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
	050457	A. BUILDING _____ B. WING _____	08/26/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ST. MARY'S MEDICAL CENTER	450 STANYAN STREET, SAN FRANCISCO, CA 94117 SAN FRANCISCO COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00280120 - Substantiated Representing the Department of Public Health: Surveyor ID # 25732, 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. T22 DIV5 CH1 ART3-70263(c)(1) (1) 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. These regulations were not met as evidenced by:		C.D.P.H. JAN 1 3 2012 L&G DIV DALY CITY	

Event ID:ZSFP11 11/14/2011 12:45:18PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Heather Ofarey RN, MSN Accreditation + Regulatory Manager 11/28/11

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.

amended Heather Ofarey 1/11/12

1/11/12 Accepted amended POC - Doris Jordan - acting HFES

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	Continued From page 1 Based on interviews, record review, the hospital failed to develop and implement written policies and procedures to ensure the safe and effective use of medication when an anesthesiologist (Anesthesiologist 1) administered Versed to one patient (Patient A) without monitoring his respiratory status. Patient A developed respiratory arrest and died on [redacted]11 due to respiratory failure secondary to acute pulmonary arrest. Findings: During an interview on 8/26/11 at 9:30 A.M., the Patient Safety Officer (PSO) provided a summary of the incident. On [redacted]11 Patient A came to the hospital for surgical removal of hardware (metal screws and plates placed to repair broken bones) of the left shoulder. At around 4 P.M. Patient A was brought down from the third floor of the hospital by gurney to the pre-op holding area in the PACU (Post Anesthesia Care Unit). Patient A was seen by his surgeons (Surgeon 1 and Surgeon 2) who obtained his final consent for surgery. They left and Anesthesiologist 1 came in to see Patient A before surgery. Patient A told Anesthesiologist 1 that he was feeling anxious. Anesthesiologist 1 gave Patient A Midazolam (Versed(r)) 2 milligrams (mg) through the patient's IV line in his arm (a needle and tubing placed in a patient's vein for the rapid administration of fluids and medication). Anesthesiologist 1 watched Patient A for five to seven minutes then left the pre-op holding room. After that Surgeon 2 came back and talked to Patient A for a short time, Patient A was awake		**T22 Div 5 CH1 ARTS3 §70263(c) (1)** The regulation is not met as evidenced by: Based on interview, record review, the hospital failed to develop and implement written policies and procedures to ensure safe and effective use of medication when an anesthesiologist administered Versed to one patient without monitoring respiratory status. The patient developed respiratory failure secondary to acute pulmonary arrest. What Corrective Action will be accomplished, both temporarily and permanently 1. Preoperative holding guideline policy developed and implemented (OR-75D) to include the following: • Monitoring equipment placed on any patient receiving anxiolysis or pain control including blood pressure, pulse rate, respiration rate and oxygen saturation. • Preoperative patients now placed in PACU beds with direct visual observation. • Preoperative patients have peripheral line placed prior to entering the pre-operative holding area. • The preoperative holding area RN notifies the licensed independent practitioner of any adverse effects of a medication such as allergic reaction, unexpected change in vital signs and CNS depression.	9/9/11 & ongoing

