

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050295	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 03/18/2019
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NAME OF PROVIDER OR SUPPLIER Mercy Hospital	STREET ADDRESS, CITY, STATE, ZIP CODE 2215 Truxtun Ave, Bakersfield, CA 93301-3602 KERN COUNTY
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00600791 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 38993, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>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.</p> <p>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.</p> <p>HEALTH AND SAFETY CODE SECTION 1279.1(a)(4)(A) (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse</p>			<p>RECEIVED STATE OF CALIF. DEPT OF PUBLIC HEALTH</p> <p>2019 MAY 17 PM 2:58</p> <p>LICENSING AND CERTIFICATION BAKERSFIELD DIST OFFICE</p>

Event ID: NL2W11

5/3/2019

2:29:48PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE:  JOSEPH L. SMITH, M.D. TITLE: CHIEF MEDICAL OFFICER (X6) DATE: 5/17/19

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 10

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.

5/20/19 POC accepted. 

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	<p>event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.</p> <p>(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.</p> <p>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.</p> <p>DEFICIENCY CONSITITUTING IMMEDIATE JEOPARDY:</p> <p>Title 22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of 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.</p> <p>Based on interview and record review, the hospital failed to implement their policy and procedures</p>				

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	<p>regarding the verification of medication prior to administration for one of one sampled patient (Patient 1). This failure resulted in Patient 1 developing a serious disability.</p> <p>Cesarean - C-Section, a surgical procedure used to deliver a baby through incisions in the abdomen and uterus.</p> <p>Spinal Block is the most common type of anesthesia used for a planned C-Section. It numbs your body from your belly button down, and the medication is injected directly into the spinal fluid.</p> <p>During an interview with the Director of Risk/Patient Safety Officer (DOR), on 8/31/18, at 1:46 PM, the DOR stated Patient 1 was taken to the operating room on 8/16/18, at 7:31 AM, for a scheduled Cesarean Section (C-Section). During the surgical procedure, Patient 1 required a second injection to her spine to numb her from the waist down (spinal block) as the first spinal injection was ineffective. During the surgery, the anesthesiologist (Anesthesiologist 1, a physician trained in anesthesia and perioperative medicine) announced the bupivacaine (a numbing medication) he used to numb Patient 1 was expired. The DOR stated approximately an hour and a half after the surgery, in the recovery room, Patient 1 became unresponsive. Her heart rate increased from 70 to 90 beats per minute. Patient 1 was taken to Computerized Tomography (CT- an x-ray assisted by a computer) immediately and began having seizures (a sudden surge of electrical activity in the brain). Patient 1 was then admitted to the Intensive</p>				

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	<p>Care Unit (ICU). The DOR started her investigation and had concern regarding the expired numbing medication. She stated the Manager of Birthing Center (MOB) emptied all medical waste containers in the operating room to look for the expired ampule of the numbing medication. The DOR stated the MOB could not find any expired numbing medication but found an empty ampule of Digoxin (a heart failure medication not indicated for spinal injection) in the waste container. The DOR stated the Omnicell (an automated medication dispensing system) in the operating room did not show Digoxin was removed. The DOR stated, in the operating room, only the anesthesiologist had access to the Omnicell. The DOR stated when the empty Digoxin ampule was discovered; the physician (MD) who took over Patient 1's care after the incident ordered a Digoxin blood level to be completed immediately. On 8/16/18, at 5:40 PM, approximately 6 1/2 hours after the surgery, Patient 1's Digoxin level was 0.6 (therapeutic value is 0.5-2 for patients prescribed Digoxin to treat a heart condition) indicating there was Digoxin in Patient 1's blood. The DOR stated at that time, MD ordered another Digoxin level using the blood collected when Patient 1 became unresponsive (2 1/2 hours after the surgery). The Digoxin level was 0.9 in the sample taken 2.5 hours after Patient 1's procedure. These two laboratory test results indicated Patient 1 was positive for receiving Digoxin earlier.</p> <p>During a review of the clinical record for Patient 1, the "Anesthesia Physician Note," dated 8/16/18, at 6:42 AM, indicated Patient 1 was admitted to have repeated C-Section at 39 weeks gestation</p>				

