

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|---|--|--|--|
| | <p>The following represents the findings of the California Department of Public Health during the investigation of an entity reported adverse event.</p> <p>Entity reported event: CA00122589</p> <p>Representing the Department: [REDACTED] [REDACTED], HFEN and [REDACTED] [REDACTED] Pharmaceutical Consultant.</p> <p>The inspection was limited to the specific entity reported adverse event investigated and does not represent the findings of a full inspection of the facility.</p> <p>1280.1(a) HSC Section 1280</p> <p>If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health and safety of a patient and is required to submit a plan or correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation.</p> <p>1280.1 (c) HSC Section 1280</p> <p>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>DEFICIENCY CONSTITUTING IMMEDIATE</p> | | | |
|--|---|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 1</p> <p>JEOPARDY</p> <p>70263(c)(1) Pharmaceutical Service General Requirements 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.</p> <p>70263(g)(2) Pharmaceutical Service General Requirements Medications and treatments shall be administered as ordered.</p> <p>Based on observation, staff interviews, and document reviews, the facility failed to provide patient safety by ensuring written policies and procedures for the distribution and administration of drugs were implemented to ensure the safe use of all medication, and failed to ensure that the correct medication was administered as ordered by the physician.</p> <p>The failure to ensure safe distribution and administration of drugs was the direct cause of the life-threatening events to Patients 1 and 2. A medication administration error resulted in Patient</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 2</p> <p>1's narcotic overdose and respiratory arrest, an unplanned C-section for her newborn infant (Patient 2), and fetal asphyxia of Patient 2 requiring resuscitation and transfer to the Intensive Care Nursery (ICN) for close monitoring.</p> <p>Findings:</p> <p>On 8/8/07 at 1:30 p.m., facility administrative and clinical personnel were interviewed about the facility's investigation of a medication error involving the administration of an incorrect narcotic analgesic to Patient 1.</p> <p>On 8/3/07 at 7:15 p.m., Patient 1 was admitted to the Labor and Delivery Unit. Patient 1 was a 23-year-old admitted for a vaginal delivery.</p> <p>On 8/4/07 at 1:50 a.m., Patient 1 was documented as "asking for pain med (medication)" and the nurse "will give IV (intravenous) pain med".</p> <p>On 8/4/07 at 2:06 a.m., Patient 1 was given Sufenta 0.05mg IV (intravenously). Sufenta is a narcotic analgesic. Patient 1's admission physician orders, dated 8/3/07 at 9:00 p.m., included an order for the medication "fentanyl (a narcotic analgesic) 50 micrograms IV (intravenously) every hour for moderate pain" but did not include any orders for Sufenta. Sufenta is five times more potent than fentanyl (Reference: Drug Facts and Comparisons 2007).</p> <p>On 8/4/07 at 2:11a.m., Patient 1's "breathing stopped" and the fetal heart rate dropped to the</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 3</p> <p>"60's" beats per minute (fetal heart rate was documented normal at 120-130 beats per minutes between 1:30 a.m. and 2:00 a.m.).</p> <p>On 8/4/07 at 2:12 a.m., the fetal heart rate had dropped to the "50's" beats per minutes, and Patient 1 was "Ambu bagged" (provided respiratory support by face mask/oxygen) and a "code blue" (emergency cardiopulmonary resuscitation) was initiated. Patient 1 was documented as "non-responsive".</p> <p>On 8/4/07 at 2:13 a.m., Narcan 2mg was given IV. Narcan is an antidote (rescue agent) for opiate or narcotic overdose.</p> <p>On 8/4/07 at 2:19 a.m., Patient 1 was "starting to respond" but the fetal heart rate continued to be low (60 -70's beats/min), and the decision was made to deliver Patient 1's fetus by an emergency C-section (Caesarian section). A C-Section is a procedure in which a baby, rather than being born vaginally, is surgically extracted (removed) from the uterus. On 8/4/07 at 2:28 a.m., the fetal heart rate showed 100-112 beats per minute.</p> <p>On 8/4/07 at 2:36 a.m., the newborn (Patient 2) was delivered by C-section. Patient 2's admitting diagnosis included "birth asphyxia" in addition to a C-section birth. Patient 2's initial Apgar score of 2 was low, and then improved to an Apgar score of 5. The Apgar scores are assigned based on an infant's condition at 1 minute after birth, at 5 minutes, and every 5 minutes until the score is greater than 7. A newborn's Apgar score is</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 4</p> <p>assigned based on the infant's heart rate, respiratory effort, muscle tone, reflex irritability and color (Reference: Manual of Pediatric Therapeutics, Ch.6 on Management of the Sick Newborn, 6th edition, 1997).</p> <p>Patient 2 was documented as "floppy" and was given Narcan 0.4mg (at 0.1mg/kg) and admitted to the ICN (Intensive Care Nursery) instead of the "Well-baby Nursery" for additional monitoring where Patient 2 remained until 8/6/07 (2 days after birth). The documented diagnosis for the newborn's admission to the ICN was birth asphyxia, metabolic acidosis (electrolyte imbalance) and narcosis (condition induced by the use of a narcotic). The physician Progress Notes dated 8/4/07 at 5:15 a.m. stated, "Potential consequences of anoxia (lack of brain oxygenation due to inadequate ventilation/respirations) will be followed." The newborn was to be monitored for encephalopathy (brain damage), seizures, and renal insufficiency.</p> <p>Staff E said Patient 1 had a PACU (recovery room) nurse in addition to the L & D nurse assigned to monitor her for the long-term effects of Sufenta after the C-section.</p> <p>The administrative and clinical pharmacy staff members were interviewed on 8/8/07 about the facility investigation of the medication error and the following responses were obtained:</p> <p>a. The Director of Maternal-Child Department (Staff E) said Patient 1's medication nurse "could not</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | | |
|--|---|--|---|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| | <p>Continued From page 5</p> <p>find” fentanyl in the L&D Unit “MedSelect” (MedSelect is an automated drug delivery device). Staff E said the L&D charge nurse directed the L&D staff nurse, who administered the medication, to check under “Sufenta”. The L&D staff nurse retrieved a sufentanyl 50 microgram vial from the MedSelect and administered the sufentanyl, contrary to the physician order for fentanyl.</p> <p>b. The Director of Pharmacy Services (Staff D) said medications in the MedSelect devices can be retrieved either by trade or generic names and the nurses involved had a “lack of familiarity with the device” and searched for the medication under an incorrect drug name. Sufenta® and Sublimaze® are the trade names for sufentanyl and fentanyl respectively.</p> <p>c. Staff D and E said the investigation concluded responsible nursing staff looked under the “incorrect name” (trade name) and may not have been familiar with the generic name, and the L&D staff nurse retrieved the wrong drug product.</p> <p>d. The Director of Quality Management (Staff F) said the investigation identified three main issues for the medication error: 1) the medication nurse’s inability to differentiate between trade and generic names, 2) the charge nurse’s lack of familiarity with medication names and sound-alike drug names that were not the same drugs, and 3) the incorrect assumption that drugs with similar sounding names were the same drugs.</p> <p>e. Staff D said the packaging (injection vial) for</p> | | | |

