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
	050590	A. BUILDING _____ B. WING _____	01/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Methodist Hospital of Sacramento	7500 Hospital Drive, Sacramento, CA 95823-5403 SACRAMENTO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00462656, CA00455078 - Substantiated Representing the Department of Public Health: Surveyor ID # 2311, 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(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 death to the patient. The hospital detected the Adverse Event on 8/18/15. The hospital notified the patient of the Adverse Event on 8/18/15. The hospital notified the Department of the Adverse Event on 8/19/15. Health and Safety Code Sec 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 death to the patient. Adverse Event Notification - Informed Health and Safety Code Section 1279.1 (c), "The facility shall inform the patient or the party		**Response to CA00462656 and CA00455078 begins here** A. Following a thorough review of the event employment of three RNs involved in administration of the medication were terminated. Responsible: Family Birth Center Director. B. Following a thorough review of the event employment of the Pharmacy Technician involved in the event was terminated. Responsible: Pharmacy Director. C. Contracted with a new vendor to supply norepinephrine and oxytocin packaged with TALLman lettering and alerts pre-affixed to the product. Responsible: Pharmacy Director.	8/27 2015 9/02 2015 8/21 2016

Event ID:CCIW11 4/20/2017 9:54:56AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Wayne E Lodda TITLE Interim Director (X6) DATE 4/27/2017

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 22

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are 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 cited, an approved plan of correction is requisite to continued program participation.

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	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 Sec 1279.1 Medication Error (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following: (A) 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. The CDPH verified an error in the administration of a medication resulted in a serious disability to Patient 1. Title 22 Div5 Ch1 Art3 Sec 70213 Nursing Services Policies and Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. (1) Policies and procedures which involve the medical staff shall be reviewed and approved by the medical staff prior to implementation. These requirements were not met as evidenced by:		D. Instructed pharmacy staff to notify pharmacy leaders when a change in packaging occurs to facilitate organization-wide education about the change. Responsible: Pharmacy Director. E. Revised policy titled *Pharmacy Staff Competency* to require completion of a minimum of 4 weeks of orientation, training, and verification of staff competency prior to the employee working independently. Responsible: Pharmacy Director. F. Education provided to pharmacy staff about the requirements for labeling high risk medications including: • An independent verification process. • Use of safety technology. • Use of the chain of command to report medication errors. Responsible: Pharmacy Director	9/12 2015 3/22 2016 9/12 2015

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	Based on observations, staff interviews, medical record and document review, the General Acute Care Hospital (GACH) failed to fully develop, implement and maintain policies for the administration of medications when: 1. The GACH failed to follow the facility policy for labeling of stock medications not labeled by the Pharmacy (Medication Management, 12/4/14, page 7) when a licensed nurse (Nurse 2) did not label the intravenous (IV) bag with the patient's name, name of the medication, dose, date and time of initiation. 2. The GACH failed to follow the facility policy for labeling of medications (Medication Management, 12/4/14, page 7) when Nurse 2 did not label the distal end of the IV tubing with the name of the medication after it had been attached to the medication. 3. The GACH failed to fully develop and implement an appropriate and effective double check system for verification of high alert medications when Nurse 2 and Nurse 3 did not actively visualize and verify the medication they were administering, even after a warning appeared on the computer screen alerting them Patient 1 was not prescribed the medication they were administering. In addition, Nurse 2 and 3 did not document the verification with the two required signatures as required by the facility policy for Oxytocin Management, 10/17/13, page 2. These failures resulted in the selection and administration of the wrong medication to Patient 1, who was in labor. The wrong medication,		G. Medications were relocated within the pharmacy to prevent high- risk medications being stored in close proximity to each other. Responsible: Pharmacy Director H. Conducted huddles with Family Birth Center staff to define the expectations of shift-to-shift communication processes including medication verification. Responsible: Family Birth Center Director	8/18 2016 9/12 2015

