

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  12/07/2018
NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento		STREET ADDRESS, CITY, STATE, ZIP CODE 2825 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO COUNTY <i>acceptable per 1/17/19 Cliff AFES</i>			
(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 reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00574266, CA00570948 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 2585, Pharmacy 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 1280.3(g): 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 1280.3 (a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars (\$75,000) for the first administrative penalty, up to one hundred thousand dollars (\$100,000) for the second subsequent administrative penalty, and up to one hundred twenty-five thousand dollars (\$125,000) for the third and every subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy</p>		<p>Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusion set forth in the Statement of Deficiencies. This Plan of Correction has been prepared and/or executed solely because it is required by federal and state laws</p> <p>The corrective action details, commence on page 4 of this 2567</p>		

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

TITLE

(X6) DATE

*Colleen Kueper*

*105 Director*

*1/17/19*

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 18

*1/17/19*

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.

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	<p>violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.</p> <p>Health and Safety Code 1280.3 (g) For the 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 1280.1 (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the following: (A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.</p> <p>Facility detected the AE on 8/28/17 Facility notified the AE to the Department on 1/25/18 Facility notified the patient/responsible part on 8/29/17</p>				

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	<p>Adverse Event Notification - Informed Health and Safety Code Section 1279.1 (c), "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 informed the patient or the party responsible for the patient of the adverse event by the time the report was made.</p> <p>T22 DIV5 CH1 ART3 70283 Pharmaceutical Services General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (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.</p> <p>T22 DIV5 CH1 ART3 70283 Pharmaceutical Services General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs</p>				

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	<p>and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours.</p> <p>(2) Medications and treatments shall be administered as ordered.</p> <p>During a Federal Complaint Validation Survey conducted by the Department, 1/24/18 through 1/28/18, an adverse event was reported by the facility on 1/25/18 and investigated at that time (intake number CA00570948). On 2/16/18, a consumer complaint regarding the same incident was received by the Department and was investigated concurrently (CA00574265).</p> <p>The Department determined the facility failed to administer medications as prescribed by the physician and in accordance with facility policy.</p> <p>The facility failed to ensure that:</p> <p>1) The facility policy and procedure for Management of High Alert Medications was developed and</p>		<p>Medication safety, related to the use of the IV pumps is continuous and ongoing and is accomplished through an interdisciplinary approach. Each discipline adding a layer of protection and /or mitigation through defined workflow processes. Each layer is designed to reduce the likelihood of patient harm from an unintended IV medication administration event. Each discipline is an ad-hoc member of the Medication Safety Committee. The Medication Safety Committee coordinates reviews and responds to IV pump issues. The committee review of individual events and or trends, provide for the development of action plans, as needed. Review of audits, and the subsequent strategies, are designed to reduce the potential for future pump malfunctions, which may result in an unintended medication administration. The committee meets quarterly. Actions detailed in this section are ongoing</p> <p>Key roles and responsibilities:</p> <p><u>Pharmacy (accountable – Pharmacy Director)</u></p> <p>Pharmacy reviews and reports all medication related safety events, which includes IV pump issues. The review determines if an incident associated with an IV medication administration has potentially occurred, or if any incident may have reached the patient. SMCS continues to review and compare the alarm alert report to any reported pump issues and or medication events.</p>		

