POC ACCEPTABLE YES NO
Reviewed By: Name
Fax
Original

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
	050444	A. BUILDING _____ B. WING _____	

FACILITY NOTIFIED
Name:
Date: 9/23/14
Time: 1048
Notified By: Name

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Mercy Medical Center	**333 Mercy Ave, Merced, CA 95340-8319 MERCED COUNTY**

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00394996 - Substantiated Representing the Department of Public Health: Surveyor ID # 2647, 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 1280.1(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. Health and Safety Code section 1279.1 (4) (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. DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY Title 22 section 70215 (b) The planning and delivery of patient care shall reflect all elements of the		**Health and Safety Code Section 1279.1 (4) (A)** **Corrective Action** **A)** Patient 1's visit was reviewed for proper administration of opioids by the Director of Pharmaceutical Services and Chief Nursing Officer, and found that Policy MM 396-IV Dosing of Hydromorphone was not followed related to dosing, assessment and monitoring. **B)** Patient 1's death was reviewed through Root Cause Analysis process and found to have concerns with documentation of assessments and monitoring **C)** Patient 1 Case reviewed during Nursing Administration Council. Discussed the need to make sure assignments were located in the same geography. **D)** Communication sent to charge nurse by Chief Nursing Officer related to assignments and making sure that assignments are located in the same geography i.e., area of	7/10/14 8/23/14 9/11/14 9/11/14

Event ID:VI3O11 9/11/2014 12:59:19PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Charles Kane TITLE: VP, COO (X6) DATE: 9/18/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 6

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.

RECEIVED
SEP 19 2014
CA DEPT. OF PUBLIC HEALTH
LICENSING & CERTIFICATION - FRESNO

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	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. Based on staff interviews, clinical record, and administrative document review, the hospital failed to assess and evaluate Patient 1's condition while receiving higher than normal doses of Dilaudid (a powerful Schedule II opioid analgesic). This failure resulted in the death of Patient 1. On 8/13/13, Patient 1 was admitted through the Emergency Department. Patient 1's clinical record, dated 8/12/13, indicated he came to the emergency department with "significant lower quadrant abdominal pain, with nausea, vomiting, subjective fevers, and diarrhea." Patient 1 began receiving Dilaudid by intravenous push (IVP) (directly into a vein) in the Emergency Department, 1mg at 12:45 a.m., and 1 mg at 3:45 a.m. After being transferred to the floor, Patient 1 received Dilaudid 2 mg at 9:22 a.m., Dilaudid 2 mg at 12:27 p.m., and Dilaudid 2 mg at 12:54 p.m. An order was received by the floor nurse at 12:46 p.m., for "Dilaudid 4 mg [milligrams] IV q [every] 2 [hours], prn [as needed] for pain." Patient 1 received 4 mg Dilaudid IVP at 5:35 p.m., 4 mg Dilaudid IVP at 8:02 p.m., and 4 mg Dilaudid IVP at 10:07 p.m. Patient 1 thus received 20mg of Dilaudid in a twenty-four hour period. (equivalent to 133 mg of Morphine) Patient 1 was found, unresponsive at 2:56 a.m. on 8/14/13 and a "code blue" (emergency resuscitation efforts) was initiated. Resuscitation was unsuccessful and		nursing stations and not all over the unit. **E).** Sentinel Event (Sentinel Event is defined using the Joint Commission definition - a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.) that includes Patient 1's visit, which was discussed at the Governing Board meeting. **F)** An Event log was created to monitor events that require Root Cause Analysis, (RCA) and to report RCA findings to appropriate committees. The date and the committee of the case presentation will be documented on the tracking log by the Director of Risk Management. **G)** All Sentinel Events or potential sentinel events requiring a Root Cause Analysis will be reported and reviewed at the following month's Patient Safety Meeting and reported on at the following months Quality Management Committee meeting	7/11/14 8/25/14