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	<p>(considered full term pregnancy). She did not have any medical history and the only medical problem was being "Pregnant." Patient 1 was taking prenatal multivitamin prior to the C-Section. She had been prescribed Digoxin medication.</p> <p>The "Anesthesia Record," dated 8/16/18, indicated Patient 1 was in "Anesth [anesthesia] Time Preop [Anesthesiologist consults the patient prior to being taken to the operating room]" at 7:26 AM and surgery start time was 8:11 AM. The remarks section of the Anesthesia Record indicated: "Pt [Patient 1] needed 2nd spinal anesthetic as 1st one was inadequate to perform C-Section . . . her sensory level was too low . . . Anesth Postop [Patient is escorted to post-op by Anesthesiologist]" at 8:55 AM.</p> <p>The "Consultation" document, dated 8/16/18, at 11:40 AM, indicated "csection [sic] around 7.30 [sic] this AM w [with] regional spinal anesthesia w bupivacaine. Went ot [sic] recovery uneventful. Bedside RN [registered nurse] reports sudden rapidly progressive AMS [altered mental status]. Became lethargic [sluggish] but was moving extremities randomly initially, and in a span of 2-3 min [minutes] became completely obtunded [less than full alertness (altered level of consciousness), typically as a result of a medical condition or trauma] . . .Pupils noted dilated [make or become wider, larger, or more open] . . .intubated [insert a tube into the trachea (tube conveying air to and from the lungs) for ventilation] for airway protection and immediate CT head and chest done, both normal. In CT room she had a 2 min TC seizure [tonic</p>			

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	<p>clonic-In the tonic phase the body becomes entire rigid, and in the clonic phase there is uncontrolled jerking] that stopped spontaneously...10 min after another 2 min TC seizure noted...Moved to ICU where I witnessed another generalized TC seizure...lasted 2-3 minutes. Did not regain consciousness since first event."</p> <p>The "Nursing Progress Note," dated 8/16/18, at 4:49 PM, indicated: "Approx [approximately] 1015 arrived to birth center for ABC [alert before code] call. Pt [Patient 1] was on monitoring, nonrebreather [assist in the delivery of oxygen therapy] in place; mult [multiple] staff including OB gyn [obstetrician, a physician who delivers babies and gynecologist, a physician who specializes in treating diseases of the female reproductive organs] & anesthesiologist at bedside. [Patient 1] Nonresponsive to stimuli, noted moving of RUE [right upper extremity] towards face, did not track, and pupils dilated. ST [sinus tachycardia- heart rhythm with an elevated rate of impulses, defined as a rate greater than 100 beats/min [minute] in an average adult] on the monitor and hypertensive [high blood pressure] . . .Intubated by anesthesia without meds. Assisted with transporting pt to CT and ICU. Multiple seizures in CT and one in ICU. . ."</p> <p>The "Physician Note," dated 8/17/18, at 8:56 AM, indicated MD entered an addendum note at 3:44 PM that indicated "Found the patient has evidence of Digoxin in her blood. The level has decreased, and now is undetectable. . ."</p> <p>The "Omnicell Transaction Details by Item" report,</p>			

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	<p>dated 7/16/18-8/16/18, indicated there were two ampules of Digoxin in the Omnicell on 8/9/18, during the monthly cycle counts.</p> <p>During an interview, on 8/29/18, at 12:58 PM, the MOB stated the hospital stopped all C-Section scheduled for that room and she checked the Omnicell to check the amount of Digoxin and the numbing medication left in the dispensing system; she found only one ampule of Digoxin left.</p> <p>During further review of Patient 1's clinical records, it indicated Patient 1 was discharged from the hospital on 8/18/18 to a Neuro ICU at another acute hospital (Hospital 2) for treatments because the patient became completely obtunded.</p> <p>The "Discharge Summary," dated 9/11/18, from Hospital 2, indicated under "Hospital Course: hospitalization 8/18/18 through 9/11/18. . .Bilateral lower extremities motor and sensation still remains no grimacing or movement to stimuli at the time of discharge." Patient 1 was discharged home with outpatient neurological rehabilitation planned.</p> <p>During an interview with the Pharmacy Manager (PM), on 8/29/18, at 1:10 PM, he stated when removing medications from the Omnicell, the anesthesiologist was responsible to select the patient name, choose the medication, remove, and then scan the medication. He stated a Digoxin ampule was found in the medical waste bin and the Omnicell in the operating room had one missing ampule of Digoxin.</p>				