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	<p>implemented to ensure safe administration practice of medications identified with high potential for devastating consequences if an error occurs and 2) Medications were administered per physician order when Patient 3 was administered 250 milligram (mg) of IV (intravenously, injected through the vein) morphine (a potent narcotic for pain) over one and a half hours instead of the prescribed 1 mg per hour.</p> <p>The medication error exposed Patient 3 to effects of morphine overdose (166 times the prescribed dose), including low blood pressure and subsequent death.</p> <p>Findings:</p> <p>Review of Patient 3's clinical record indicated he was admitted to the facility on 8/11/17 for acute respiratory failure (inability of the lungs to maintain normal respiratory function). Patient 3 needed high flow oxygen into the nose to ensure oxygen delivery to blood and organs.</p> <p>Review of Patient 3's physician orders, dated 8/27/17 at 3:45 p.m., indicated "morphine 250 mg in NaCl 0.9% [saline solution] 250 ml [milliliter] IV Drip [premixed in the pharmacy] CONTINUOUS [continuously administered at the specified rate] ...Initial dose 1 mg/hour [1ml/hr (hour) is equal to 1 mg of morphine/hr]."</p> <p>Review of Patient 3's MAR (medication administration record) indicated the morphine drip was started on 8/27/17 at 8:54 p.m. and stopped at 9:02 p.m. (8 minutes later).</p>		<p><u>Bio med staff - (accountable - Bio Med Director)</u></p> <p>Bio Med reports on pump maintenance, evaluations and volume of issues resolved and / or number of pumps removed from service.</p> <p><u>Sterile Processing Department (SPD (Accountable - SPD Manager)</u></p> <p>SPD reports on disinfection processes and pump integrity escalations to Bio Med. All IV pumps are sent to SPD for cleaning and disinfection.</p> <p><u>RN staff (Accountable - Chief Nursing Director)</u></p> <p>Nursing representation reviews and reports on documentation audits, and concurrent interview audits for visual inspection, rate verification, and volume limiting chambers.</p> <p><u>Actions</u></p> <p>Actions taken to ensure that corrective actions were effective:</p> <p>The hospital developed corrective actions from the analysis of events, information obtained from the manufacturer, external sources and subsequent internal investigation findings. Interventions designed to prevent IV pump medication errors, including free flow events have been added to medication management policies / procedures.</p>		

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	<p>Review of Patient 3's nursing notes dated 8/27/17 indicated:</p> <ul style="list-style-type: none"> <li>- At 9:02 p.m.: "pt [patient] with decrease in RR [respiratory rate], oxygen saturation down to 70's. Morphine gtt [drip, infusion] turned off."</li> <li>- At 9:06 p.m.: "EICU [Electronic Intensive Care Unit] called, no call back from PMA [Pulmonary Medicine Attending], pt with sz [seizure- sudden, uncontrolled electrical disturbance in the brain] activity lasting about 25 seconds."</li> <li>- At 9:07 p.m.: "Dr... returned page. Updated on situation. New order received to start on BIPAP [bi-level positive airway pressure is a type of device that helps with breathing] ..."</li> <li>- At 9:27 p.m. "Dr...at bedside. Discussing situation with wife."</li> <li>- At 9:50 p.m. "Decision made by wife with Dr... present to transition to comfort care [care directed at preventing or relieving suffering at end of life]."</li> </ul> <p>During an interview on 1/26/18 at 2:58 p.m., RN 6 verified that shortly after the morphine drip was initiated on 8/27/17, Patient 3's respiratory rate and oxygen saturation dropped. RN 6 stated he had stopped the morphine and called Respiratory Therapy and the MD [Medical Doctor].</p> <p>Review of Patient 3's physician orders dated 8/27/17 at 10:52 p.m., indicated "morphine 250 mg in NaCl 0.9% 250 ml IV Drip CONTINUOUS...dose 1mg/hour."</p> <p>Patient 3's MAR for 8/27/17 indicated the morphine drip was restarted at 11:59 p.m. with a comment in</p>		<p><u>Bio med staff - (accountable -Bio Med Director)</u></p> <p>Education - BioMed (eQuip)</p> <p>All staff demonstrate competency for diagnostic inspection and repair per manufacturer guidelines. Completed 3/18</p> <p>100% of IV pumps were inspected and tested per manufacturers' recommendation. Pump manufacturer bio techs remained on site and assisted with the review, until completed.</p> <p>All preventative maintenance and repairs are documented in our computerized maintenance management system (CMMS)</p> <p>Bio-med completes a scheduled (at least annually) preventative maintenance inspection on all pump infusion pumps utilizing the Pump System Maintenance software. At the completion of the inspection a sticker is placed on the device indicating: date of current inspection, date of next inspection and name of inspector.</p> <p>Any IV pump that does not pass its scheduled inspection per manufacturer-guidelines/software or is identified by frontline staff or pharmacy through medication safety reporting, is tagged, sequestered from clinical areas and steps will be taken by Bio-med. If there is a repeated failure of the same type during the preventative maintenance inspection window (not to exceed one year), the pump is referred to Risk Management for further action.</p> <p>Actions detailed in this section are ongoing</p>	