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	Patient 1 was pronounced deceased at 3:15 a.m. on 8/14/13. On 7/9/14 at 7:45 a.m., during an interview, RN 1 stated he took care of Patient 1 on 8/13/13 on the PM (7 p.m. to 7:30 a.m. 8/14/13) shift. RN 1 stated, "I don't know why that didn't strike me [as a high dose] at the time." RN 1 stated he did not recall ever giving 4 mg Dilaudid IVP to any other patient (meaning the high dose of 4 mg). RN 1 stated he is sure he checked on Patient 1 "sometime between 11 p.m. and 12 a.m., but "it probably wasn't 11:30 (as indicated in the electronic record)." RN 1 stated he didn't check on Patient 1 again, until 8/14/13 at 2:56 a.m., at which time he found Patient 1 unresponsive (3 hours and 26 minutes after the last time checked). RN 1 stated most of his charting was "late entry" because he was very busy that night. He stated he believed the charting was accurate for when Patient 1 was checked on after he received pain medication. RN 1 stated he should have monitored Patient 1 more closely. The hospital's policy and procedure titled, "Hourly Rounds" implemented 5/2013 indicated; "... Nursing personnel will round every hour from 0600 (6 a.m.) - 2200 (10 p.m.) and every two hours from 0000 (12 a.m.) - 0600 and more frequently if the patient's condition requires it..." According to the clinical record, RN 1 did not check Patient 1 between 11:30 p.m. on 8/13/13 and 2:56 a.m. on 8/14/13, a span of 3 hours and 26 minutes.		**H)** Policy MM-396 Intravenous Dosing of Hydromorphone was reviewed for content and made the following change, "*pulse oximetry to the assessment performed within 30 minutes of the administration.*" **I)** Revised policy was Fast-Tracked; which expedites the committee approval process then will follow the formal approval process. **J)** Education was provided to the nursing staff on the changes made to Policy MM-396 Intravenous Dosing of Hydromorphone via read and attestation prior to the next work shift. **K)** Upon re-evaluation of the policy further changes were made to include, "*1.Documentation of patient monitoring should be completed within 30 minutes of administration for all elements.* *2.Level of sedation using Pasero Opioid Sedation Scale (POSS) Acceptable Sedation levels include:* *a. Sleeping, easy to arouse*	8/15/14 8/15/14 8/29/14 9/8/14

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	RN 1 also did not document Patient 1's pain, sedation level, respiratory status or blood pressure following the two Dilaudid doses administered at 8:02 p.m. and 10:07 p.m. On 7/8/14 at 10 a.m., the 5th floor Clinical Nurse Manager 1 stated, "I've tried to emphasize documentation, telling nurses to paint a picture of patients' condition. Documentation by both day and night nurses [for Patient 1] was not good." The Coroner's "Report of Autopsy" dated 3/28/14, indicated: "CAUSE OF DEATH: Sudden cardiorespiratory arrest. DUE TO: Acute hydromorphone intoxication. OTHER SIGNIFICANT CONDITIONS: Morbid obesity, obstructive sleep apnea ..." The toxicology report (reports the presence of alcohol or drugs in the blood) dated 11/6/13, indicated, "Opiate detected... Hydromorphone = 0.05 mg [milligrams]/ [per] L [Liter]... Blood Hydromorphone ranges Effective Level: (0.008-0.032 mg/L Potentially Toxic: (> 0.032 mg/L) The hospital's policy and procedure titled, "Hydromorphone (Dilaudid) Intravenous Dosing of" policy number MM-396, dated 12/11, indicated, "1. Policy: Due to the potential adverse outcomes associated with the use of hydromorphone (Dilaudid) [the hospital] staff will assure that the appropriate dose is administered and appropriate monitoring is performed for all patients who require hydromorphone for pain control...		*b.-1- awake and alert, dose may be increased* *c.-2- slightly drowsy, easily aroused UNACCEPTABLE levels:* *d.-3- frequently drowsy, falls asleep during conversation, needs continued monitoring, consider decreasing dosing or offering non-opioid medications* *e.-4- minimal or no response to verbal and physical stimulation-consider Narcan* *3.Respiratory status (to include rate and depth of respirations),* *4.Pulse oximetry* *5.Blood pressure* *6.Pain scale"* **L)** Revised policy, Policy MM-396 Intravenous Dosing of Hydromorphone, Fast-Tracked; which expedites the committee approval process. Fast-Tracked policy will then follow the policy approval process. **M)** Nursing staff education is being provided through read and attestation prior to beginning their next work shift.	9/9/14 9/9/14

