pharmacy Technician:** **1.** As of 12/1/18, 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. Monitoring: Ongoing. EPIC drug preparations are regularly reviewed, added, and revised based on clinical practice changes. 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	3/6/18 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. 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). Findings:		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.** As of 1/4/18, pharmacy Leadership reinforced the use of a Master Formula to verify recipes and preparation instructions by IV room staff. 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 3/6/18

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	On 11/28/17, the Department received a written complaint that Patient A received a chemotherapy medication at twice 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 nausea and extreme pain after the administration of the drug and experienced progressive neurological decline. Patient A was admitted 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 nutrition 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 died 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 medulloblastoma 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 1136 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 fluid). 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 approved by Pharmacy & Therapeutics Committee on 2/6/18. 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. **Registered Nurse:** **1.** As of 1/4/18, 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. Completed and ongoing.	3/6/18 3/6/18

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	of knowledge and attention (information a person has stored in memory about people, places and things). Patient A's speech was clear and fluentwith cranial nerves (the nerves of the brain, whichemerge from or enter the skull) intact. Patient A had normal comprehension and full upper and lower body motor strength. However, Patient A had discoordination on the finger-nose assessment (touching the finger to the nose) and was unable to walk in tandem (where the toes of the back foot touch the heel of the front foot at each step). Review of the physician's order dated 9/25/17 at 1718 hours, showed MD 2 ordered etoposide 0.5 mg IT for days one to five, to be given every two weeks for four weeks (a total of 20 doses) starting on 11/14/17. Review of the hospital's P&P addressing Chemotherapy Administration Guidelines dated 11/16 showed the intrathecal or IT chemotherapy agents would be administered by a physician specializing in cancer treatment. In this case, the medication was administered by MD 2, a neuro-oncologist (physician specialized in cancer treatment for the nervous system). In addition, the hospital required a "time-out" process for intrathecaladministration of the medication. The time out process required a nurse anda physician (neuro-oncologist) to agree with: the patientname, the description of the procedure (medication administered via the intrathecal route), medication name, medication dose, as well as to verify the medication label, and scan the medication labelat bedside to ensure the information was accurate.		**2.** As of 2/6/18, all Infusion Center nurses were 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 were 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 was entered into the personnel file of each nurse. Infusion Center manager will perform 10 random audits per month until 100% compliance is achieved for 3 months. The nurses will demonstrate where the hyperlink in the patient's MAR and Medication order screen in EPIC regarding intrathecal dosing guidelines. **3.** The Infusion Center Orientation/Competency Validation Record was revised as of 2/6/18 to require orientation/education/competency in Medication Administration: Intrathecal Injection under the Care of the Patient Requiring Medication and IV Therapy. Complete and ongoing **4.** As of 2/6/18, the Annual Skills Day for the Infusion Center Nurse will incorporate education on intrathecal administration of chemotherapy. Completed and will be ongoing. **Time-Out Process:** 1. The Time Out (Procedural/Surgical Verification) policy was revised as of 2/5/18 to require a time out when any chemotherapy agent is administered intrathecally. The time	3/6/18 3/6/18 3/6/18 3/6/18

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	Review of Patient A's Assessment dated 11/14/17 at 1000 hours, RN 2 documented Patient A was within defined limits (WDL) on the neurological assessment, and the Richmond Agitation Sedation Scale [RASS (measures the level of sedation and agitation)] showed Patient A was alert and calm. Patient A's respiratory (breathing), cardiac (heart), gastrointestinal (digestive system), and musculoskeletal assessments were WDL. In addition, Patient A's skin integrity and psychosocial assessments were also WDL. Review of the Action Summary showed etoposide 100 mg in a volume of 5 ml (milliliters) via the IT route was administered to Patient A by MD 2 on 11/14/17 at 1253 hours. Review of the Interdisciplinary Notes dated 11/14/17 at 0930 hours [the time in which the note summary was first created in the eHR (electronic health record) and later filed (time unknown)] showed immediately after the infusion of the IT etoposide, Patient A became diaphoretic (sweating) and complained of extreme head pain with nausea and vomiting. Patient A was transported to the hospital's Emergency Department (ED) for assessment. Review of the ED to Hospital Admission Note dated 11/14/17, showed Patient A arrived at the ED on 11/14/17 at 1521 hours, and was admitted as an inpatient to the hospital at 1745 hours. On 1/4/18 at 1150 hours, MD 1, the Director of		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. Monitoring: The Infusion Center Manager will perform 10 random audits per month of time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs. 2. As of 2/5/18, all Infusion Center nurses were 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 a patient receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. Monitoring: The Infusion Center Manager will perform 10 random audits per month of this time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs	3/6/18