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	<p>nurse's notes "P1 now on comfort care, wife ready for morphine...to start." Patient 3's morphine drip was stopped on 8/28/17 at 1:25 a.m. (1 hour 26 minutes later) and a subsequent nurse's notes indicated "gtt stopped pump without any alarms bag empty."</p> <p>Review of nurses' notes dated 8/28/17 at 1:25 a.m., indicated "Upon checking IV pump, noticed morphine gtt was completely empty with IV tubing full of air. IV pump still running with green light present, no alarms present. IV states volume infused = 1.5 ml. Morphine gtt turned off, charge RN (Registered Nurse) ...on unit and notified... [charge RN] checked pump, correctly set with tubing fully inserted into channel correctly...BP [blood pressure] = 85/52 (normal blood pressure for a healthy adult is 120/80)."</p> <p>Review of a document titled Default Flowsheet Data in Patient 1's clinical record noted blood pressure from 3 a.m. to 6 a.m. on 8/28/17 ranged from 81/48 to 69/37. A nurse's note dated 8/28/17 at 3:57 a.m. indicated a fluid bolus was ordered to support blood pressure.</p> <p>Morphine carries a black box warning, which is the strongest warning the United States Food and Drug Administration (US FDA) can require a manufacturer to put on the drug label. Part of the black box warning indicated "Life-Threatening Respiratory Depression-Serious, life-threatening, or fatal respiratory depression may occur with use of Morphine Sulfate Injection. Monitor for respiratory depression, especially during initiation of Morphine</p>		<p><u>Pharmacy (accountable – Pharmacy Director)</u></p> <p>Pharmacy reviews all medication related safety issues and determines whether a possible error in IV medication administration has occurred, or if any error reached the patient.</p> <p>1/28/18-3/29/18 pump evaluation process - Pharmacy daily report (CQI) of flow events greater than 300 seconds on 100% of infusion pumps.</p> <p>Those devices with flow events greater than 300 seconds were reported to the Nursing Department and BioMed removed from patient use, tagged and referred to <i>BioMed (eQuip)</i> for diagnostic inspection.</p> <p>Daily reports run from 1/28/2018 to 3/28/2018 yielded 43 flow alarm events. Upon diagnostic inspection and event investigation, no free-flow of fluids occurred</p> <p>Current process -Manufacturer Alarms Analytic Reports (CQI) are compared to Medication Administration reports and the summary is reported to the Medication Safety Committee.</p> <p><u>Sterile Processing Department (SPD (Accountable – SPD Manager)</u></p> <p>All IV pumps are to be sent to SPD for cleaning and disinfection. SPD staff were educated in March 2018 reflecting manufacturer recommendations. Staff were also provided a checklist to assist in visual screening of IV</p>		
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	<p>Sulfate Injection or following a dose increase. Because of delay in maximum CNS effect with intravenously administered morphine (30 min), rapid IV administration may result in overdosing." The information for morphine, under warnings, indicated "Hypotensive [low blood pressure] Effect...may cause severe hypotension in an individual whose ability to maintain their blood pressure has been compromised by depleted blood volume...Morphine must be injected slowly; rapid intravenous administration may result in chest wall rigidity...Increased Risk of Seizures in Patients with Seizure Disorders...Excitation of the central nervous system, resulting in convulsions (seizure activity), may accompany high doses of morphine given intravenously..."</p> <p>(Retrieved from <a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5b96e83a-d878-4dd5-8480-83a985db4609">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5b96e83a-d878-4dd5-8480-83a985db4609</a> - official provider of FDA information [package inserts])</p> <p>Review of Patient 3's vital signs (blood pressure, heart rate etc.), indicated that his MAP (mean or average arterial blood pressure during a single cardiac cycle; MAP of at least 60 is necessary to perfuse the coronary arteries that supply blood to the heart, brain, and kidneys; normal range is approximately 70 - 110) was above 60 before the morphine infusion was started on 8/27/17 at 11:59 p.m. Review of Patient 3's MAP after the morphine drip was stopped on 8/28/17 at 1:25 a.m., indicated that it had dropped to 57 at 3 a.m. Review of Patient 3's physician orders, dated 8/28/17 at 4:15 a.m., indicated IV Dopamine (used to treat low blood pressure) 0-10 microgram/kilogram/minute to be</p>		<p>pumps for potential flaws which may lead to an IV pump failure. All staff demonstrated competency on the cleaning and visual inspection of infusion pumps</p> <p>March 2018. Training will continue on new hire and annually thereafter. Initial training completed March 2018</p> <p>Actions detailed in this section are ongoing</p> <p><u>RN staff ( Accountable – Chief Nursing Director)</u></p> <p>Staff have been educated to perform visual inspection of pumps, screening for cracks and pump integrity prior to use. Any pumps identified with issues, which may increase the risk for medication administration errors are removed from service and sent to bio med for diagnostic testing. Education was provided in 2017 and again in 2018 and was reinforced during observation audits detailed in following action (#2)</p> <p>2. The High Risk Medication Policy was revised. Revision Include:</p> <p>Smart pumps are to be used on all continuous infusions of high alert medication. A volume limiting chamber (volutrol) will be used on certain high alert medications administered by continuous IV infusion through the large volume pump (LVP) module per policy.</p> <p>When a volume limiting chamber is indicated, a two-hour volume will be added to the chamber. Use of the volume limiting chamber will be documented every shift with "Rate Verify" on the MAR and "volutrol" in the comment box.</p>		
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	<p>filtrated every 10 minutes for a goal of MAP between 60 and 65.</p> <p>Review of physician notes dated 8/28/17 at 3:50 a.m., indicated "RN called to report 250 mg bag of morphine possibly given to the patient over one hour...May use BIPAP to support breathing."</p> <p>Review of the Patient 1's Completed Medication Record indicated that Dopamine was started at 4:44 a.m. on 8/28/17 for MAP less than 60.</p> <p>Review of nurses notes dated 8/28/17 at 5:55 a.m. indicated "New orders received to stop pressors [dopamine] and remove BIPAP." Nurse's note dated 8/28/17 at 6:12 a.m. indicated "BIPAP removed."</p> <p>On 8/28/17 at 6:33 a.m., Patient 3 was pronounced dead. The clinical record indicated there were no orders, lab results, or blood draws to measure morphine toxicity levels following the identification of the empty morphine bag. Patient 3's discharge summary (summary of the major treatments and events while hospitalized) dated 8/28/17 at 6:58 a.m., did not address morphine administration.</p> <p>The above findings were acknowledged by the ADHO (Administrative Director of Hospital Operations) during interviews on 1/24/18 at 9:20 a.m. and on 1/26/18 at 1:51 p.m.; and with RN 8 on 1/26/18 at 10 a.m.</p> <p>During an interview on 1/26/18 at 2:58 p.m., RN 6 stated that on 8/27/17 he started Patient 3's morphine infusion (11:59 p.m. per MAR) with the</p>		<p>In the event that a volume limiting chamber is not available for an indicated high alert medication, staff will document <i>Rate Verify</i> (as defined in the Medication Administration policy) on the MAR every 2 hours.</p> <p>Independent double-checks: The SMCS list of medications requiring an independent double-check may not match the EHR list for dual signature medications. Alternative documentation may be employed so that SMCS staff can align their documentation with the SMCS standard (e.g. add a co-sign with a note in MAR; use "given not co-signed" option when a co-signature is not required).</p> <p>3. The Medication Administration Policy was revised. Revision include: Use of the I.V. Pump:</p> <ol style="list-style-type: none"> <li>Choose the appropriate age-, weight- and/or unit-based profile when starting the infusion pump.</li> <li>Enter the patient's Medical Record Number (MRN) when asked for "Patient I.D."</li> <li>The Guardrails drug library is to be used for all medications, unless the particular drug does not exist in the library</li> <li>Only those medications with the bolus feature built into the pump for that drug may be bolused from the pump.</li> </ol>	