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	Continued From page 2 and not slurring his speech. Surgeon 2 then left. After 10 to 15 minutes Anesthesiologist 1 returned to check on Patient A. Anesthesiologist 1 found him unresponsive (not awake and not breathing). Anesthesiologist 1 called out to the PACU (Post Anesthesia Care Unit) personal to 'Call a Code' (emergency hospital response team that treats patients who have stopped breathing or have had a cardiac arrest). Patient A had no pulse was given CPR (Cardio Pulmonary Resuscitation), intubated (emergency breathing tube placed into the throat) and defibrillated several times (electrical shock delivered to the heart to make the heart beat normally). Patient A's pulse came back but he never regained consciousness and was transferred to the ICU (Intensive Care Unit). Patient A was in the ICU for three days were he died on [redacted] Midazolam (Versed(r)) is a sedative hypnotic antianxiety drug that is indicated for preoperative sedation. According to Lexi-Comp(r), a provider of drug information for health care professionals, indicated under the title: "Medication Safety Issues :Midazolam,Warning/Precautions [U.S. Boxed Warning]: May cause severe respiratory depression, respiratory arrest or apnea. Use with extreme caution, particularly in non critical settings. Appropriate resuscitative equipment and qualified personnel must be available for administration and monitoring... Monitoring Parameters Respiratory and cardiovascular status, blood pressure, blood pressure monitor required during I.V.(in the vein) administration... Nursing: Physical Assessment/Monitoring ...For inpatient		2. Preoperative holding guideline policy (OR-75D) approved by Quality Improvement Council, Medical Executive Committee and Community Board. (Attachment A). 10/6/11 3. The Procedural Sedation Committee was reconvened with Chief of Anesthesia and Director of Peri-operative Department as co- chairs. Committee reviews data, discharge criteria and anesthesia requirements. 10/25/11 and monthly 4. A RN is assigned to monitor any patient waiting in pre-operative holding area. 9/9/11 & ongoing 5. "Each patient will be monitored during sedation or anesthesia. The patient's oxygenation, ventilation and circulation are monitored continuously" per policy Procedural sedation and anesthesia care (MM-5130) Attachment B revised 9/7/11. 9/7/11 6. Nursing staff in preoperative and PACU areas educated regarding patient supervision and patient hand off. August 15, 2011 and ongoing Responsible parties: Director Peri-operative Services Chief of Anesthesia C.D.P.H. JAN 1 1 2012 L&C DIV DALY CITY	

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Continued From page 3

use, institute safety measures. I.V.: Monitor cardiac and respiratory status continuously. Monitor closely following administration. See: (Lexicomp Online: Midazolam <http://online.lexi.com/crlsql/servlet/crlonline>(as of 8/29/2011)

Review of the "Pre Procedure Patient Prep Record dated [redacted]11 at 12:41 PM for Patient A showed the following vital signs: Temperature, 36.8 degrees C (Centigrede), Heart Rate, 101 bpm (beats per minute), Respiratory Rate, 18 Breaths/Min., BP Method, lying- left arm 122/86, SPO2 (oxygen saturation) 96% Room Air.

Record review of the hospital's Same Day Surgery Log, dated [redacted]11, indicated Patient A was transported to the pre-op holding area in the PACU at 4:10 P.M. Record review of Patient A's Code Blue Record indicated Patient A was found pulseless and apneic (not breathing) at 4:35 P.M

During an interview, on 8/31/11 at 1 P.M. with Anesthesiologist 1, he was asked about the incident that had occurred with Patient A. Anesthesiologist 1 said, "I saw Patient A in the little holding area next to the PACU. Patient A had a fall about a year ago where he had got orthopedic surgery of his shoulder at another hospital. He was coming to our hospital for surgery to remove the hardware in his shoulder that did not work out. He said he had a history of [redacted] His vital signs were: blood pressure 122/88, pulse of 102/min. . He said he was anxious so I gave him 2 mg of Versed(r) into

Description of Monitoring process to prevent recurrence of deficiency.

1. Nurse staffing/ scheduling in preoperative and PACU areas monitored daily for adequacy. — 9/9/11& ongoing
2. Staffing variances addressed and filled to meet patient care needs. Anticipated staffing needs addressed and filled to meet patient care needs. — 9/9/11& ongoing