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	norepinephrine (used to increase blood pressure in very ill patients), was obtained, hung and infused in full to Patient 1 instead of the prescribed medication, oxytocin, which is used to stimulate/augment uterine contraction for delivery. The failure to fully develop and/or implement medication policy and procedures led to this error and to Patient 1's development of cardiomyopathy, a condition affecting the heart muscle which makes it harder for the heart to pump and deliver blood to the entire body. Cardiomyopathy can lead to heart failure and possible death. Findings: During a tour of the Labor and Delivery Birthing area with the Nurse Manager (NM) on 11/2/15 at 3:30 p.m., the medication room was observed. This room contained the Omnicell, a locked unit for the storage of prescribed medications (prepared and labeled by the pharmacy) and stock medications (to be removed and labeled by the nurse with a physician's order). The NM stated the cart was stocked daily by the Pharmacy and included the storage bin for the stock of Oxytocin, a medication frequently used to induce or stimulate labor. 1, 2. During an interview on 11/2/15 at 11:15 a.m., the Director of Women's and Children's Services (DWCS) and a facility pharmacist (Pharm 1) acknowledged that any stock medications removed from the Omnicell must be visualized for identification, verified by a physician's order and labeled with the patient's name, name of		I. Education provided to RNs working in post-partum about medication management including signed attestation to verify understanding of requirements. Key points included: • 7 rights of safe medication administration. • Use of two patient identifiers • Scanning the patient's armband and the medication with verification against the eMAR. • Reading alerts that may come up when scanning. • Labeling IV tubing • Use of drug library on programmable IV pumps. • Requirement to immediately notify department leaders if a wrong medication was found on the unit, or a medication was labeled incorrectly Responsible: Family Birth Center Director	8/ 2015

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	medication, date, time and dosage. (Medication Management policy, pages 6, 7) The DWCS and Pharm 1 revealed the bag of medication the nurses removed from Omnicell for administration to Patient 1 was norepinephrine, but had a hot pink sticker that read oxytocin 15 units affixed, in error, to a clear outer bag. The oxytocin hot pink sticker was designated to be placed by pharmacy staff on oxytocin bags to alert nursing staff that oxytocin was a high-risk medication, which required nurses to double check upon initiation and whenever a new bag was hung (Medication Management, page 9, Medication Error Prevention (High Risk and Black Box Warning Medications), page 4). 3. The DWCS and Pharm 1 stated that oxytocin was designated as a high-risk medication that required, by policy (Medication Management, page 9, Oxytocin Management, page 4), verification by two registered nurses prior to administration with the use of an electronic barcoding device (Medication Management, page 9, Oxytocin Management, page 2). The device a (Barcode scanner) is used to scan the armband to confirm the patient's identification prior to administration; then the same device is used to scan the medication. If the medication were ordered (by the prescriber), processed (entered into the pharmacy computer system for the patient indicating its appropriateness with respect to dose, duration, indication for use) and approved by the pharmacist, then scanning the medication would confirm that it was ordered accurately for the specified indication and it was approved for use for that patient.		J. Education provided to nursing staff throughout the organization about the medication management policy/process including safety alerts, and appropriate response to medication events. Responsible: Chief Nurse Executive K. Clarified the process of ordering oxytocin post-delivery. Review of the verbal order process was discussed with the OB committee of the medical staff. Responsible: Family Birth Center Director L. Education about medication security provided to the family birth center staff. Responsible: Family Birth Center Director	8/24 2015 8/24 2015 8/24 2015

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	In addition, the DWCS explained that for high-risk medications, such as oxytocin, two nurses were required to mark and verify the intravenous line from the bag to the patient with a brightly colored alert sticker for easy identification. The DWCS further stated that at the change of shift, a two-nurse verification process should take place for every intravenous medication being infused. The process included tracking (holding between fingers) each of the lines from the bag (to identify the drug) to the pump (to verify the rate), to the site of infusion (to visually inspect the infusion site). The DWCS stated that this (bedside double check) process was not done, on 8/18/15, between RN 2 (night shift) and RN 4 (day shift) during the change of shift report, between 7-7:30 a.m. In addition, the DWCS acknowledged the two nurse verification process should occur with every rate change and when a new bag is initiated. The DWCS revealed there were no signatures of verification of the oxytocin in Patient 1's medical record. The DWCS explained that on 8/18/15 at 5:59 a.m., one of the two nurses at the bedside (RN 2 with RN 3 as the verifier), scanned the armband for Patient 1 then scanned the medication. DWCS stated that when the nurse scanned the medication bag (supposedly oxytocin) that was pulled from the Omnicell, instead of a confirmation screen, a warning appeared on the computer system linked to the scanning device. The nurses thought the reason for the error/warning was that the medication had expired. The nurses related this information to the mother of Patient 1, and said that they needed to double-check the expiration date of the bag. They		M. Reviewed the policy titled Adverse Drug Reaction. A PharmaGram (educational flyer) was distributed to clinical staff emphasizing the importance of reporting an adverse drug reaction using the online event reporting system. Responsible: Pharmacy Director N. Removed non-required ancillary labels from medications/medication packaging on dobutamine, dopamine, and lidocaine located in pharmacy stock, automated dispensing cabinets, and crash carts. Responsible: Pharmacy Director	3/25 2016 2/24 2016