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	Neurocritical Care (Neuro ICU, high level of care for patients with severe nervous system issues) and the primary physician overseeing Patient 1's care, was interviewed. MD 1 stated on arrival to the Neuro ICU Patient 1 was "not doing very good." MD 1 stated Patient 1 was "awake and interactive" initially, but had since "slowly deteriorated" to "complete unresponsiveness." MD 1 stated the overall outlook for Patient 1 was "not good." On 2/2/18 at 1557 hours, Patient A was observed with RN 4, the primary nurse. Patient A was lying in bed with both eyes partially closed. Patient A was on a ventilator machine (machine to assist breathing) which was connected by a tube to her tracheostomy (tube to help with breathing) and a feeding tube inserted through an incision in the abdominal wall was in place and was connected to a feeding pump (a machine which infuses nutrition in a liquid form through the feeding tube). RN4 stated Patient A was nonresponsive and required total assistance with her needs. 1. Pharmacist 1 failed to properly transcribe the order into the eHR , and Tech 1 failed to properly follow the compounding recipe, creating the incorrect medication dose. Review of the hospital's P&P titled Medication Management: Medication Verification, Preparation, and Dispensing dated 2/17 showed in part: "... 1. When a medication order is received, the pharmacist shall review the order for appropriateness and completeness prior to confirming the order in the computer system. 2.		3. As of 2/6/18, the time-out process will be added to the Annual Skills Day for the Infusion 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 had both intraTHECAL and intraVENOUS route options to prevent confusion. Completed and on-going. **2.** As of 12/1/17, 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. Completed and on-going.	3/6/18 3/6/18 3/6/18

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	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 RX [pharmacy] of final preparation." On 1/4/18 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 the physician. The medication orders would then be verified by two		**3.** As of 12/1/17, UCI implemented hard stop limits for all intrathecal chemotherapy injections. Users are not 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. Completed and ongoing. **4.** As of 1/4/18, twenty-one intrathecal treatment plans with standardized intrathecal doses pre-configured were built to increase efficiency and decrease the risk of order entry error. Completed and ongoing. **5.** As of 2/28/18, safety parameters have 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). Completed and ongoing	3/6/18 3/6/18 3/6/18

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	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 IT route and so a work-around was done to transmit the order for Patient A. 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 this order as correct on 11/13/17 at 1720 hours. Review of the medication dispensed to Patient 1 by Pharmacist 1 showed the medication was labeled as etoposide 100 mg in 5 ml of normal saline (solution to dilute the medication) and was prepared by Technician (Tech) 1 and checked by Pharmacist 2. The label also showed the administration route was "intrathecal," and not IT as ordered. On 1/4/18 at 1025 hours, Pharmacist 1, the Supervising Pharmacist in the Oncology (cancer treatment) area and one of the two pharmacists involved in the verification of Patient A's medication order was interviewed. Pharmacist 1 stated etoposide 0.5 mg in 5 ml should have been dispensed; instead, the pharmacy dispensed etoposide 100 mg in 5 ml. Pharmacist 1 stated he did not note that the administration route was "intrathecal" during the verification and assumed the route was IVPB (intravenous piggy back - medication diluted in a specified amount of fluid, and		**MD Verification:** **1.** As of 1/4/18, 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. Completed and ongoing. **2.** 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. Completed.	3/6/18 3/6/18