Responsible parties:
Director Peri-operative Services

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	Continued From page 4 his IV line as a pre-medication. I gave it slow over a minute. Then I observed him for five minutes. He was still talking to me. I left the pre-op holding room to go to the bathroom and check my equipment in the Operating Room in preparation for Patient A's surgery. I knew that the orthopedic resident (Surgeon 2) would be checking on Patient A. At about 4:30 P.M. I came back to check on Patient A. He was unresponsive. I yelled to the nurses in the PACU to call a 'Code' and one of the RN's came over to help me start CPR." The surveyor asked Anesthesiologist 1 if Patient A's respiration, heart and blood pressure was being monitored when he administered the Versed. Anesthesiologist 1 said, "No, we only put monitors on, when we are doing conscious sedation like in the cath (heart) lab or if a patient was getting a GI (gastrointestinal) procedure. The Versed(r) I gave was to treat Patient A's anxiety." The surveyor also asked Anesthesiologist 1 if he informed any of the nurses that he gave Versed to Patient A was before he left the pre-op holding area. Anesthesiologist 1 said, "No, I thought the Orthopedic resident (Surgeon 2) was coming by to see Patient A again." Record review of Patient A's hospital Discharge Summary, dated [redacted]1, indicated: "Discharge Diagnosis...Anoxic Brain Injury...Cardiopulmonary Arrest...Respiratory Failure... Patient A was in the waiting area (pre-op holding) at the PACU (Post Anesthesia Care Unit)) and was found to be unresponsive by the anesthesiologist and Code			

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	Continued From page 5 Blue was called...Upon arrival CPR was immediately started and the patient had been intubated. The first rhythm during the code was V-fib (dangerous life threatening heart rate). The patient was repeatedly shocked, given medication...and eventually maintained a sinus rhythm (normal heart rate)...At that point he was transferred to the ICU. According to PACU staff before the Code Blue, the patient had been seen by multiple doctors and was alert and oriented and conversing fine. In the PACU it was unclear exactly what happened but the patient was found unresponsive and apneic and a Code Blue was called. It is unclear how long the patient had been down, questionable 5 to 10 minutes. The only medication that he received prior to being found down was Versed(r), unclear of dose but most likely 2 mg IV...The patient most likely suffered from a respiratory failure leading to a cardiopulmonary arrest and was later found to have anoxic brain injury Death on [redacted]2011 due to respiratory failure secondary to acute pulmonary arrest." In an interview, on 8/31/11 at 1:15 P.M., the Director of Peri-Operative Services (DOP) was asked to describe the procedure for admitting patients into the pre-op holding area. DOP said, "At the time of the incident, Petient A was brought down from the third floor by the surgical attendant to the pre-op holding area room in the PACU. After 2:30 P.M. no nurse checks the patient in to pre-op holding. The surgeons and anesthesia come in and see the patient. The circulator nurse (nurse who assists surgeons in operating room) comes in			

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	Continued From page 6 checks the patient consent and pre-op check list and takes him to the operating room. No nurse in the PACU is really responsible for watching the patient in the pre-op holding area after 2:30 P.M." DOP was then asked if any monitoring devices (i.e. pulse oximeter, a medical device that indirectly monitors the oxygen saturation of a patient's blood, EKG or electrocardiogram, a medical device that monitors the electrical activity of the heart, automatic blood pressure cuffs) were placed on patients who got Versed(r)(r) in the pre-op holding area to monitor their cardiac and respiratory status. DOP said, "We don't routinely put monitors on in the pre-op holding area for a patient that got Versed(r)." DOP was then asked if there was a policy for giving Versed(r) in the pre-op holding area. DOP said, "There is no policy for that, we are making changes." In an interview, on 9/1/11 at 12:30 P.M., the Chief of the hospital's Anesthesia Department (CAD) was asked if there was any anesthesia department policy and procedure that covered giving Versed(r) in the pre-op holding area. The CAD said, "No." The CAD was then asked if it was her usual and customary practice to give Versed(r) to a patient in the pre-op holding area. CAD said," If I give Versed(r) in the pre-op holding area, I or the circulator nurse would take the patient immediately back to the OR so we can start the surgery or if I left the patient I would tell somebody			