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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	
	<p>smart pump by first checking that the tubing was in the correct place, cassette was in the chamber correctly, the infusion was programmed correctly and verified it with another nurse. RN 6 stated that he checked Patient 3's vital signs, including his blood pressure and respiratory rate, and they "looked good." RN 6 said he was in and out of Patient 3's room after starting the infusion. RN 6 stated that at 1:25 a.m. on 8/28/17 when he returned to Patient 3's room, Patient 3's wife pointed to the morphine bag indicating it looked empty. RN 6 verified that the bag was empty but no alarms were sounding. RN 6 notified another nurse and called the physician. RN 6 stated he checked the floor and the bed to see if any of the morphine solution had leaked out but was unable to find anything wet.</p> <p>Facility policy "High Alert Medications, Management of" dated 6/30/16, classified IV infusions of morphine as a high alert medication. The policy indicated "High alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients."</p> <p>A group interview was held on 1/24/18 at 9:06 a.m. with the Director of Pharmacy (DOP), Director of Education (DOE), Assistant Administrator of Integrated Quality Services (AAQS), Chief Nurse Executive (CNE), ADHO, Administrator for Women's and Children's Center (AAWC), BIOM (Bio Med Staff) 1 and BIOM 2. The CNE stated that the</p>		<p>e. For ALL medications infusing through the large volume pump (LVP) module on the pump, staff will document Rate Verify in the MAR</p> <p>Rate Verify will be documented at the following intervals:</p> <ol style="list-style-type: none"> <li>1. At the start of any new continuous IV infusion (New Bag documentation is equivalent to Rate Verify for new IV infusion)</li> <li>2. If the pump module door is opened or any manipulation of the cassette</li> <li>3. At shift change, admission, or transfers from other units or procedural areas</li> </ol> <p>When documenting "Rate Verify," staff attest to:</p> <ol style="list-style-type: none"> <li>1. Visual check of cassette loaded appropriately</li> <li>2. Visual check of IV flowing appropriately in drip chamber for set rate</li> <li>3. Visual check of rate of infusion on pump module</li> </ol> <p>RN education to the revisions and expectations of the High Alert Medication and Medication Administration policies was completed in May 2018 and repeated Q4 2018</p>		

