CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

POC ACCEPTABLE YES ☐ NO ☐
Reviewed By: Name
Date:
Time:
Notified By: Name

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050557	A. BUILDING _____ B. WING _____ Name: Facility Notified Date: Time:	07/14/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Memorial Medical Center	1700 Coffee Rd, Modesto, CA 95355-2809 STANISLAUS COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFIENCIES (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)	(XS) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00512428 - Substantiated Representing the Department of Public Health: Surveyor ID # 2850, 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 1280.3(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. The following reflects the findings of the Department of Public Health during an Entity Reported Incident (ERI) investigation. The inspection was limited to the specific hospital event investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: ID # 34832, HFEN Health and Safety Code 1279.1(b)(4)(A) (b) For purposes of this section, "adverse event" includes any of the following: (4) Care management events, including the		The plan of correction is prepared in compliance with California law and is not an admission of liability or wrongdoing. **Corrective Action/Improvement Plan:** A comprehensive plan of correction has been established related to this allegation on 1/23/17, including updated policies / procedures, education / reeducation / orientation plans related to existing and updated policies / practices, inventory of high-alert medications, and additional safety communications training. The Governing Body will ensure the provision of quality healthcare in a safe environment. The medication error incident was reported to the Governing Body on 1/11/2017. All corrective action improvement plans include reports and reviews to the appropriate Medical Staff Committee, Medical Staff Safety and Quality Committee, Medical Executive Committee and the Governing Body. **Implementation Plan:** **A.** Updated policy and procedure, "Physician's Orders: Receiving, Transcribing, Reviewing (IPPC)" was revised to include the following specification: "If medication is directly controlled by the physician due to variable dose/frequency, the order must include medication concentration".	1/23/17 1/11/17

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Nancy D Coats | TITLE: HR Director | (X6) DATE: 9/29/17

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 8

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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	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. Health & 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. DEFICIENCY CONSTITUTES IMMEDIATE JEOPARDY Title 22 -Section 70213 Nursing Service Policies and Procedures: (d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. Based on staff interview, clinical record and administrative document review, the hospital failed to follow policies and procedures for the administration of high risk medications (drugs that have a heightened risk of causing significant patient harm when used in error) when Registered Nurse (RN) 1 took a verbal order to administer heparin (blood thinner used to prevent clots) from Medical		**Monitoring and Tracking for Effectiveness:** This updated policy and procedure was reviewed and approved by the Medical Staff Department Chair of Imaging and the Angio Lab and was reviewed and approved by the Pharmacy & Therapeutics (P&T) Committee on 1/26/2017. The Chief Medical Executive made a report to the Medical Staff Safety and Quality Committee on 2/1/2017 and to the Medical Executive Committee on 2/15/2017 and received policy approval. The Chair of the Medical Executive Committee, the Chief of Staff, reported the achievements to date to the Governing Body on 3/2/2017 and received policy approval. **Title/Position of Individual Responsible for Implementation of Corrective Actions:** Chief Medical Executive Chief of Staff **Completion Date: 3/2/2017** **Implementation Plan:** **B.** The updated policy and procedure, "Medication: Administration (IPPC)" was reviewed by nursing staff in the Angio Lab particularly the section that requires checks by two qualified health care professionals on all high alert drugs. This process was included in all new hire orientation beginning 1/25/2017 and ongoing.	1/26/17 2/1/17 2/15/17 3/2/17 3/2/17 1/25/17 and ongoing

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	Doctor (MD) 1, did not clarify or validate the heparin order with two medical professionals and administered intravenously (directly into a vein) 25,000 units of heparin (one unit of heparin is the standard measurement of heparin when administering the drug) which was 25 times the usual dose for Pt 1's procedure. This failure resulted in Patient (Pt) 1 receiving an overdose of heparin and suffering a massive internal (inside the body) bleeding, which led to (Pt) 1's avoidable death. FINDINGS: Pt 1's clinical record indicated she was admitted to the hospital on 11/20/16 for altered mental status (general changes in brain function, such as confusion) and renal (kidney) failure requiring hemodialysis (regular mechanical filtering of wastes from the blood). Pt 1 had an arteriovenous (AV) fistula (a connection between an artery and a vein surgically created for hemodialysis). Pt 1's AV fistula was clotted and no longer accessible for hemodialysis. The medical plan was to declot (remove the blood clots) the AV fistula. Pt 1 arrived in the Interventional Radiology (IR) Department on 11/22/16 at 3:30 p.m., for the procedure to declot the AV fistula. During the procedure, Pt 1 received 25,000 units of heparin intravenously diluted in a 250 milliliter (unit of volume in the metric system equivalent to about 8 ounces of fluid) bag of saline (salt-based solution). Pt 1 was subsequently transferred to the Intensive Care Unit (ICU) (an area where patients in critical condition are cared for). Pt		**Monitoring and Tracking for Effectiveness:** This outcome was reported through the Medical Staff Safety and Quality Committee on 2/1/2017 by the Chief Medical Executive. Additionally, the Chief Medical Executive reported the findings to the Medical Executive Committee on 2/15/2017. The Chief of Staff reported the outcomes and progress to the Governing Body on 3/2/2017. **Title/Position of Individual Responsible for Implementation of Corrective Actions:** Chief Medical Executive Chief of Staff **Completion Date: 3/2/2017** **Implementation Plan:** **C.** The hospital started using an upgrade to the electronic health record in the procedural areas specific to Interventional Radiology and the Cath Lab. It includes a one-step medication order entry section and a section for documentation of administration. It requires entry of the concentration for high alert medication orders. The physician can review all in one screen. **Monitoring and Tracking for Effectiveness:** A total of 30 patient records with heparin orders directly controlled by the physician due to variable dose/frequency will be	2/1/17 2/15/17 3/2/17 3/2/17 2/23/17