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	Continued From page 7 in the PACU that I had given Versed(r)." In an interview, on 9/1/11 at 12 noon Surgeon 2 was asked what he remembered about the "Code Blue" incident with Patient A. Surgeon 2 said, "Patient A had come in to get surgery on his left shoulder that day, [redacted] He had a nonunion of the hardware in his left shoulder from a previous surgery. The attending orthopedic surgeon (Surgeon 1) and myself saw him in the little pre-op holding room in the PACU. I was going to assist Surgeon 1 when Patient A went back to the operating room. Surgeon 1 asked him if he had any history of blood clots. Patient A said no. Surgeon 1 then checked the operative consent with the patient and we left the room together. I went to do some more work on a different floor since Patient A had not been transported to the operating room yet. I came back a few minutes later and just popped my head into the pre-op holding room and asked Patient A how he was doing. He said he was doing OK and was eager to go to surgery. I left the room and went over to the PACU nurses station to do some work since Patient A had not gone back to the operating room yet. About 10 to 15 minutes later I heard someone call out from the pre-op room to call a 'Code', presumably the Anesthesiologist, I could hear but could not see Patient A from where I was standing. I ran over and saw that Patient A was unresponsive, me and another orthopedic resident assessed Patient A pulses. There was no pulse so we started CPR while Anesthesiologist 1 managed the airway." Surgeon 2 was then asked if he had any			

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	Continued From page 8 communication with Anesthesiologist 1 about Patient A prior to the cardiac arrest. Surgeon 2 said, "No, I might have passed by him when the Anesthesiologist came into the room, but I don't remember." Surgeon 2 was then asked when he saw Patient A the second time if he knew he had been given Versed(r). Surgeon 2 said, "No, I was unaware of that." In an interview, on 9/1/11 at 12:45 P.M., the circulator nurse (RN 1) was asked about what she remembered about the incident with Patient A. RN 1 said, "I remember coming into the pre-op holding room , checking the pre-op check list and talking with Patient A at around 1600 hours (4 P.M.). He was talking a lot and laughing. Anesthesiologist 1 was there talking with the patient. I then left the room to go check my equipment in the operating room. RN 1 was then asked if she knew if Anesthesiologist 1 had given any kind of medication to Patient A. RN 1 said, "No, I only stayed for a short time in the pre-op room then went to the OR (operating room) to check my equipment." RN 1 was then asked if Patient A had any type of monitors on (pulse oximeter, EKG) when she left the pre-op holding area. RN 1 said, "I don't think so. I don't know for sure. If a patient has monitors on before surgery they bring them to the PACU instead of the pre-op holding so the nurses there			

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	Continued From page 9 can watch them." In an interview, on 9/1/11 at 1 P.M., a PACU nurse was interviewed (RN 2). RN 2 was asked if any of the PACU nurses check patients into to the pre-op holding area after 2:30 P.M. RN 2 said, "It is catch as catch can, if the recovery room nurses are busy with patients of their own, and nobody is in the pre-op holding area to watch them. The OR circulator nurse does the vast majority of the check in at that time." Review of the hospital's policy: MM-5130 Appendix B-2 Procedural Sedation for Adults, dated 1/2009, "Midazolam (Versed(r)) Indications: Sedation, conscious sedation prior to diagnostic, therapeutic or radiographic procedures.... Adverse Reactions: respiratory depression, apnea, dyspnea, respiratory arrest, bradycardia (slow heart rate), tachycardia (rapid heart rate), hypotension (low blood pressure), somnolence, oversedation, headache, dizziness, paradoxical agitation, confusion, ataxia, seizure-like activity, cardiac arrest. Monitor blood pressure, heart rate, pulse oximetry continuously; check respiratory rate, sedation level and airway patency frequently." The hospital's failure to ensure that there was adequate monitoring of Patient A's respiratory status after administration of Midazolam in the pre-op holding area put Patient A at risk for irreversible and life threatening side effects, including respiratory depression, cardiac arrest and death. This failure caused or was likely to cause, serious injury or death to the patient, and therefore			

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	Continued From page 10 constituted an immediate jeopardy under 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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