

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050230	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/13/2012
NAME OF PROVIDER OR SUPPLIER Garden Grove Hospital and Medical Center		STREET ADDRESS, CITY, STATE, ZIP CODE 12601 Garden Grove Blvd, Garden Grove, CA 92843-1908 ORANGE 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: CA00340189 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 25447, Pharmaceutical Consultant II</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 1280.1(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.</p> <p>Health & Safety Code Section 1280.1(c):</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>Health and Safety Code Section 1279.1 (a):</p> <p>The facility shall report an adverse event to the Department no later than five days after the adverse event has been detected.</p> <p>The CDPH verified that the facility had not informed</p>		<p>Health and Saefy Code 1279.1(a) How the correction will be accomplished, both temporarily and permanently. The policy and procedure on Adverse Events Reporting was reviewed with Directors/Managers during Leadership Meeting and hospital staff members during Patient Safety Meetings. Reportable adverse events, listed below, shall be reported to CDPH (California Department of Public Health) no later than 5 days after the event has been detected; or, if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than twenty-four (24) hours after the adverse event has been detected. The event will be investigated using the Root Cause Analysis process to mitigate and prevent similar incidents and to evaluate and improve quality of care.</p> <ol style="list-style-type: none"> 1. Surgery performed on a wrong body 2. Surgery performed on the wrong patient 3. The wrong surgical procedure performed on a patient 4. Retention of a foreign object in a patient after surgery or other procedure 5. Death during or up to 24 hours after induction of anesthesia after surgery 6. Patient death or serious disability associated with the use of a contaminated drug, device or biologic 7. Patient death or serious disability associated with the use or function of a device inpatient care 8. Patient death or serious disability associated with intravascular air embolism 9. An infant discharged to the wrong person 	01/11/2013

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10. Patient death or serious disability

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

[Handwritten Signature]

TITLE

[Handwritten Title]

(X6) DATE

10/22/2013

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 11

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.

POC accepted 10/24/13 Surveyor 2097

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	<p>the Department of the adverse event.</p> <p>Health and Safety Code Section 1279.1 (c):</p> <p>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>The CDPH verified that the facility had not informed the patient or the party responsible for the patient of the adverse event.</p> <p>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY:</p> <p>Title 22 DIV5 CH1 ART3 70213 (a) Nursing Service Policies and Procedures.</p> <p>(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.</p> <p>The above regulation was NOT MET as evidenced by:</p> <p>Based on interview and medical record review, the hospital failed to ensure their procedure regarding the read back of verbal orders to a physician was implemented during a bedside procedure. A registered nurse (RN 1) failed to read the verbal medication orders back to the physician (MD 1) for accuracy of the dosage prior to administration of Versed. The generic name of Versed is midazolam, a medication of the benzodiazepine class used to sedate patients, reduce anxiety, and reduce memory of surgical and other medical procedures).</p>		<p>Associated with patient disappearance for more than four hours</p> <p>11. Patient suicide or attempted suicide resulting in serious disability</p> <p>12. Patient death or serious disability associate with a medication error</p> <p>13. Patient death or serious disability Associated with a hemolytic reaction</p> <p>14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy</p> <p>15. Patient death or serious disability directly related to hypoglycemia</p> <p>16. Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates</p> <p>17. Stage 3 or 4 ulcer, acquired after admission</p> <p>18. Patient death or serious disability due to spinal manipulative therapy performed at the health facility</p> <p>19. Patient death or serious disability associated with an electric shock</p> <p>20. Incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas</p> <p>21. Patient death or serious disability associated with a burn</p> <p>22. Patient death associated with a fall</p> <p>23. Patient death or serious disability associated with the use of restraints or bedrails</p> <p>24. Any instance of care ordered by or provided by someone impersonating a health care provider</p> <p>25. Abduction of a patient of any age</p> <p>26. Sexual assault on a patient within or on the grounds of the facility</p> <p>27. Death or significant injury of a patient or staff member resulting from a physical</p>	