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	infused into the vein over a specified period). Pharmacist 1 stated 100 mg was the usual dose for IVPB etoposide, but not for the IT administration done through the intrathecal route. Pharmacist 1 further stated both he and pharmacist 2 used the summary review of the order instead of opening the order details in the eHR during the order verification where the administration route would have shown correctly as IT. Pharmacist 1 presented the product stocked and used by the hospital for the etoposide preparation. The medication concentration supplied by the manufacturer was 100 mg in 5 ml. Pharmacist 1 confirmed the medication was dispensed in the same concentration as supplied by the manufacturer and was not further diluted prior to administering to Patient A. Review of the compounding recipe (a document containing the ingredients and instructions to prepare the medication) for etoposide infusion (IVPB) with Pharmacist 1 showed the dose was to be diluted in 500 ml normal saline. The preparation instructions from the compounding recipe for etoposide intrathecal were as follows: "DILUTION: Use a sterile empty 30 ml vial, add 0.5 ml... etoposide 20 mg/ml (20 mg per ml or 10 mg per 0.5 ml) into... NS [normal saline] 19.5 ml for final concentration of [10 mg per 20 ml or 0.5 mg per ml] PREPARATION: Calculate the volume [of the needed dose]. Withdraw this amount from the vial into syringe...." On 1/4/18 at 1440 hours, Tech 1 was interviewed. Tech 1 stated he had three years of experience in		**Pharmacist Medication Compounding:** The following changes to the pharmacy verification process for intravenous and intrathecal compounded medications have been implemented: **1.** As of 11/17/17, a distraction-free zone was created in compounding areas. Unnecessary phone calls to the IV room are minimized, allowing the staff to focus on quality checks. Nursing began using the "Dispense Track" function in EPIC to minimize status check phone calls to pharmacy. Completed and ongoing. **2.** As of 1/4/18, 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. Completed and ongoing. **3.** As of 1/4/18, 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. Completed and ongoing.	3/6/18 3/6/18 3/6/18

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	Oncology but had not prepared the medications for an IT route before. Tech 1 stated this was his first time preparing an IT medication; however, the tech stated he felt "comfortable" preparing it and did not use any reference (such as the compounding recipe) to guide him with the preparation. The medication label for the medication dispensed to Patient 1 was reviewed with Tech 1. The label showed there were two components required for this preparation: etoposide 100 mg and normal saline 5 ml. Tech 1 stated he did not use normal saline for the preparation and did not question the presence of the solution on the label. Tech 1 stated he encountered similar situations before and was told it was "OK" to ignore the presence of the solution on the label. During an interview on 1/4/18 at 1440 hours, the Director of Pharmacy stated she expected Tech 1 to use the compounding recipe for the etoposide intrathecal, especially when it was his first time preparing the medication. Pharmacist 2, who verified Tech 1's compounded etoposide prior to dispensing, was not available for interview. On 1/4/18 at 1125, the Director of Risk and Regulatory, Director of Pharmacy, and the Assistant Director of Pharmacy were interviewed. The staff acknowledged the pharmacist who checked the preparation of the etoposide should have checked the dose and route of administration and caught the error, but he did not.		4. As of 2/28/18, a skills-based competency on the compounding final check process was developed for pharmacists to integrate into their daily workflow. This competency will be focused upon, but not limited to, the following aspects: a. Ability to retrieve patient information from EHR to validate dosing and regimen appropriateness based on information available on the 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 appropriated resources when unsure of medication doses presented on compounding labels. Monitoring: Results of annual skills-based competency for IV Room and Infusion Center pharmacists will be reported to Medication Safety Committee, P&T, Quality & Safety Oversight Committee, Medical Executive Committee and the Governing Body.	3/6/18