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NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento			STREET ADDRESS, CITY, STATE, ZIP CODE 2625 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO 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>facility could not come up with what happened in Patient 3's case. The CNE stated that the physician did not feel Patient 3 could have received the full 250 mg of morphine based on his vital signs. The infusion pump was taken to the Biomed (Biomedical engineering is the application of the principles and problem-solving techniques of engineering to biology and medicine) department who ran a detailed report on the pump and no problem was identified. The DOP stated they looked for any diversion (medication diverted to someone other than the patient for whom it was intended) indicators but were unable to find any. The CNE stated that there was no coroner's report received at present. The AAQS stated that the event was not classified as a sentinel (unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient not related to the natural course of the patient's illness) event but a facility quality analysis was done.</p> <p>In the group interview BIOM 2 stated that they received the pump, and using the manufacturer software, they tested it, did a visual inspection and were not able to replicate the error. BIOM 2 stated that pharmacy normally checks what buttons a user pressed on the infusion pump. DOP stated that this was not done for this pump.</p> <p>Review of the Biomed produced detailed report (CCI report) of the smart pump activity indicated an entry on 8/28/17 at 12:02 a.m. Indicating infusion started, and on 8/28/17 at 1:23 a.m. Indicating infusion alarmed, free flow (when infusion can be injected into the patient at an uncontrolled rate) alarm, 4857</p>		<p>During the initial education period, the clinical nursing leaders conducted daily concurrent 1:1 interviews audits at the bedside. The purpose of the interviews were to ensure that the RNs could accurately demonstrate the expectations of visual inspections, rate verification and use of volume limiting chamber. The return demonstration audits initiated 2/18. 98% of active staff were interviewed in Feb through March of 2018. The Pump audit continued through 2018. After the initial audit, an average of 200 audits were completed per month. The audit concluded 12/2018.</p> <p>An additional monthly Pump Documentation Audit of 150 – 900 MRs conducted starting 5/18, and is ongoing. This audit is to confirm compliance to documentation requirements per policies.</p> <p>4. To provide clear direction to pump users of expectations for pump use, the hospital has provided 100% of RN Staff education detailing, that the IV pump may free flow without an audible alarm, and the importance of flow verification and documentation expectations. This information has been added to a "badge buddy" designed to assist RNs in continual understanding of expectations for IV pump use. Communication / Education was implemented 2/26/18 and completed 3/14/18.</p> <p>5. If an RN experiences an issue or concern while using an infusion pump, the pump is removed from patient use when safe to do so, tagged and referred to BioMed (eQuip) for diagnostic inspection.</p>		

