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 |
|---|---|---|---|
| | 050435 | A. BUILDING _____ B. WING _____ | 01/06/2012 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| FALLBROOK HOSPITAL DISTRICT | 624 E. ELDER ST., FALLBROOK, CA 92028 SAN DIEGO COUNTY |

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| | The following reflects the findings of the Department of Public Health during an inspection visit:<br><br>Complaint Intake Number:<br>CA00254765 - Substantiated<br><br>Representing the Department of Public Health:<br>Surveyor ID # 22363, HFEN<br><br>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.<br><br>Health and Safety Code Section 1280.1(c): 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.<br><br>Informed Adverse Event Notification 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.."<br><br>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.<br><br>1279.1 (b) For purposes of this section "adverse event" includes any of the following:<br>1279.1 (b) (4) (A) A patient death or serious disability associated with a medication error, | | | |

RECEIVED
CA DEPT OF PUBLIC HEALTH
JAN 27 2012
LICENSING & CERTIFICATION
SAN DIEGO NORTH DISTRICT OFFICE

Event ID: 7G7611 1/10/2012 10:33:37AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Marilyn R. Fiel TITLE: CQO (X6) DATE: 1-27-12

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| | **Continued From page 1**<br>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.<br><br>70263 (g) (2) Medications and treatments shall be administered as ordered.<br>70215 (b): The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission.<br>70213(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing services.<br>70213(b) Policies and procedures shall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and , as circumstances require, patient advocacy.<br><br>Based on interview and record review, the facility failed to ensure that Obstetric/Newborn nursery staff implemented its policy and procedure related to the delivery of medication to a newborn baby patient (Patient A) following delivery. As a result, Patient A received an injection of Methergine (medication used for the prevention and control of postpartum hemorrhage in mothers following delivery) following delivery. The methergine injection was intended for Patient A's mother. The | | | |



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| | **Continued From page 2**<br>Obstetric/Newborn nursery staff further failed to intervene or advocate for the patients as it related to reporting the medication error to the baby's or the mother's physician in a timely manner. Patient A developed seizures and required emergency transfer to another hospital, as well as endotracheal intubation (insertion of a tube into the trachea to establish an airway), multiple tests and treatment for seizures acquired secondary to the injection of methergine<br><br>Findings:<br><br>Patient A, a newborn baby, was delivered at the facility on [redacted]11 at 11:44 p.m. according to the Physician Record of Newborn Infant. Per the same record, Patient A was a normal spontaneous vaginal delivery, 9 lbs 11 oz, with Apgar scores of 8 and 9 at 1 and 5 minutes. (The Apgar score is based on breathing heart rate, muscle tone, reflexes and skin color. The 1 minute score determines how well the baby tolerated the birthing process and the 5 minute score determines how well the baby is adapting to the new environment. Scores of 8 or 9 are normal).<br><br>Following delivery the physician in the delivery room ordered methergine for Patient A's mother. RN 1 administered 0.2 mg of methergine intramuscularly to Patient A, the mother's newborn baby. According to the medication delivery system (pyxis) readout and interview with the pharmacist, the first dose of methergine was removed at 12:01 a.m. A second dose of methergine was later removed from the pyxis at 12:03 a.m., which was then delivered to | | Preparation and/or execution of this Plan of Correction (POC) does not constitute admission or agreement by the provider of the conclusions set forth on the Statement of Deficiencies. This POC is prepared because it is required by the provisions of Health and Safety Code. | |



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| | **Continued From page 3**<br>Patient A's mother, according to RN 2. There was no documentation to indicate Patient A was given methergine.<br><br>According to The Physician Record of Newborn Infant, the pediatrician was not notified until approximately 2:35 a.m. on [redacted]11 that Patient A received methergine following delivery at 12:00 a.m. The pediatrician noted that nursing reported seizure like movement from Patient A at 2:30 a.m. When the pediatrician arrived, at approximately 3:00 a.m. Patient A was noted to be "...periodically groaning, doesn't open eyes...tonic clonic seizure like movement..." Phenobarbital (seizure medication) was administered at 3:21 a.m. and shortly thereafter the seizures subsided. Patient A was transported to Hospital 2 at 4:50 a.m. and arrived at Hospital 2 at 6:40 a.m. Shortly after arrival Patient A was intubated and placed on mechanical ventilation. Patient A was noted to have "acute methergine poisoning" was placed on Phenobarbital for seizures and nitroprusside for hypertension (high blood pressure). Patient A was eventually discharged on [redacted]11. According to the physician's report Patient A will require further neurological examinations due to ischemic injuries (damage or death to brain tissue) seen on an MRI (Magnetic Resonance Imaging) of the brain.<br><br>The Initial Newborn Profile and the Physician Record of Newborn Infant were reviewed with administrative staff on 1/13/11. There were 2 registered nurses and 1 physician during the delivery of Patient A. According to administrative staff, generally one RN was assigned to mother and | | Immediately following the event, the Chief Nursing Officer (CNO) reviewed existing policies and procedures governing:<br>• Notification of adverse events<br>• Chain of command<br>• Administration of medications<br>No revisions to the policies were found to be necessary. The two individuals directly involved in the event were subject to disciplinary actions in accordance with the hospital's policy and procedure. | 1/09/2012 |