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 6</p> <p>Sufenta and Sublimaze had some differences but "not much". Staff D said Sufenta and Sublimaze was not on the facility's "look-alike, sound-alike" list as it had been removed by ISMP (Institute for Safe Medication Practices) in 2006. ISMP is a nationally recognized organization devoted entirely to medication error prevention and safe medication use. Staff D said the facility's "Departmental Policy and Procedural Directive" on "Sound Alike / Look Alike Drugs" (last revised on 1/05) did not include Sufenta or Sublimaze.</p> <p>f. Staff D identified nursing knowledge deficit, and "failure to validate" medication information when nursing staff was unfamiliar with the drug name as the causes of the medication error.</p> <p>On 8/8/07 the administrative and clinical pharmacy staff members were asked about corrective actions taken to ensure the prevention of future recurrences, and the following responses were obtained:</p> <p>a. Staff C and E said the two nurses directly involved with the medication error were "counseled". No additional L&D nursing staff or staff on other patient care units were counseled or informed of the possible confusion of Sufenta with Sublimaze. Staff C and E said improving the nurses' familiarity with the MedSelect devices and their functions will be done in the future.</p> <p>b. Staff D said an "alert message" was to be inputted into the MedSelect, but the facility had not decided what the alert message would state.</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | | | |
|--|---|---|--|--------------------|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 08/08/2007 |
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | | | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE | |
| | <p>Continued From page 7</p> <p>c. Staff C said a medication "warning" was added to the MedSelect identifying Sufenta for "Anesthesia Administration Only". Administration and clinical staff confirmed Sufenta continued to be available in the MedSelect devices in the Operating Room (OR), the Recovery Room (PACU), and the Labor and Delivery (L&D) units. They stated that Sufenta can be retrieved and administered by any personnel who can access MedSelect devices in those units.</p> <p>d. Additional recommendations proposed but not implemented by the facility included limiting the access to Sufenta to anesthesiologists, additional training and education to all nursing staff about look-alike/sound-alike medication combinations, and additional visual alerts to the Sufenta and Sublimaze vials and "High Alert" medications stored in the MedSelect devices.</p> <p>On 8/8/07 at 3:20 p.m., an L&D staff nurse (Staff G) was asked if she could access Sufenta through the MedSelect device. Staff G was able to retrieve a vial of Sufenta despite the "For Anesthesia Administration Only" pop-up warning. There was no alert, or warning, or visual evidence in the MedSelect device that Sufenta was not equivalent to Sublimaze. There was no difference in the lettering of any of the drug names listed in the MedSelect device.</p> <p>A medication error (the administration of sufentanyl 50mcg equivalent to 250mcg of fentanyl) was determined to be the direct cause of the life-threatening events to Patients 1 and 2. This</p> | | | | |