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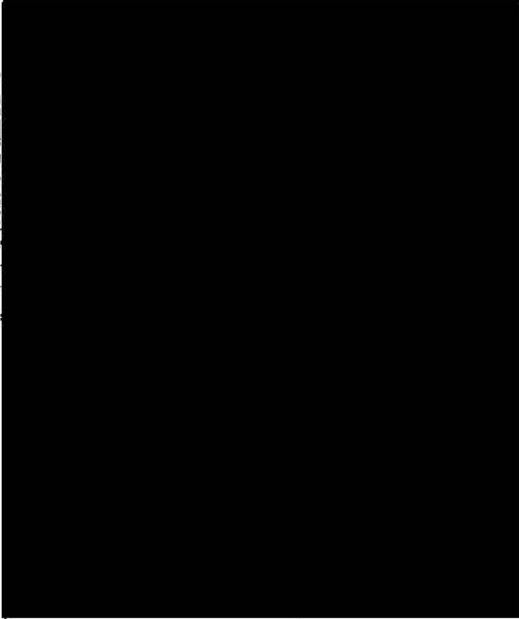
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050108	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  12/07/2018
NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento			STREET ADDRESS, CITY, STATE, ZIP CODE 2825 Capitol Avenue, Sacramento, CA 95818-6618 SACRAMENTO 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>seconds (1 hour 21 minutes, which coincided with the time between Patient 3's morphine infusion restarting and discovering the morphine bag empty). BIOM 1 and BIOM 2 were unable to explain the "free flow alarm" part of the CQI report. They indicated they will check with manufacturer.</p> <p>Review of manufacturer communication with the hospital, dated 1/24/18, indicated "Free Flow alarm" is seen in the CQI data if the pump door is open and the safety clamp is open while the infusion set is primed. Manufacturer indicated the pump should alarm if the safety clamp is open with the door open. The document indicated free flow could happen with the pump door closed in rare cases. The document indicated "If you believe the devices weren't working as expected, or if there was a patient event in which it is suspected that an actual free flow/over infusion occurred, Customer Advocacy can complete an investigation with the tubing, Pump module and PC Unit [sic - the main pump component that allows customization of infusions]." The facility blamed department had sequestered (isolated) the pump but it had not been sent to the manufacturer.</p> <p>During the group interview, the AAQS stated that this information about a free flow alarm for 4857 seconds was not discussed during the facility quality investigation of the event. The group was unaware that a free flow alarm was indicated on the detailed infusion pump report. AAQS confirmed that no audits were conducted to look at detailed infusion pump reports to check for free flow issues.</p>				

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NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento			STREET ADDRESS, CITY, STATE, ZIP CODE 2026 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO 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>Review of a facility document dated 8/25/16 indicated a high priority alert from the smart pump manufacturer indicating "Damaged Door Components May fail to Engage Anti-Free Flow Mechanism, Potentially Leading to Gravity Flow."</p> 				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050108	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  12/07/2018
NAME OF PROVIDER OR SUPPLIER  Sutter Medical Center, Sacramento			STREET ADDRESS, CITY, STATE, ZIP CODE 2025 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO 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>Review of the facility quality analysis document addressing Patient 3's morphine medication error dated 9/5/17 indicated "... pump design may allow for flow of IV fluids without alarm if tubing is not properly placed or door is not properly closed."</p> <p>[REDACTED]</p> <p>Review of the facility training document which was provided to staff after the 8/28/17 incident involving Patient 3 had very similar information to the previous training. The training documents did not indicate that free flow could happen and the pump will not alarm.</p> <p>During an interview on 1/25/18 at 2:58 p.m., RN 6, who started Patient 3's morphine infusion on 8/27/17 at 11:58, stated that he was given training on the infusion pump in 2016 and again in 2017. He stated that he did not learn anything new in the second training.</p> <p>During a group meeting on 1/24/18 at 6:30 p.m., the AAQS confirmed that facility policies and procedures did not address the infusion pump free flow potential. The AAQS stated that no documentation was required by nursing staff to visualize the drip chamber to ensure no free flow was taking place after starting an infusion. The AAQS stated that the facility was not tracking any data regarding monitoring of staff compliance or free flow indicators on infusion pump reports. Review of the smart pump manufacturer document dated 10/17 indicated that a "Free Flow Alarm" was a</p>				