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	IV. Guidelines: ...D. Hydromorphone should not be administered more frequently than every three (3) hours...E... the administration of hydromorphone is known to cause life threatening respiratory depression [slower and more shallow breathing causing a decrease in oxygen and an increase in carbon dioxide in the body] even at recommended doses therefore patient monitoring as described below is essential. F. Patient Monitoring: 1. Sedation level requires evaluations of: a. Respiratory status and changes in blood pressure performed within thirty (30) minutes of administration. b. Pain relief requires evaluation with pain scale....G. Documentation 1. Monitoring values for sedation and pain relief will be recorded in the electronic medical record." The Drug Insert for Hydromorphone Hydrochloride Injection, USP, revised 11/2011, indicated "WARNING: RISK OF RESPIRATORY DEPRESSION AND ABUSE [respiratory depression is a decrease in the number of breaths per minute]... ADVERSE REACTIONS ...Serious adverse reactions include respiratory depression and apnea [pauses in breathing], circulatory depression [not enough blood flowing through the blood vessels], respiratory arrest [breathing stops], shock [results from too little blood flow to the body's organs] and cardiac arrest [heart stops beating]." According to Lexicomp, an online drug information resource for medical professionals, 1.5 mg of Dilaudid is equal to 10 mg of Morphine. The		**N)** Policy PC-323 Hourly Rounding was reviewed for content, no changes were made. Education was provided to nursing staff on elements, "*(B) 1. The primary registered nurse (RN) or licensed vocational nurse (LVN) assigned to each patient is responsible for ensuring that hourly rounds are made according to policy. 2. The nurse who admits the patient to the inpatient unit shall include a brief explanation of hourly rounds a part of orientation to the nursing unit so that the patient knows the frequency to expect to see nursing staff. Nursing Personnel will round every hour from 0600-2200 and every two hours from 0000-0600, and more frequently if the patient's condition requires it.*" **O)** Education provided to nursing staff via read and attestation to understanding elements highlighted in Policy PC-56B Pain, Assessment and Management of, and in Policy PC-323 Hourly Rounding.	8/21/14 8/29/14

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	following side-effects for Dilaudid are listed in the "Warnings/ Precautions" section for Dilaudid. "CNS [CNS is the Central Nervous System consisting of the brain and spinal cord. This system controls heart rate, breathing, and gag reflex in addition to other bodily functions] depression: May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (e.g., operating machinery or driving). Hypotension [low blood pressure]: May cause hypotension... Respiratory depression: [U.S. Boxed Warning]: May cause potentially life-threatening respiratory depression even with therapeutic use, especially with initiation or dose increases; ... The use of ethanol, other opioids, and other CNS depressants may increase the risk of adverse outcomes, including death. Obesity: Use with caution in patients who are morbidly obese." The hospital's failure to ensure Patient 1 was assessed and evaluated while receiving high doses of Dilaudid is a deficiency that has caused, or is likely to have caused, death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1. 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 1280.1(c).		**Monitor:** 10 random chart audits completed by Nursing Clinical Managers monthly per Nursing Unit for 100% compliance with policy MM-396 Intravenous Dosing of Hydromorphone, for documentation of reassessment 30 minutes after administration to ensure adherence to the policy changes. If noncompliance is observed, the individual involved will receive counseling and re-education. Further noncompliance will result in progressive disciplinary corrective action. Monthly audits completed by the Director of Risk Management for 98% compliance with reporting all Sentinel Events to the appropriate committees. The audit will utilize the Quality Management Committee Meeting Minutes and Governing Board Meeting minutes for report of Sentinel Events. 10 observation will be completed by the Clinical Manager weekly on each inpatient nursing unit to validate that the 3 Ps (Pain, Potty, Position), Environment/ safety	8/15/14 9/25/14 8/29/14

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