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	repeated the process again. Again, the same error alert appeared on the screen. The two nurses, at the bedside (RN 2, RN 3), after confirming the medication had not expired, ignored the warning that appeared a second time and resumed the action of administration the medication which was not oxytocin, as prescribed, but norepinephrine which had been placed in the wrong assigned area in the Omnicell. They manually documented the medication "oxytocin" onto the Medication Administration Record (MAR) and started the infusion at 5:59 a.m., on 8/18/15. The actual medication being administered was Norepinephrine 4 milligram (mg) intravenous drip. The DWCS provided, to the surveyors, a copy of the visual ALERT (or similar alert) that appeared at the time the oxytocin was initiated: "The scanned medication, norEPINEPHrine (Levophed) 4 mg. was not within the Medication Task List." Review of the GACH policy titled Medication Management, dated 12/4/14, revealed the following direction to ensure the safe administration of medications: Page 7, "Label IV medications removed from the Omnicell (without a pharmacy label) with the patient's name, name of the medication, dose, date and time." Page 7, "Label the distal end of the IV tubing with the name of the medication. Label the IV tubing after it has been attached to the medication. Page 9, "High Alert medications that are required to have a co-signature include: Oxytocin (upon		O. Concurrent medication safety audits were conducted during administration of oxytocin to verify the following: • Independent double check (including order, drug, and dose). • Documentation of co-signature • Accurate labeling of medication, IV tubing, and IV pump settings • Use of pump and barcode scanning. The results of the audit were: 8/2015=54/56=96.4% 9/2015=47/48=97.9% 10/2015=16/16=100% 11/2015=12/12=100% 12/2015=8/8=100% Remediation was completed for every process deviation identified. Responsible: Family Birth Center Director	8/2015 to 12/2015

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	initiation and whenever a new bag is hung)" Review of the GACH policy "Oxytocin Management, Intrapartum", approved on 10/17/13, revealed the following direction to ensure safe and effective use of oxytocin for induction of labor: Page 2, "Oxytocin medication bag and tubing at connection site to mainline are clearly identified by oxytocin (Pitocin) labels. Every port to be covered with a Small Light Pink Pitocin label". Page 2, "Oxytocin is a high alert medication which requires 2 RN signatures upon initiation of every new bag". The DWCS also added at shift change a report was to be given to the oncoming nurse by the outgoing nurse, to go over and address what the patient was receiving. She acknowledged if the shift change check were performed that day, then the error could have been identified sooner. Consequently, the large amount of Norepinephrine (when the rate of oxytocin was increased to 999 ml/hr.) that was infused after delivery and led to the development of headaches and shortness of breath necessitating the transfer to the Intensive Care Unit (ICU) could have been prevented. On 11/2/15 at approximately 11:30 a.m., Pharm 1 produced the bag of Norepinephrine, the one that was infused, and sequestered by the pharmacy. The bag had a manufacturer label which identified the medication as Norepinephrine 4 mg, but did not have a patient specific label attached to it, which should have included the patient's name, name of medication, dose, date or time noted on the bag.		P. Revised the policy titled Medication Error Prevention (High-Risk and Black Box Warning Medications) to include a requirement for the nurse to scan one medication at a time when removing high-alert medications from the automated dispensing cabinet. The policy was approved on 6/1/2016. Compliance is monitored and variances are reported to department managers for follow-up with the staff member responsible for the scanning procedure variance. Responsible: Pharmacy Director	On going

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	Pharm 1 acknowledged labeling in accordance with facility's policy was not done. Title 22 Ch1 Div5 Art3 Sec 70263. Pharmaceutical General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with 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. The above requirements were not met as evidenced by: Based on observations, staff interviews, medical record and document review, the General Acute Care Hospital (GACH) failed to ensure safe storage and use of medications, when policies and procedures for medications lacked detailed instructions and specific steps to be taken to ensure safe medication storage and use and prevent medication error due to medication mix up. As a result, look alike medications were not recognized as a potential for medication error. The medications,		Q. Unannounced spot audit performed on 4/26/2017 to verify accuracy of storing oxytocin in automated dispensing cabinets of Family Birth Center. The results were: Automated dispensing cabinet 1 25/25=100% bags of oxytocin labelled and stored correctly Automated dispensing cabinet 2 3/3=100% bags of oxytocin labelled and stored correctly Responsible: Registered Pharmacist	4/26 2017