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	<p>During an interview with the Director of Pharmacy (DOP), on 9/6/18, at 8:55 AM, he stated a direct medication error caused Patient 1's disability. The DOP stated Patient 1 received Digoxin into her spine instead of bupivacaine. The medication error caused severe disability to her arms and legs. The DOP stated cycle counts were performed monthly for the Omnicell and the last count was completed on 8/9/18, indicating the two same vials of Digoxin had been in the Omnicell since 10/17. The DOP stated the Digoxin was located in drawer 5's rear left corner and the bupivacaine was located in drawer 7's rear left corner. The DOP stated the anesthesiologist was aware he had full access to non-narcotic medications for emergencies and the anesthesiologist was the "First and last verification" of the medication being administered. The DOP stated during the C-Section for Patient 1, the first ampule of bupivacaine was entered into the Omnicell system when removed; but a second ampule was not manually entered or scanned and the report indicated the Omnicell drawer was opened. The DOP stated Digoxin should only be given intravenously (administered into, a vein or veins) when administered from the ampule.</p> <p>During an interview with Anesthesiologist 1, on 9/6/18, at 10:56 AM, he stated he was the Anesthesiologist for Patient 1's C-section. He stated the first spinal anesthesia he injected was not effective and he had to administer the second injection. He stated it was rare for a patient to have two spinal injections; therefore, he believed the bupivacaine was expired. He stated he was in a hurry when he pulled the second ampule of</p>				

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	<p>bupivacaine from the Omnicell and he did not input the medication into the Omnicell. He stated he drew 1.5 milliliters (ml) of the 2 ml of the Digoxin ampule and injected into Patient 1's spine. The Anesthesiologist stated the symptoms the patient exhibited matched the outcome that was expected when Digoxin was administered intrathecal. The Anesthesiologist stated he had full access to the medications in the operating room Omnicell. He did not look at the name of the medication before he administered it to Patient 1.</p> <p>During an interview with Anesthesiologist 2, on 9/6/18, at 11:25 AM, he stated Digoxin was a cardiac medication that was extremely toxic to the nerve system (a system of the body that in vertebrates includes the brain, spinal cord, nerves, and sense organs and receives, interprets, and responds to stimuli from inside and outside the body).</p> <p>During an interview with Surgeon 1, on 9/6/18, at 12:25 PM, he stated he assisted in the C- Section procedure for Patient 1. Surgeon 1 stated he remembered, during the surgery, he heard Anesthesiologist 1 announced the bupivacaine was outdated, and because of that the first spinal injection was not effective. Surgeon 1 stated Patient 1 did not have history of cardiac issues and would not have any reason to take Digoxin. He stated he would not have expected Digoxin to be administered into the spine during the C-Section.</p> <p>The hospital policy and procedure titled "Medication Management" undated, indicated ". . .70. Use all of</p>				

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	<p>the components of the seven rights for every medication administered. a. Right Patient a) Right Patient [sic] b) Right Medication c) Right Time d) Right Dose e) Right Route f) Right Reason g) Right Documentation, (completed after administration). 71. Before administration, verify that the medication selected matches the medication order and product label."</p> <p>The hospital failed to implement its policy and procedure in medication administration to prevent the wrong medication from being administered to Patient 1, which resulted in Patient 1 developing a serious disability. This failure caused, or is likely to cause, serious disability or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).</p> <p>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).</p>				