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	<p>RN 1 administered midazolam to Patient A during a bedside endoscopic procedure (a procedure in which an instrument is used to see inside a cavity or a hollow part of the body such as the windpipe) which resulted in the administration of an overdose of this medication, followed by respiratory depression (decrease in breathing) and severely low blood pressure. MD 1 placed a breathing tube into the patient's windpipe to allow mechanical breathing and ordered administration of Romazicon, a midazolam antidote. MD 1 also ordered that the patient be transferred from room 414, an inpatient medical surgical bed, to the Intensive Care Unit where Patient A received medication to treat Patient A's low blood pressure. Patient A was not able to be weaned from the ventilator (breathing machine) and died 9 days later.</p> <p>Findings:</p> <p>Review of the hospital's P&P titled Physician's Orders, reviewed 8/11, showed face to face verbal orders are to be taken only in emergencies or when no other alternative exists. The verbal orders should be read back to the physician to avoid misinterpretation and staff taking the verbal order was to document the "read back" on the physician's order sheet.</p> <p>Review of the hospital's P&P titled Sedation (Moderate) showed a dose of 0.5-1 mg (milligrams) of midazolam slow IV (intravenous) push is administered for minimal sedation and, an initial dose of 0.5-2 mg slow IV push is administered over at least 2 minutes for moderate sedation. The</p>		<p>assault</p> <p>28. Adverse event or series of adverse events that cause the death or serious disability of a pt, personnel or visitor</p> <p>29. Privacy Breaches of Patients or Employees in regards to access, use, or disclosure of protected information</p> <p>The title or position of the person responsible for the correction Risk Manager, Director of Performance Improvement, Director of Nursing, Administrator, Compliance Officer</p> <p>A description of the monitoring process to prevent recurrence of the deficiency. Incidents Reports will be reviewed daily or as appropriate by Risk Manager or designee to identify any reportable adverse events. Monthly and/or quarterly reports will include Total number of Incident Reports (denominator) and number of adverse events reported (numerator). This will be presented to Patient Safety Meeting, Quality Council, PI Committee, MEC and Governing Board.</p>	

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	<p>same policy showed intravenous sedation may be administered "only in the following recognized anesthetizing locations" which included Intensive Care Unit, Post Anesthesia Care Unit, Gastrointestinal Laboratory, Radiology Department and Emergency Department.</p> <p>Medical record review for Patient A showed the patient, who was [REDACTED] years old, was admitted to the Emergency Department on [REDACTED] 12 at 1100 hours, for coughing and increased work of breathing. The patient had a history of dementia (progressive deterioration in cognitive function), diabetes (high blood sugar), and hypertension (high blood pressure).</p> <p>The radiology report, dated [REDACTED] 12, showed the patient had right lower lobe atelectasis (partial collapse of lung tissue) and infiltrates (liquid or material deposited in the lungs).</p> <p>On [REDACTED] 12, Patient A was diagnosed with pneumonia (infection of lungs).</p> <p>On 12/13/12 at 0830 hours, concurrent medical record review of Patient A and interview with Registered Nurse Performance Improvement Director (ADM 3) showed the following documentation from [REDACTED] 2:</p> <p>* On [REDACTED] 12 at 0800 hours, the nursing flowsheets showed Patient A's vital signs were as follows: respiratory rate: 36 respirations per minute (normal rate is 12-20), heart rate: 91 beats per minute (normal rate is 60-100), 100% oxygen saturation on</p>		<p>Health and Safety Code Section 1279.1 (c) How the correction will be accomplished, both temporarily and permanently. The policy and procedure on Adverse Events Reporting, including disclosure of adverse events to patient and patient representative, was reviewed with Directors/Managers during Leadership Meeting and hospital staff members during Patient Safety Meetings. The patient or the party responsible for the patient will be notified by the Chief Executive Officer/Administrator or designee, Chief Medical Officer (CMO) or designee, Primary Physician or designee of the nature of the adverse event by the time the report is made to CDPH. The disclosure will be documented in the patient's medical record.</p> <p>The title or position of the person responsible for the correction Risk Manager, Administrator</p> <p>A description of the monitoring process to prevent recurrence of the deficiency For every adverse event identified and reported, the Risk Manager or designee will review the medical record for documentation of disclosure to patient or patient representative. This will be reported monthly and/or quarterly to Patient Safety Meeting, Quality Council, PI Committee, MEC and Governing Board.</p>	01/11/2013