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	one to induce labor (oxytocin) and the other used to increase blood pressure (norepinephrine), were stored next to one another in the pharmacy, selected and delivered to different hospital units including labor and delivery. Therefore, the wrong medication, Norepinephrine, which had a hot pink oxytocin alert sticker affixed to it by pharmacy staff erroneously, was obtained by unit nurses, hung, and infused in full to a patient in labor. The failure to develop and/or implement clear and detailed medication policies and procedures for storing medications and effectively training pharmacy personnel led to this medication error and to Patient 1's development of cardiomyopathy, a condition affecting the heart muscle which makes it harder for the heart to pump and deliver blood to the entire body. Cardiomyopathy can lead to heart failure and possible death. Findings: On 11/2/15 at 11 a.m., a Pharmacist (Pharm 1) stated during an interview that when pharmacy technicians pull medications from pharmacy stock for delivery, a pharmacist verified (double-checked the selected medications) to ensure the selection was consistent with the list which indicated what was to be restocked in a specific area of the hospital. Pharm 1 added that all High Risk medications (any medications that have a heightened risk of causing significant patient harm when used in error), including oxytocin, would be delivered to the		R. Unannounced spot audit performed on 4/26/2017 to verify accurate storage of high-risk medications in the pharmacy in separate bins, on separate shelves. The results were: Oxytocin = 140 bags/140=100% Norepinephrine = 28 bags/28=100% Dopamine = 10 bags/10=100% Dobutamine = 9 bags/9=100% Heparin = 17 bag/17=100% Nicardipine = 6 bags/6=100% Responsible: Registered Pharmacist	4/26 2017

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	medication dispensing cabinet (Omnicell) by two pharmacy technicians who would verify the accurate medications were being placed in the designated storage area in the Omnicell. Pharm 1 acknowledged that on "that day", time uncertain, an undetermined number of IV solutions, 4 mg Norepinephrine in 250 cc bags, were inadvertently placed by two pharmacy technicians in the space specified for oxytocin in the Omnicell in Labor and Delivery. Pharm 1 stated the two pharmacy technicians were required to verify the medication, the alert label (name of drug on a hot pink sicker), and the storage area to ensure the safe and secure placement but had failed to do this. Continuing the interview with the Director of Women's and Children's Services (DWCS) and Pharm 1, it was revealed that at approximately 9 a.m. on 8/18/15 a 250 cc bag of Norepinephrine that had a hot pink oxytocin alert sticker had been found in another labor and delivery room while cleaning the room after an earlier delivery. The nurse (RN 6) who found the bag, informed the Clinical Coordinator (CC 1) who advised RN 6 to call the Pharmacy. Pharm 1, in a concurrent interview, stated she was the one who took the call from RN 6 and she instructed the pharmacy technicians to check the Omnicell units in labor and delivery to see if there were any additional bags of Norepinephrine present. Pharm 1 stated Norepinephrine would never be stocked in labor and delivery as it is a High Risk cardiac medication. Pharm 1 stated she assumed nursing would be checking all the IV's being infused to make sure there were no other norepinephrine bags being infused in error in that unit. The DWCS		S. Unannounced point prevalence study performed on 4/26/2017 to verify accuracy (Independent double check documented, Medication and IV tubing labeled appropriately, Pump set accurately using drug library, Medication orders match medication being administered and eMAR) of oxytocin administration by RNs on the Family Birth Center. The study results were: # patients on Family Birth Center = 13 # patients receiving oxytocin = 4 # accurate administrations = 4 % accurate administrations = 100% Responsible: Clinical Coordinator Family Birth Center	4/26 2017