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| | **Continued From page 4**<br>1 to baby, but it was not uncommon that they help each other out during the delivery. Typically following the delivery the mother's nurse assumes care of mother and child.<br><br>RN 2 was assigned to Patient A, and spoke about the incident during an interview on 2/3/11 at 7:30 a.m. According to RN 2, she recalled Physician X requested methergine for Patient A's mother following delivery due to uterine bleeding. RN 2 recalled leaving the room to get the methergine for mom. RN 2 returned with the methergine and handed it to RN 1. RN 2 stated RN 1 wasn't doing anything with the methergine, so RN 2 drew up the methergine and handed it to RN 1. RN 2 stated she watched RN 1 place the adult needle on the methergine and then turn and give the injection to the baby (Patient A) instead of the baby's mother. RN 2 recalled saying "What are you doing?" to which RN1 replied "What?" RN 2 recalled telling RN 1 "You just gave the methergine to the baby" According to RN 2, RN 1 then stated "Oh my God what did I do..." RN 2 then returned to the pyxis and retrieved another dose of methergine for Patient A's mother. RN 2 stated she saw RN 1 leave the room after Physician X and assumed RN 2 was following the physician to tell him what had just happened. According to RN 2, approximately 15 minutes later she discovered RN 1 hadn't notified the physician. RN 1 suggested to RN 2 that she call the pediatrician on call and tell him about the methergine she gave to Patient A. RN 2 stated an hour later RN 1 had still not notified the pediatrician. According to RN 2 she observed RN 1 looking up methergine on the internet for side | | Upon completion of the policy reviews, the CNO provided education to all nursing staff regarding:<br>• Immediate reporting of adverse events with notification to physician and other appropriate individuals.<br>• Nursing and organization-wide chain of command processes to be followed to ensure appropriate notifications are completed.<br>• Appropriate processes in medication administration, including:<br>o Following the 5 rights of medication administration<br>o Using two patient identifiers prior to administering medications<br>o Implementing verbal orders with a `say back' process that is repeated after medication is obtained and prior to administration<br>o Administering only those medications for which you possess knowledge of the medication's actions, usual dose, route, side effects and any special considerations in administration | 1/09/2012 |



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| | **Continued From page 5**<br>effects. RN 2 stated she noted seizure like activity from Patient A at approximately 2:30 a.m. that morning and then RN 2 notified the pediatrician on call.<br><br>RN 1, who was assigned to Patient A's mother, declined to interview.<br><br>Physician X (the obstetrician who delivered Patient A), spoke about Patient A on 1/10/11. Physician X recalled both nurses were in the room when he asked for methergine but did not recall any problems reported to him at that time when the nurse administered the medication. According to Physician X he wasn't notified that anything had gone wrong until he came in the next day. Physician X stated that he would have expected to be notified right away. Physician X further stated that had he been notified he would have taken action immediately and called a pediatrician.<br><br>The house supervisor (HS) on the evening of [redacted]11 to [redacted]11 was interviewed on 2/10/11. According to the HS no one notified her of the incident. The HS recalled hearing a page requesting respiratory services to the newborn area, finding this unusual, she followed respiratory to the newborn nursery. When the HS arrived at the nursery, she overheard the nurses talking about poison control. When she inquired as to the reason, RN 2 explained the baby had received methergine following delivery. According to the HS, the nursery was not busy that evening and only had 1 delivery.<br><br>The facility's policy and procedure entitled | | Immediately following the event, the Human Resources Director audited personnel files of all licensed nursing staff assigned to the Women's Center to ensure that they had received education during their orientation period concerning event reporting and disclosure. This orientation process will be implemented for any newly hired member of the nursing staff.<br><br>CNO and Director of Human Resources modified the organization's Annual Employee Update and Skills Fair to include immediate disclosure of medication errors. Completion of the Annual Update and Skills Fair is required of all licensed nursing staff including House Supervisors.<br><br>The Human Resources Director and/or the CNO will audit records of orientation and ongoing education regarding medication administration, error/adverse event reporting and disclosure to ensure that all licensed nursing staff members have received the appropriate education and demonstrate ongoing competence to administer medications. | 1/09/2012<br><br>2/06/2012 |



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| | **Continued From page 6**<br>Medication Use and Administration was reviewed with administrative staff on 2/10/11. According to the policy, patient identification should be verified prior to the administration of any medication, using 2 identifiers. The policy further stipulated that the licensed health care practitioner will have knowledge of the actions, uses, normal dosage, route, side effects and special considerations before administering the medication. The policy further detailed the requirements to accurately document all medications administered as well as physician notification of medication administration errors.<br><br>The facility failed to ensure that Obstetric/Newborn nursery staff intervened, and advocated on behalf of Patient A after injecting the newborn [Patient A] with a medication ordered and intended for the newborn's mother. The facility staff failed to identify Patient A prior to medication administration using two identifiers per the facility policy. The facility failed to ensure nursing staff were informed of the medication and its potential side effects prior to administration. Finally, the facility nursing staff failed to inform the physician immediately after the known administration of methergine to the newborn infant (Patient A) rather than to the mother.<br><br>These deficiencies, jointly, separately or in any combination, have caused or are likely to cause serious injury or death to the patient, and therefore constitute an immediate jeopardy within the meaning of Health and Safety Code section 1280.1(c). | | Any instance of noncompliance will be immediately referred to the Nursing Unit Manager. Results of the auditing will be summarized and reported monthly to the Quality Improvement Committee, Medical Executive Committee and Governing Board. Monitoring will continue until at least one full year of compliance has been reported.<br><br>The Risk Manager will monitor reported medication errors to ensure timely disclosure of the errors has occurred. Instances of noncompliance will be immediately addressed with the Nursing Manager of the involved nursing unit and the CNO. Results of the monitoring will be summarized and reported monthly to the Quality Improvement Committee, Medical Executive Committee and Governing Board. Monitoring will continue until at least one full year of compliance has been reported. | 2/06/2012<br><br>2/06/2012 |



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