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	<p>50% oxygen at 15 liters per minute via a mask (normal 96-100% on room air), and blood pressure 133/79 (normal average 120/80). The Respiratory flowsheets from [REDACTED]12 at 0930 hours showed a respiratory rate of 24 on 50% oxygen at 15 liters per minute via a mask.</p> <p>* At 1000 hours, MD 1 started a bronchoscopy procedure (a type of endoscopy procedure to view the lung airway) for Patient A with RN 1's assistance. The bronchoscopy was performed at the bedside of Patient A in Room 414, which is located outside the "recognized anesthetizing locations" as stipulated in hospital policy titled, Sedation (Moderate).</p> <p>* At 1022 hours, Patient A was administered Versed 2 mg IV push and at 1023 hours, Patient A was administered Versed 2 mg IV push. A total of 4 mg of Versed was administered to Patient A in a 1 minute period. Versed is a benzodiazepine sedative used in surgical procedures and it can produce respiratory depression (decrease in breathing) and severely low blood pressure.</p> <p>According to the physician's procedure note, after the administration of the Versed, the patient developed apnea (stopped breathing) and developed hypotension (low blood pressure). The patient was given CPR (chest compressions) and the emergency cardiovascular medication, epinephrine.</p> <p>According to nursing notes from [REDACTED]13 at 1035 hours, the patient was the subject of a code blue (emergency response initiated for a patient without</p>		<p>Title 22 DIV5 CHI ART3 70213 (a) Nursing Service Policy and Procedure How the correction will be accomplished, both temporarily and permanently The policy and procedure on "Physician Orders" was reviewed and revised to include healthcare professionals i.e. RT and Pharmacists, to perform a read back for each verbal order prior to medication administration including serial dosing (titrating orders) during moderate sedation procedures. The staff was re-educated to perform read back for every verbal and/or telephone order received from physician.</p> <p>The title or position of the person responsible for the correction Director of Performance Improvement, Director of Nursing</p> <p>A description of the monitoring process to prevent recurrence of the deficiency Monthly and quarterly report will include number of observed verbal and/or telephone orders (denominator) and number of observed complete "read back" with date, time and signature of verbal and/or telephone orders (numerator) will be presented to Patient Safety Meeting, Quality Council, PI Committee, MEC and Governing Board.</p>	01/11/2013

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	<p>heartbeat or respirations).</p> <p>* At 1025 hours, Patient A received Romazicon (a benzodiazepine reversal agent, antidote used to reverse the effects of Versed) 0.5 milligrams and normal saline and albumin (a plasma expander) boluses in an attempt to support the low blood pressure to prevent death from circulatory collapse.</p> <p>* At 1029 hours, Patient A's blood pressure dropped to 60/38 mmHg (normal range is 120/80 mmHg) and her oxygen saturation level was 72% (normal range 95-100%).</p> <p>* At 1031 hours, MD 1 placed a breathing tube to provide for artificial respiration and oxygenation of the vital organs.</p> <p>* At 1033 hours, Patient A was infused with normal saline bolus, and the patient's blood pressure measured at 82/48 mmHg.</p> <p>* At 1040 hours, Patient A was transferred to the Intensive Care Unit (ICU), a higher level of care, where the patient was administered Levophed, a medication used to treat severely low blood pressure.</p> <p>* The patient continued to require medications for blood pressure support, and the patient expired nine days later, on [REDACTED] 12 at 1040 hours.</p> <p>On 2/5/13 at 1012 hours, in a telephone interview, ADM 1 confirmed the manufacturer, Hospira supplied the hospital's stock of midazolam.</p>		<p>Title 22 DIV5 CHI ART3 70213 (a) Nursing Service Policy and Procedure</p> <p>How the correction will be accomplished, both temporarily and permanently The policy on Moderate Sedation was reviewed and revised to expand areas allowed for sedation i.e. MedSurg, ICU and Telemetry and hospital staff was re-educated of the revision.</p> <p>The title or position of the person responsible for the correction Risk Manager, Director of PI</p> <p>A description of the monitoring process to prevent recurrence of the deficiency The Director of PI will perform a monthly review on all sedation procedure performed. The total number of sedations will be the denominator and total number of sedation procedures performed on allowed areas will be the numerator. This will be reported monthly and/or quarterly to Patient Safety Meeting, Quality Council, PI Committee, MEC and Governing Board.</p>	01/11/2013	

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	<p>According to the manufacturer, midazolam has a boxed warning (also called a "black box" warning) which is the most serious warning required by the Food and Drug Administration to be placed in the product labeling (also called the package insert) for this medication. The boxed warning for midazolam shows "Intravenous Midazolam has been associated with respiratory depression and respiratory arrest... In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy (brain injury) has resulted..."</p> <p>Excerpts from the package insert below describe the safeguards needed to avoid adverse events associated with midazolam, including: product selection and dilution to ensure slow administration; reduced dosage and slower administration in elderly patients; a maximum dose of 1.5 milligrams over a period of no less than 2 minutes, a waiting time of an additional 2 or more minutes to fully evaluate the sedative effect; restriction of use in the absence of availability of necessary equipment and skilled personnel; use in elderly patients, and risks associated with use during endoscopy procedures.</p> <p>The geriatric Dosage section of the package insert of midazolam, showed the following:</p> <p>"Midazolam hydrochloride 1 mg/mL formulation is recommended for sedation/anxiolysis/amnesia for procedures to facilitate slower injection . Both the 1 mg/mL and the 5 mg/mL formulations</p>			