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	acknowledged the nursing staff did not immediately check to see that all IV medications running in labor and delivery at that time were appropriate and matched physicians orders. On 11/12/15 at 10:45 a.m., another facility pharmacist (Pharm 4) was interviewed. Pharm 4 confirmed the process for restocking medication into the Omnicell. Pharm 4 stated that when medications were checked, the pharmacist was verifying that what was pulled and ready to be delivered matched the fill list; however, Pharm 4 said that he was not sure if the ones he checked contained Norepinephrine bags. Pharm 1 stated during a concurrent interview, on 11/2/15 at 11:15 a.m., that one of the technicians (Tech 14) that refilled the medications into Omnicell on the day of the incident was in training and had not completed the pharmacy orientation and training requirements prior to assuming an independent assignment. On 11/12 /15 at approximately 10 a.m., a pharmacy technician (Tech 13) stated during interview that the technician (Technician14) that filled the oxytocin on the day of the incident was newly hired and had not completed the new hire orientation. Tech 13 was training "Tech 14", but Tech 13 had only worked for 3 nights with another pharmacy technician for her training, and then was working on her own. Tech 13 stated she accompanied Tech 14 to the obstetrical service the morning of 8/18/15 and stocked the Omnicell with the medications from the Pharmacy. Tech 13 stated the IV medications were all in one		T. Audit results for items Q, R,, and S were submitted for reporting to the Quality Management Committee of the Medical Staff at the next scheduled meeting for integration into the established QAPI process. Responsible: Risk Manager **Response to CA00462656 and CA00455078 ends here**	4/26 2017

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	bag and neither she nor Tech 14 barcoded each medication or verified the identity of each individual bag of intravenous medication. Tech 13 stated that prior to this incident, two pharmacy technicians delivered medications to the Omnicells, but no second verification was performed of any medication, including those designated as high risk. On 11/2/15, at approximately 11 a.m., during a concurrent interview with DWCS and Pharm 1, when asked about the policy for training pharmacy personnel, they confirmed that there was no policy addressing training requirements, or verifying accuracy of trainee's work. Review of the "Department Specific Orientation Checklist Pharmacy department" for Tech13 and 14 revealed that the checklists for both technicians were not complete. Checklist was a 5-page document containing specific areas or tasks and columns for instructions given and competency demonstrated. The form for Tech 13, who was hired in May 2015, was not completed. The form did not have the preceptor's name and had instructions and competency demonstrations mainly on one day, 5/27/15 with very few (about 10 from a total of approximately 80 items) signed on 5/21/15. Some sections of the form were left completely blank. Similarly, the form for Tech 14, who was hired on 8/3/15, had instructions and competency demonstrations mainly on one day, 8/10/15 and very few on 8/6/15. Some sections of the form were left			

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	completely blank. The checklist included different sections such as specific life safety training, hazardous material, emergency preparedness, department standards, pharmacy process and procedures, and personnel procedures. These sections included specific elements and competency tests as the evaluation mechanism for competence. One of the sub-elements instructed the employee to read "all the policies in the IV (intravenous) binder titled, Compounding Sterile Preparation related P&P." All the above items had initials and the 8/10/15 date indicating that they were completed on that day for Technician 14. Evaluating the list of items that needed to be completed, which included written instructions and required completing the competency demonstration by observation or by testing, it would appear improbable that this list of items could be completed in one day. Pharm 2 and Pharm 3, in an interview on 11/12/15 at 2:10 p.m., stated the period of orientation for a Pharmacy Technician should be "two weeks". Pharm 2 and Pharm 3 acknowledged the orientation checklist should be completed before the Pharmacy Technician can work independently. On 11/12/15 at 10 a.m., Tech 13 explained that a volunteer was helping the technician handling medications. According to Tech 13, the volunteer had applied the hot pink alert sticker labeled oxytocin to IV bags. In an interview on 11/12/15 at 10:30 a.m., Pharm 2			

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	and Pharm 3 acknowledged a volunteer had been working in the Pharmacy. Pharm 2 and 3 revealed there was no job or role description for a volunteer in the Pharmacy and that the volunteer in question had not had orientation, training or evaluation of the work performed. Pharm 2 and 3 stated they were not aware the volunteer had been working directly with pharmacy medications or stock. Pharm 2 and 3 acknowledged a volunteer should not have been allowed to handle or restock medications. Pharm 2 stated the volunteer had been relieved of duties in the pharmacy immediately after the incident. On 11/2/15, at approximately 3 p.m. two technicians (Techs 11, 12) demonstrated the process for delivering High-Risk medication. Pharmacist Technician 11 (Tech 11) selected a high-risk (Norepinephrine) medication from the fill list, pulled two bags of norepinephrine for restock into the Omnicell in the Intensive Care Unit (ICU). For the delivery, another technician (Tech 12) went with Tech 11. At the Omnicell, Tech 11 signed on, and pointed to the light indicator on the cabinet where the medication was to be placed, opened the door and stated that she was to verify the count and check the expiration date of what was already in the cabinet. Tech 11 did that and instructed Tech 12, who was having side conversation with other people in the medication room, to enter the data into the Omnicell. Tech 11 completed the process by checking the expiration dates of the two bags to be added and verified the name of the medication and the high alert pink sticker on them. And she told Tech 12 to key in the amount added. Tech 12 was not next to Tech 11 in order to see and verify any of			