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 8</p> <p>medication administration error resulted in Patient 1's narcotic overdose and respiratory arrest, an unplanned C-section for her newborn infant (Patient 2), and fetal asphyxia of Patient 2 requiring resuscitation and transfer to a higher level of care (admission to the neo-natal intensive care unit) for the close monitoring.</p> <p>The confusion with Sufenta and Sublimaze (sound-alike and look-alike medications) was the direct cause of the life-threatening events to Patient1 and her newborn infant, Patient 2.</p> <p>The interviews conducted with administrative and clinical pharmacy staff and reviews of medical records and policies and procedures revealed the facility identified the life-threatening events for Patients 1 and 2 were due to confusion between Sufenta and Sublimaze. The only pharmacy services corrective action taken was the addition of a "For Anesthesia Administration Only" warning for Sufenta in the MedSelect device. No additional corrective action had been taken to minimize the risk of confusing Sufenta and Sublimaze and minimize the risk of additional medication errors based on the sound-alike drugs Sufenta and Sublimaze.</p> <p>The facility's "Departmental Policy and Procedural Directive" on "Sound Alike/ Look Alike Drugs" (last revised on 1/05) identified its purpose was "to ensure the safety and minimize the potential for error in the ordering, dispensing, and/or administration of sound-alike and look-alike medication".</p> | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | | |
|--|--|--|---|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
| | <p>Continued From page 9</p> <p>The policy identified various processes were in place to identify these medications in the facility and procedures to address the opportunities for error and strategies employed to minimize the risk of medication errors.</p> <p>Although the policy identified thirty-nine (39) such drug combinations in the facility, it did not include Sufenta (sufentanyl) and Sublimaze (fentanyl), the facility investigation into the life-threatening events for Patients 1 and 2 determined the events were caused by a medication error due to sound-alike (Sufenta and Sublimaze) and look-alike (similar size vials and packaging).</p> <p>The policy identified at least ten procedures for the safe use of sound-alike, look-alike medication combinations:</p> <ol style="list-style-type: none"> 1) A list of all such medications shall be compiled and disseminated to the hospital staff as an alert to exercise caution when dealing with listed medications. 2) Ongoing (annual) staff education about these medications. 3) Prudent product selection and avoidance of high risk look-alike products. 4) General awareness of sound-alike/look-alike medications through posted lists. 5) Pharmacy computer system alerts appearing during order processing. 6) Changing the appearance of look-alike product names on computer screens, pharmacy and nursing shelf labels and bins (including automated | | | |