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	<p>may be diluted with 0.9% sodium chloride or 5% dextrose in water."</p> <p>"Patients Age 60 or Older, and Debilitated or Chronically Ill Patients: Because the danger of hypoventilation, airway obstruction, or apnea is greater in elderly patients and those with chronic disease states or decreased pulmonary reserve, and because the peak effect may take longer in these patients, increments should be smaller and the rate of injection slower. Titrate slowly to the desired effect, e.g., the initiation of slurred speech. Some patients may respond to as little as 1 mg. No more than 1.5 mg should be given over a period of no less than 2 minutes. Wait an additional 2 or more minutes to fully evaluate the sedative effect. If additional titration is necessary, it should be given at a rate of no more than 1 mg over a period of 2 minutes, waiting an additional 2 or more minutes each time to fully evaluate the sedative effect. Total doses greater than 3.5 mg are not usually necessary."</p> <p>The Warning section of the package insert of midazolam, showed the following:</p> <p>"Prior to the intravenous administration of midazolam in any dose, the immediate availability of oxygen, resuscitative drugs, age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and skilled personnel for the maintenance of a patent airway and support of ventilation should be ensured. Patients should be continuously monitored with some means of detection for early signs of hypoventilation, airway</p>			2013 OCT 29 6:11 04

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	<p>obstruction, or apnea, i.e., pulse oximetry. Hypoventilation, airway obstruction and apnea can lead to hypoxia and/or cardiac arrest unless effective countermeasures are taken immediately... When used for sedation/anoxiolysis/ amnesia, midazolam should always be titrated slowly in adult or pediatric patients."</p> <p>The Dosage and Administration section of the package insert of midazolam showed the following:</p> <p>"Serious cardiorespiratory adverse events have occurred after administration of midazolam. These have included respiratory depression, airway obstruction, oxygen desaturation, apnea, respiratory arrest and/or cardiac arrest, sometimes resulting in death or permanent neurologic injury." "Higher risk adult and pediatric surgical patients, elderly patients and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered." "Pediatric and adult patients undergoing procedures involving the upper airway such as upper endoscopy or dental care, are particularly vulnerable to episodes of desaturation and hypoventilation due to partial airway obstruction."</p> <p>Review of the hospital's incident report showed RN 1 reported the administration of two doses of Versed as ordered by MD 1.</p> <p>On 12/13/12 at 0925 hours, in a concurrent interview and medical record review with the hospital's Administrator, Chief Nursing Officer</p>				2013 OCT 29 AM 11 08

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	<p>(ADM 1), and ADM 3, ADM 3 stated there was "an implementation failure with verbal orders. The nurse did not read back." ADM 3 discussed the hospital's investigation after a Risk Incident Report was self-reported by RN 1 and explained a root cause analysis was conducted because of the serious nature of the patient's event. ADM 3 added "the patient's spontaneous ventilation was adequate before the procedure." ADM 1 and ADM 3 agreed if RN 1 had read back the versed orders to MD 1 for clarification of the dose, the adverse event would have been prevented. When asked about documentation of the Versed orders in the patient's medical record, ADM 1 stated the hospital did not have a record of the Versed orders because RN 1 did not write it down which was contrary to the hospital's P&P.</p> <p>Further review of the hospital's documents showed no record of the hospital's analysis of this event to indicate that this was a medication error.</p> <p>On 12/12/12 at 1540 hours, in an interview and concurrent medical record review with Patient A's attending physician (MD 1), MD 1 said the patient had to be intubated as a direct result of the Versed administration. MD 1 recalled he noticed the patient's condition changed (respiratory rate and level of consciousness) after administration of Versed. MD 1 said, "I asked RN 1 how much Versed had been administered." MD 1 elaborated, "I was shocked when he told me 4 milligrams. I didn't order that." The physician looked down, shook his head, and stated, "If (RN 1) had read back the versed order to me I would have stopped him." MD</p>			2013 OCT 29 AM 11:04

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050230	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/13/2012
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NAME OF PROVIDER OR SUPPLIER Garden Grove Hospital and Medical Center	STREET ADDRESS, CITY, STATE, ZIP CODE 12601 Garden Grove Blvd, Garden Grove, CA 92843-1908 ORANGE COUNTY
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(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
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	<p>1 recalled, "I said Versed 1 milligram or 0.5 milligrams. I usually order 0.5 milligrams." MD 1 confirmed RN 1 had administered the versed without first performing a read back. MD 1 said the patient had to be intubated as a direct result of the versed administration. He acknowledged the patient was breathing on her own before the procedure and never regained the ability to breathe on her own or speak again.</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 1280.1(c).</p>			
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2013 OCT 29 AM 11:04

Event ID:7RCT11

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