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<p>Title 22 DIV5 CH1 ART3-702223(b)(2) Surgical Services: the hospital failed to implement their policy and procedures regarding the verification of medication prior to administration for one sampled patient (Patient). This failure resulted in Patient 1 developing a serious disability.</p>	<p>Corrective Actions: At time of self-report the findings of investigation were reviewed with all Hospital Leaders present. Actions items and plans of correction were developed. Upon receipt of citation findings were further reviewed at a morning meeting with all clinical unit leaders present.</p> <p>Anesthesia Services/Pharmacy:</p> <p>Pharmacy: Spinal Bupivacaine moved to single use secure pockets, only accessible by manual entry in Omnicell with guided removal. All anesthesia providers notified.</p> <p>Pharmacy: Digoxin removed from all Birth Center Anesthesia Omnicells.</p> <p>Anesthesia: Omnicell training by computer; the link was uploaded to all computers in the doctor's lounges including surgery for access and completion. All Anesthesia Providers completed under arrangement by Chief of Anesthesia and Director of Pharmacy. Certifications of completion on record at Mercy patient safety departments. Completed 1/20/2019.</p> <p>Anesthesia: Scan or log-in of 100% of medications removed required by all Anesthesia providers instituted immediately and on-going (no end date). Scanning compliance monitoring conducted by Chief of Anesthesia or designee.</p> <p>Pharmacy: Scanner functionality is verified nightly by pharmacy during medication refills to ensure correct medication AND placement. Scanners locked into place at Omnicell station to ensure there are no disruptions in functionality which could lead to medication scanning inconsistencies. Observations with monitoring by Director of Pharmacy.</p> <p>Anesthesia Monitoring:</p> <p>The Chief of Anesthesia or designee will perform random unannounced surgical case auditing for anesthesia medication safety, to include; either manual Omnicell entry for medication removal or scanning of removed medication during case at 100% expectation of accuracy. The audit will consist of 10 instances per week (5 per campus) or 20/month. Audit results are reported monthly to Mercy Hospitals of Bakersfield's Quality Assurance/Utilization Review Committee and through Medical Executive Committee. Audits will continue until 100% compliance has been sustained for three months.</p>	<p>8/16/2018</p> <p>8/20/2018</p> <p>8/30/2018</p> <p>8/30/2018</p> <p>9/21/2018</p>

	<p>Responsible Party: Chief of Anesthesia</p> <p>Pharmacy Monitoring: Director of Pharmacy or Designee will review and monitor 10 instances per week (5 per campus) or 20/month. Audit items: Random confirmation of Anesthesia Omnicell scanner functionality to ensure medications can be scanned when removed by anesthesiologist for patient safety. Results are reported monthly to Mercy Hospitals of Bakersfield's Quality Assurance/Utilization Review Committee and through Medical Executive Committee. Audits will continue until 100% compliance has been sustained for three months.</p> <p>Responsible Party: Director of Pharmacy</p> <p>All Clinical Units and Public Lobby:</p> <p>Details and requirements referencing policy: Medication Management, specifically "medication verification" placed in the Patient Safety & Regulatory Bulletin and blast emailed to all hospital staff, huddled on clinical units hospital, and dispensed in public lobby hospital wide. Pertinent bulletin details provided (page 8, no. 70 & 71), included; <i>use all of the components of the seven rights for every medication administered and before administration, verify that the medication selected matches the medication ordered and product label.</i></p> <p>An excerpt of findings with emphasis on requirement to review the summary of the finding and policy, Medication Management was placed in the Dignity Health Mercy Hospitals electronic educational system for review and signed attestation by: Clinical staff in Endoscopy, Family Birth Center, Interventional Radiology, and Surgery – areas where anesthesia is administered. A strongly emphasized need to maintain adherence to Policy and Procedure, by all Clinical Departments where anesthesia medications are administered and Pharmacy Services are available is relayed. Further, medications may only be ordered by Licensed Independent Practitioners (LIPS) or Licensed Care givers that by law are permitted to do so within their scope of practice and State/Federal Law.</p>	<p>5/9/2019</p> <p>5/13/2019</p>
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