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|---|--|--|--|
| | <p>Continued From page 10</p> <p>dispensing cabinets), pharmacy product labels, and MARs (Medication Administration Records) by highlighting, through bold-face, and/or tall man letters, the parts of the names that are different (e.g. hydrOXYzine, hydrALazine).</p> <p>7) Configure computer selection screens and automated dispensing cabinet screens to prevent the paired confused drugs from appearing consecutively.</p> <p>8) Affix "Name Alert" stickers to areas where look and sound-alike products were stored.</p> <p>9) Store products with look or sound-alike names in different locations, whenever possible, and use a shelf sticker to help locate the product that has been moved.</p> <p>10) Maintain awareness of problematic product names and error prevention recommendations provided by ISMP (Institute for Medication Practice www.ismp.org) FDA (Food and Drug Administration www.fda.org) and USP (United States Pharmacopeia www.usp.org).</p> <p>Observations and staff interviews during the investigation on 8/8/07 did not show any of the procedures for the safe storage and usage of "sound-alike/look-alike drugs" had been implemented either before or after the life-threatening events to Patients 1 and 2 resulting from sound-alike/look-alike drugs.</p> <p>No evidence was provided that any of the procedures described in the policy had been applied to the Sufenta/Sublimaze combination which was recognized by the facility as a pair of sound-alike/look-alike drugs that caused a</p> | | | |
|--|---|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|--|---------------|---|--------------------|
|--------------------|--|---------------|---|--------------------|

| | | | | |
|--|--|--|--|--|
| | <p>Continued From page 11</p> <p>potentially fatal medication error.</p> <p>No evidence was provided to document any of the procedures for the "Sound-alike/look-alike drugs" had been implemented for any other drug combinations listed in the policy and in accordance with that policy.</p> <p>There was no evidence of the implementation of identified various processes identified in that policy to address the opportunities for error or any strategies had been employed to minimize the risk of medication errors.</p> <p>The facility failed to:</p> <ol style="list-style-type: none"> provide a medication as prescribed to one patient resulting in a medication error and that caused life-threatening events for two patients (Patient's 1 and 2). implement immediate corrective actions so as to ensure the safe distribution, dispensing and administration of a pair of sound-alike/look-alike drugs (Sufenta and Sublimaze). implement their own policy and procedures with respect to sound-alike/look-alike drugs to ensure for the safe administration of these drugs. include adequate alerts and warning to the automated drug dispensing devices in accordance with facility policy and procedures so as to prevent a recurrence of dispensing and administration errors. take corrective action with all associated personnel so as to prevent future medication dispensing and administration errors of sound-alike/look-alike drugs. | | | |
|--|--|--|--|--|

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

| | | | |
|--|---|--|---|
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050283 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 08/08/2007 |
|--|---|--|---|

| | |
|--|--|
| NAME OF PROVIDER OR SUPPLIER VALLEYCARE MEDICAL CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 5555 WEST LAS POSITAS BOULEVARD, PLEASANTON, CA 94588 ALAMEDA COUNTY |
|--|--|

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|--------------------|---|---------------|---|--------------------|
| | <p>Continued From page 12</p> <p>The cumulative effects of these system problems resulted in the facility's inability to ensure for the provision for safe and effective use of drugs.</p> <p>The violation(s) has caused or is likely to cause serious injury or death to a patient(s).</p> | | | |

Event ID:21C211

3/18/2008

12:44:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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.