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NAME OF PROVIDER OR SUPPLIER  Sutter Medical Center, Sacramento		STREET ADDRESS, CITY, STATE, ZIP CODE 2025 Capitol Avenue, Sacramento, CA 95816-5515 SACRAMENTO 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>reportable alarm to the manufacturer.</p> <p>Review of facility policy "Medication Administration (Adult and Pediatric)" dated 10/1/14 did not reflect any of the above training.</p> <p>Review of facility policy "Patient Safety Reports: High Risk Event and Unusual Occurrences Reporting and Management", dated 8/8/17, indicated, "All activities of the RCA (Root Cause Analysis- facility quality analysis of an event) will be presented by members of the team to the Quality Council and Patient Safety Committee. Relevant recommendations and actions will be reviewed by appropriate committees (Medical Staff Committees, Council on Patient Care Standards, etc.) ...Findings and recommendations from the root cause analysis or significant/never event analysis will be reported to the appropriate Medical Staff Committee, Quality and Patient Safety Committee, Medical Executive Committee, and the Medical Policy Committee."</p> <p>Review of the facility quality analysis document addressing Patient 3's morphine medication error dated 9/5/17 indicated "High Impact: Acquire locking devices for narcotic drips...anticipated 1st quarter 2018." During an interview on 1/25/18 at 9:30 a.m. with CNE and AAQS they indicated that the analysis was scheduled to go to Council Care Standards, Quality and Medical Executive Committees but had not been done.</p> <p>In an interview on 1/26/18 at 9:45 a.m., the CNE and AAQS stated that the hospital owned 3500 infusion pumps, the same type of pump involved in the over</p>				

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NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento		STREET ADDRESS, CITY, STATE, ZIP CODE 2828 Capitol Avenue, Sacramento, CA 95816-6616 SACRAMENTO 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>administration (free flow) of morphine to Patient 3. They stated that at any given day 350 to 500 were being used.</p> <p>In an interview on 1/26/18 at 12:30 p.m., the Chief Executive Officer (CEO) indicated that the conclusions of the facility quality analysis of Patient 3's death potentially related to a medication error included the possibility of free flow but no one was certain that it occurred. The investigators considered free flow, machine failure, design failure, diversion, and potential human error. The hospital leaders judged that additional nurse training with return demonstration was sufficient to address the human error. The Biomed technicians and manufacturer did not confirm device failure so they assumed free flow had not occurred. They could not prove diversion.</p> <p>[REDACTED]</p> <p>It was concluded that free flow did not occur in Patient 3. Remedies for the other incidents which occurred at the other facilities were also directed at human error and retraining nurses but not possible equipment failure. No further corrective actions were undertaken. Hospital leaders were aware that additional steps using a limited volume device (volutrol) could add protection from recurrence of pump free flow, however, there was a shortage of volutrol equipment for all the corporate hospitals to institute such a corrective action. The CEO acknowledged that during the Department survey this week, the team identified a printout of Patient 3's infusion pump that showed over 4000 seconds of free flow which had not been identified by the</p>				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050188	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  12/07/2018
NAME OF PROVIDER OR SUPPLIER  Sutter Medical Center, Sacramento		STREET ADDRESS, CITY, STATE, ZIP CODE 2025 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO 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>hospital RCA investigators. [REDACTED]</p> <p>The CEO also acknowledged that yesterday (1/25/18) the County Coroner verbally stated that Patient 3 received a significant amount of morphine, confirming actual administration of excessive morphine prior to death. The CEO acknowledged that with the additional evidence learned this week, pump failure was more likely and additional steps (use of volutrol for high risk medications) was needed to minimize risk and recurrences.</p> <p>Review of the document titled Sacramento County Certificate of Death indicated the following: "Cause of Death...Morphine Overdose...Time Interval between Onset and Death...Hours."</p> <p>Therefore, the Department determined the facility failed to administer a medication as prescribed by the physician or in accordance with facility policy. The facility failed to ensure that</p> <p>1) The facility policy and procedure for Management of High Alert Medications was developed and implemented to ensure safe administration practice</p>				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  D50100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  12/07/2018
NAME OF PROVIDER OR SUPPLIER Sutter Medical Center, Sacramento		STREET ADDRESS, CITY, STATE, ZIP CODE 2825 Capitol Avenue, Sacramento, CA 95816-5616 SACRAMENTO COUNTY			
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	<p>of medications identified with high potential for devastating consequences if an error occurs and</p> <p>2) Medications were administered per physician order when Patient 3 was administered 250 milligram (mg) of IV (intravenously, injected through the vein) morphine (a potent narcotic for pain) over one and a half hours instead of the prescribed 1 mg per hour.</p> <p>The medication error exposed Patient 3 to effects of morphine overdose (166 times the prescribed dose), including low blood pressure and subsequent death.</p> <p>These failures, jointly, separately, or in any combination, resulted in non-compliance with one or more requirements of licensure and caused or was likely to cause serious injury or death.</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 1280.3(g).</p>				

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