### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 050444

**Street Address, City, State, Zip Code:** 333 Mercy Ave, Merced, CA 95340-8319, MERCED COUNTY

<table>
<thead>
<tr>
<th>(X4) ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>(X5) Complete Date</th>
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<tbody>
<tr>
<td></td>
<td>The following reflects the findings of the Department of Public Health during an inspection visit:</td>
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<td>Complaint Intake Number: CA00394996 - Substantiated</td>
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<td>Representing the Department of Public Health: Surveyor ID # 2647, HFEN</td>
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<td>The inspection was limited to the specific facility event investigated and does not represent the</td>
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<td>findings of a full inspection of the facility.</td>
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<td>Health and Safety Code Section 1280.1(c): For purposes of this section &quot;immediate jeopardy&quot; means</td>
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<td>a situation in which the licensee's noncompliance with one or more requirements of licensure has</td>
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<td>caused, or is likely to cause, serious injury or death to the patient.</td>
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<td>Health and Safety Code section 1279.1 (4) (A): A patient death or serious disability associated</td>
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<td>with a medication error, including, but not limited to, an error involving the wrong drug, the</td>
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<td>wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the</td>
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<td>wrong route of administration, excluding reasonable differences in clinical judgment on drug</td>
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<td>selection and dose.</td>
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<td><strong>DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY</strong></td>
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<td>Title 22 section 70215 (b) The planning and delivery of patient care shall reflect all elements</td>
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<td>of the planning and delivery of patient care shall reflect all elements of the</td>
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**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

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**By signing this document, I am acknowledging receipt of the entire citation packet.**

**Any deficiency statement ending with an asterisk (*) denotes a deficiency which may be excused from correcting provided 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 plan 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 necessary to continue program participation.**
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 1mg at 3:45 a.m. After being transferred to the floor, Patient 1 received Dilaudid 2mg at 9:22 a.m., Dilaudid 2mg at 12:27 p.m., and Dilaudid 2mg at 12:54 p.m. An order was received by the floor nurse at 12:46 p.m., for "Dilaudid 4mg [milligrams] IV q [every] 2 [hours], pm [as needed] for pain." Patient 1 received 4mg Dilaudid IVP at 5:35 p.m., 4mg Dilaudid IVP at 8:02 p.m., and 4mg 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...
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.
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 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.

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
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).
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needs addressed and documentation of rounds on the white board. If noncompliance is observed, the individual involved will receive counseling and re-education. Further noncompliance will result in progressive disciplinary corrective action.

Results are reported monthly to the Quality Management Committee (QMC), Medical Executive Committee (MEC) and Governing Board until 99% compliance is sustained for four months then frequency will be re-evaluated

**Responsible Person(s):**
Chief Nursing Officer
Clinical Nursing Managers