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	On 1/4/18 at 1400 hours, further interview with the Director of Risk and Regulatory, Director of Pharmacy, and the Assistant Director of Pharmacy was conducted. The staff acknowledged the order verification training for the pharmacists did not emphasize the importance of using the order details [to see all relevant information] as it should. 2. MD 2 failed to identify the dose of etoposide IT was incorrect when MD 2 authenticated the transcribed order in the new eHR. Review of the Medical Staff Bylaws section 3, subsection 3 dated 11/28/16, showed the responsibility of a medical staff member is to abide by the Medical Staff Bylaws, Rules and Regulations, and all other lawful standards, policies, and rules of the medical center. Review of the hospital's P&P titled Medication Management: Medication Administration, Monitoring and Documentation dated 11/17 showed care providers administering medications will use his or her best judgement to assure the medication, dose, and route are consistent with the patient's condition and history. Discrepancies or questions will be resolved before the medication is administered. On 12/12/17 at 1031 hours, an interview and concurrent review of the hospital's documents was conducted with MD 2. MD 2 stated he entered a Computerized Physician Order Entry (CPOE) for etoposide 0.5 mg IT for Patient A on 9/25/17 at 1718 hours, in the old eHR system, prior to the hospital's transition to the new eHR system on 11/4/17.		**MD Verification:** **1.** As of 1/4/18, 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. Complete and ongoing **2.** As of 12/1/17, UCI implemented hard-stop limits for all 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. Complete and ongoing **3.** As of 1/4/18, twenty-one intraTHECAL treatment plans with standardized intraTHECAL doses pre-configured were built to increase efficiency and decrease risk of order entry error. Complete and ongoing	3/6/18 3/6/18 3/6/18

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	Review of the Transcribed Order in the new eHR dated 11/13/17 at 1554 hours, showed etoposide 100 mg chemo infusion (instead of etoposide 0.5 mg IT). The order was electronically verified by MD 2 on 11/13/17 at 1720 hours. MD 2 stated he did not identify the discrepancy in the dosage and route of the medication when he verified the order after it was transcribed. 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 missed the chance to ident ify the dose of etoposide was incorrect for the IT route when the dose was "not verified" by him prior to the medication administration to Patient A. 3. RN (registered nurse) 2 and 3 failed to review and evaluate the dose of etoposide was correct by failing to review the initial order in the eHR when RN 2 released the etoposide 100 mg order for dispensing by the hospital's outpatient infusion center pharmacy. Review of the hospital's P&P titled Medication Management: Medication Administration, Monitoring and Documentation dated 2/17 showed care		**MD Verification:** **1.** As of 1/4/18, 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. Complete and ongoing **2.** As of 12/1/17, UCI implemented hard-stop limits for all 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. Complete and ongoing **3.** As of 1/4/18, twenty-one intraTHECAL treatment plans with standardized intraTHECAL doses pre-configured were built to increase efficiency and decrease risk of order entry error. Complete and ongoing	3/6/18 3/6/18 3/6/18

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	providers administering medications will use his or her best judgement to assure the medication, dose, and route are consistent with the patient's condition and history. Discrepancies or questions will be resolved before the medication is administered. Review of the hospital's P&P titled Medication Management: Chemotherapy, Appendix C dated 11/16 showed the RN who initiated the chemotherapy order should review and validate the medication to be given with what had been ordered in the eHR. On 2/2/18 at 1103 hours, an interview was conducted with RN 3 and the Infusion Center Manager. When asked about the process of preparing a patient for outpatient chemotherapy, RN 3 stated the list of patients who were to receive treatments were reviewed first thing in the morning. RN 3 stated she reviewed the medication cyclesfor each patient and the medication orders for appropriateness . If a medication seemed offor unusual in some way, she looked up themedication on an online medication reference used by the hospital and notified the charge nurse and MD. RN 3 also stated she looked up a medication on the reference system if she was not familiar with the type of chemotherapy to be given. If the order was appropriate , RN 3 released the order to the pharmacy for distribution once the patient arrived and was assessed as stable to receive chemotherapy. The Manager verified RN 3's statements of the process werecorrect. Review of Patient A's medical record showed RN 2			