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	the tasks performed by Tech 11. Tech 12 was then interviewed about her role in the restocking process, she stated that she was supposed to co-sign, pointed to the Omnicell and said, "I am supposed to co-sign, and I provided my fingerprint." During a concurrent interview on 11/2/15 at 11:15 a.m. with the DWCS and Pharm 1, the facility policy for restocking the Omnicell and the double check system for high risk medication was requested. Review of the facility policy titled "Dispensing Medications from Omnicell", approved 6/26/14, gave no specific instructions for the restocking of the machine by the Pharmacy Technicians. It only included the following: "Inventory levels will be checked daily." In addition, the policy stipulated "All medications require barcode scanning upon filling Omni cell". A GACH policy titled Medication Management, dated 12/4/14, was reviewed. The purpose of the policy was "to provide guidelines for the safe prescribing, ordering, transcribing, administration and storage of medications". The following was noted: Page 5: "Dispensing Medications: 1. a pharmacist must check all medications dispended from the pharmacy, including those placed in Omni cell." Page 5: "Distribution of Medications: 1. Pharmacy staff delivers medications and IV admixtures to the nursing units and places medications in the designated secure storage areas." Page 9: " Document Administration: 10. Followed the policy on Medication Error Prevention (High-risk			

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	Medications). "High Alert" medications that are required by policy to have a co-signature include: e. Oxytocin (upon initiation and whenever a new bag is hung)." Title 22 Ch1 Div5 Sec 70263 Pharmaceutical General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. (2) Medications and treatments shall be administered as ordered. The above requirements were not met as evidenced by: Based on observations, staff interviews, document and record review, the General Acute Care Hospital (GACH) failed to administer a medication as ordered when a patient (Patient 1) was given a minimum of 3.8 milligrams (mg) of a medication used for			

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critically ill patients to increase blood pressure (Norepinephrine) by error instead of oxytocin (a medication to regulate and enhance uterine contractions during labor) as ordered by the physician.

The failure to administer a medication as ordered resulted in severe symptoms on cardiac distress, a necessity for a transfer to a higher level of care at a Level III facility [which provided a higher level of care] and subsequent damage to the heart muscle.

Findings:

Patient 1 (Pt 1), a 39 year old, was admitted to the GACH in active labor on 8/17/15 at 9:30 p.m. with her first pregnancy at term (39.5 weeks). On 8/18/15 at 5:59 a.m., the obstetrician (MD 1) ordered the administration of oxytocin, a medication used to augment labor. At that time Patient 1 was almost fully dilated (the cervix being opened for the baby to pass through the birth canal) however the contractions were varied in length and duration. Instead of oxytocin, norepinephrine was initiated intravenously, in error, because the bag that was removed from the oxytocin specified storage cabinet in Omnicell had the pharmacy hot pink sticker (Oxytocin 15 units) applied on it in error. On 8/18/15 at 5:59 a.m., the intravenous drip of "oxytocin" was started at two milli-units (mu)/minute according to the protocol. Oxytocin was prepared at a concentration of 60 mu per milliliter (ml) (15 units in 250 ml bag).

Since a norepinephrine bag was selected in error, Pt

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	1 was receiving Norepinephrine 32 mcg/hr., instead of 2 milli-units/minutes of oxytocin. The dosing range for norepinephrine infusion starts at 210 micrograms/hour (mcg/hr.) to a maximum of 8400 mcg/hr. Norepinephrine concentration was 16 mcg/milliliter (ml) (4 mg in 250 ml bag). Norepinephrine is used to produce vasoconstriction (narrowing of the veins) for the treatment of severely ill patients to increase the blood pressure and perfuse the vital organs. According to Lexicom, a drug information source online, side effects of Norepinephrine include headache, weakness, dizziness, respiratory difficulty or cessation of breathing, and precordial (heart) pain. Norepinephrine can cause severe constrictions of the veins resulting in reduced blood flow to vital organs: brain, heart and kidney. It also increases the work of the heart resulting in increased oxygen use and demand. These effects are dependent on the dose/rate administered: so these effects are increased (worsen) as the rate increases. Therefore, it is recommended the patient receiving this medication be closely monitored according to the manufacturer's instructions for administration. The patient should not be left unattended and the infusion flow rate must be closely monitored. Blood pressure should be checked every 2 minutes from the time the norepinephrine infusion is started until the desired effect is achieved, then every 5 minutes while the drug is being infused. The "oxytocin" dose was increased at periodic intervals, when Pt 1 delivered the baby at 10:33			

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a.m., the "oxytocin" rate was 8 mu/min. At that rate, Pt 1 was actually receiving 28 mcg/hr. of norepinephrine.

Following the delivery, MD 1 ordered the oxytocin to be delivered at a rapid rate until the bag would be emptied. Oxytocin is routinely given post-delivery to stimulate the uterus to contract and control bleeding. Shortly after the initiation of the bolus (a single, large dose of 15 units of oxytocin at 10:40 a.m.), the following was noted:
10:45 a.m. C/O headache, B/P 172/84
10:50 a.m. C/O nausea, difficulty breathing. Used own inhaler, history asthma, some relief.
11:01 a.m. Vomiting, medication given for nausea, B/P 222/131, HR 77

When the oxytocin bolus was being delivered, the rate of infusion was put at 999 ml/hr. That rate equated roughly to 15,984 mcg/hr. of norepinephrine. Such dose is estimated to be almost twice the maximum dose of norepinephrine (the range of norepinephrine infusion is 210 mcg/hr. to a maximum of 8400 mcg/hr.).

At 11:01 a.m., a call was made for the Rapid Response Team (RRT) to assess Pt 1. The RRT consists of staff from critical care (ICU), nursing and respiratory services, who immediately respond to the bedside when a significant change of condition may be indicative of a pending cardiac or respiratory arrest (code blue). The ICU nurse (RN 1), upon arrival to the bedside, observed that the medication being administered in the 250 cc bag was labeled by the manufacturer as Norepinephrine (Levophed),

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	a high-risk medication used in ICU to increase blood pressure by making the blood vessels narrower. The medication was immediately discontinued; however, Pt 1 was now complaining of chest and back pain and therefore transferred to the ICU. 11:10 a.m. B/P 150/84, HR 120 11:14 a.m. B/P 78/50, HR 109 11:17 a.m. B/P 76/41, HR 106 11:25 a.m. B/P 80/51, HR 104 11:27 a.m. Transferred to ICU On 8/18/15 at 6:45 p.m., Pt 1 was transferred to a cardiovascular service at a Level III GACH for treatment of cardiac distress related to a medication error. A GACH policy titled Medication Management, dated 12/4/14, was reviewed. The purpose of the policy was "to provide guidelines for the safe prescribing, ordering, transcribing, administration and storage of medications". The following was noted: Page 5: "Administer Medications: 4. Use all of the components of the seven rights for every medication administered. b. Right Medication." Page 6: "Label the distal end of the IV tubing with the name of the medication. Label the tubing after it has been attached to the medication." Page 9: "Document Administration: 10. Followed the policy on Medication Error Prevention (High-risk			

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	Medications). "High Alert" medications that are required to have a policy to have a co-signature include: e. Oxytocin (upon initiation and whenever a new bag is hung)." A GACH policy titled Oxytocin Management, Intrapartum, dated 10/17/13, page 2, stipulated "6. Oxytocin is a high alert medication which requires 2 RN signatures upon initiation of every new bag." The DWCS and Pharm 1 acknowledged that neither the pharmacists, the pharmacy technicians or the nursing staff had read and verified the medication label, but rather relied on a hot pink sticker with the word "oxytocin", which had been placed on the outside of the bag to be used on the IV tubing at the time of administration. This hot pink sticker was used to identify oxytocin as a High Alert medication that would require two documented verifications prior to administration. The DWCS stated the pink sticker could be placed on the IV tubing to alert all staff to the presence of a high-risk medication. The DWCS acknowledged neither of the two nurses present at the time of the initiation of the IV solution (RN 2, RN 3) had labeled the medication with the name of the patient, name of the medication, dose, time and date. 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(g).			