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	released the etoposide 100 mg order and participated in the timeout process as well as participated in assisting MD 2 in administering the medication to Patient A. There was no documented evidence to show RN 2 intervened regarding the high dose of etoposide prior to it being administered. RN 2 proceeded to release the drug to the pharmacy. RN 2 was not available for interview. 4. The time out process, conducted prior to the administration of the etoposide, failed to identify the incorrect dose of the medication when RN 2 failed to identify the medication error during the timeout process and prior to the administration of etoposide. 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, "Dose verification shall include the following steps: 1. The administering practitioner shall obtain and prepare the medication. 2. The second qualified practitioner shall *verify* that the intended medication and dose were obtained and prepared correctly...." Review of the hospital's P&P titled Medication Administration, Administration Time, Monitoring and Documentation dated 11/17 showed in part: "... To delineate acceptable standards for the medication administration... per physician orders in keeping		**Time-Out Process:** **1.** The Time Out (Procedural/Surgical Verification) policy was revised as of 2/5/18 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. Monitoring: The Infusion Center Manager will perform 10 random audits per month of time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs **2.** As of 2/5/18, all Infusion Center nurses were 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 a patient receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. Monitoring: The Infusion Center Manager will perform 10 random audits per month of this time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs **3.** As of 2/6/18, the time-out process will be added to the annual skills day for the infusion center nurses. Complete and ongoing	3/6/18 3/6/18 3/6/18

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	with applicable safety recommendations and regulatory requirements... Careproviders administering medications, regardless of the setting, shall... Use his or her best judgement to assure that the medication, dose and route are consistent with the patient's condition and history and resolve any concerns with an ordering practitioner responsible for the patient...." Review of the hospital's P&P Medication Management: Chemotherapy , Appendix C: Chemotherapy Administration Guidelines, dated 11/16, showed "... a. Intrathecal... administration of chemotherapy agents can only be performed by a credentialed physician or advanced practitioner with demonstrated clinical competence. b. Confirm that a "Time Out" occurred and document such in the electronic medical record...." Two licensed personnel would independently verify the chemotherapy orders prior to administration. The name of the second RN or licensed personnel would be documented to acknowledge the double check. On 1/4/18 at 1011 hours, an interview was conducted with the Chief Medical Officer (CMO) concerning the time out procedures for the administration of chemotherapy. The CMO stated the timeout procedure was to happen with no interruptions; the patient was identified using two patient identifiers; and a description of the procedure was read and reviewed with the patient, including the medication involved. The CMO stated for the IT medication, the dosage should be mentioned, and the time out procedure ensured the right patient, right drug, and right plan.		**Time-Out Process:** The Time Out (Procedural/Surgical Verification) policy was revised as of 2/5/18 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. Complete and ongoing **2.** As of 2/5/18, all Infusion Center nurses were 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 a patient receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. Monitoring: The Infusion Center Manager will perform 10 random audits per month of this time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs. As of 2/6/18, the time-out process will be added to the Annual Skills Day for the Infusion Center nurses. Complete and ongoing	3/6/18 3/6/18 3/6/18

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	On 1/4/18 at 1315, RN 1 was interviewed in the presence of the Director of Risk and Regulatory, Director of Pharmacy, and Assistant Director of Pharmacy. RN 1 had 10 years of experience in Oncology and would be involved in the time out procedure for the IT administration of medication in Oncology (as a qualified practitioner). RN 1 was asked to review the hospital's process for Time Out. RN 1 explained the time out process consisted of reading the information on the medication label out loud [to the physician], and sometimes the information on the computer screen was read [to the physician]. RN 1 stated for the time out procedure, she verified the completion of the consent for the procedure with the MD. To verify the medication, RN 1 stated both the MD and RN read the label on the medication. The medication was then taken to the patient and the label was compared with the patient's armband. RN 1 then stated the medication label was to be compared with the order in the eHR. However, RN 1 stated one could also read the order back from the computer while another verifier reviewed the medication label. RN 1 then stated another process whereby she compared the medication label with the order then compared the MAR with the MD. Review of a sample Time Out flowsheet in the eHR with RN 1 showed the following: - Time Out Time - Introduction between members		**Time-Out Process:** The Time Out (Procedural/Surgical Verification) policy was revised as of 2/5/18 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. Complete and ongoing As of 2/5/18, all Infusion Center nurses were 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 a patient receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. Monitoring: The Infusion Center Manager will perform 10 random audits per month of this time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs As of 2/6/18, the time-out process will be added to the Annual Skills Day for the Infusion Center nurses. Complete and ongoing	3/6/18 3/6/18 3/6/18

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	- Correct patient identity confirmed - Agreement on the procedure to be done - Accurately completed and signed consent form - Confirmation that the correct side and site are marked - All allergies and reactions have been reviewed - Patient is in the correct position - Relevant images and results are properly labeled - Safety precautions taken based on the patient's history or medication use - The need to administer antibiotics or fluids for irrigation -Name of antibiotic given/taken There was no documented evidence to show RN 2 followed the above procedures for the time-out process. RN 2 proceeded to release the drug to the pharmacy, perform the timeout process without stating the medication dose, and documented the administration on the MAR without identifying the high dose of etoposide. RN 2 did not identify the high dose of etoposide, or alert the pharmacy, MD 2, or the charge nurse on duty at any time prior to it being administered to Patient A. Further review of the timeout flowsheet failed to show an area to document verification of the medication dose, route, and appropriateness of the medication as part of the time out process as required by the P&P. When asked how the medication was verified, RN 1 stated she would check the medication label against the MAR when she picked up the medication from the pharmacy, then the MD would check the medication with her at the time out procedure.		**Time-Out Process:** **1.** The Time Out (Procedural/Surgical Verification) policy was revised as of 2/5/18 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. Complete and ongoing **2.** As of 2/5/18, all Infusion Center nurses were 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 a patient receiving intrathecal chemotherapy unless there is documented evidence of their education to the policy. Monitoring: The Infusion Center Manager will perform 10 random audits per month of this time out process until 100% compliance is achieved for 3 months. Once completed results to be reported to Regulatory Affairs. **3.** As of 2/6/18, the time-out process will be added to the Annual Skills Day for the Infusion Center nurses. Complete and ongoing	3/6/18 3/6/18 3/6/18

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

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University of California Irvine Medical Center	101 The City Dr S, Orange, CA 92868-3201 ORANGE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	During an interview on 1/4/18 at 1349 hours, the Director of Risk and Regulatory and the Director of Pharmacy acknowledged there were inconsistent practices during Patient A's time out procedure and the hospital's P&P lacked guidance for the staff regarding verification of high risk medications during the time out process. On 1/4/18 at 1641 hours, the above findings were verified and shared with the Director of Risk and Regulatory, Director of Pharmacy, and Assistant Director of Pharmacy. This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(9).			

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 **all** 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.**
     - 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.**

- The policy "MM: Medication Verification, Order Processing and Dispensing" was revised to reflect this verification practice. It will be presented at the Pharmacy & Therapeutics Committee on 2/6/2018 for approval.
- 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. **Completed: 1/4/2018.**
- The "Culture of Safety" is reinforced at every team meeting. It is stressed that safety supersedes speed and is essential for quality of care.

2. 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.

3. <u>The Pharmacist checked the compounded medication without verifying for appropriateness</u>
    - 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 **(<u>Completed: 11/17/2017</u>)**
                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). **<u>Completed: 1/4/2018</u>**.
            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). **<u>Completed: 1/4/2018</u>**.
            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. <u>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.</u>
    - 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 **(<u>Completed: 2/5/18</u>)**

- 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 **all** 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

William C. Wilson, MD, Chief Medical Officer

Pat Patton, RN, Chief Nursing Officer