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	1 died at 2:17 a.m. on 11/23/16. On 12/6/16 at 2:15 p.m., during an interview, RN 1 stated she was working in IR on 11/22/16 when Pt 1 arrived for her procedure. She stated she helped RN 2 in performing required tasks, including medication administration. RN 1 stated MD 1 asked for a heparin drip (intravenous infusion of heparin) in a pressure bag (an inflatable cuff that can be manually inflated to a desired level of pressure to regulate the rate fluid enters the patient's body). RN 1 stated she asked MD 1, "25,000 units of heparin in a 250 milliliter bag of saline?" and, according to RN 1, MD 1 said "yes." When asked if she double checked the bag of heparin with another RN (verifying the medication order with another healthcare professional), RN 1 stated "No". RN 1 stated she dropped the IV (intravenous) tubing onto the sterile field (germ free area), holding on to the pointed end connecting it to the bag of [25,000 units of heparin diluted in 250 milliliters of saline] which was in the pressure bag. RN 1 stated MD 1 manually controlled the rate of the drip with a roller clamp. RN 1 stated, "If MD 1 had told me he was going to give the whole bag, I would have never spiked it [attached the solution containing the 25,000 units of heparin]". On 12/6/16 at 3:30 p.m., during an interview, RN 2 stated she was working in IR with RN 1 administering sedation (drugs used to relax the patient and block pain) to Pt 1. When asked about the sequence of events prior to the heparin administration, RN 2 stated she "did not hear an order from MD 1 for a heparin drip"; she stated, "I		reviewed each month for 3 months. Our compliance of the concentration being included in orders of high alert medications is at 100% for the first 3 months. We count the number of heparin orders with specified concentration compared to all the heparin orders. We will continue to monitor until 100% compliance is achieved for 2 quarters. Results will be sent to the Pharmacy and Therapeutics Committee, Safety and Quality Committee, Medical Executive Committee and the Governing Body. Heparin orders without the concentration will be reviewed by the Chairperson of the Pharmacy and Therapeutics Committee and Radiology Committee Department Chairperson for follow-up (see **Attachment E**). **Title/Position of Individual Responsible for Implementation of Corrective Actions:** Chair, Pharmacy & Therapeutic Committee Chair, Radiology Committee **Completion Date: 8/31/2018** **Implementation Plan:** **D.** High alert medications, specifically 25,000unit/250 ml bags, have a high alert double check sticker placed by Pharmacy technician. In addition, Pharmacy performed an inventory of the medication cabinets in the Angio Lab and removed all 25,000 units/250ml bags of heparin on	8/31/18

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	wasn't paying attention." She stated she saw a pressure bag but didn't look at what was in it. On 12/7/16 at 9:10 a.m., during an interview, RN 3 stated she was in the IR room recording the events of the procedure. RN 3 stated she heard RN 1 call out the heparin drip via right arm fistula, without confirming the dosage. RN 3 stated the normal dose for this procedure is 1,000 units of heparin in 500 milliliters of saline. After the procedure, radiology technician (RT) 1 showed her an empty bag which had contained 25,000 units of heparin. RN 3 said, when she saw the empty 250 milliliter bag and realized the patient received 25,000 units of heparin, she told everyone in the room (RN 1, RN 2, RT 1, MD 1) "this is bad," referring to the 25,000 units of heparin Pt 1 received. On 12/7/16 at 11:55 a.m., during an interview regarding the sequence of events prior to the heparin administration for Pt 1, MD 1 stated he asked RN 1 for a heparin drip in a pressure bag to keep the vein free of blood clots. MD 1 stated RN 1 asked if he wanted heparin and MD 1 said "yes". He stated he was unaware RN 1 provided a pre-mixed bag of 250 milliliters of normal saline with 25,000 units of heparin for the drip. MD 1 stated his normal practice is for a heparin drip in a pressurized bag to maintain patency (keep the vein open). When asked if he wanted heparin, he said, "Yes, heparin in saline." He stated, in his practice, heparin drip is 500 units/liter (1,000 milliliter) bag of saline. MD 1 stated he did not provide RN 1 a verbal order for 25,000 units of heparin.		12/28/2016. A Pyxis machine was installed in the Angio Lab on 4/11/2017. **Monitoring and Tracking for Effectiveness:** Pharmacy maintained a log of the double check stickers on a monthly basis (see **Attachment A**), initiated on 1/24/2017 until the Pyxis machine was installed on 4/11/17, per plan. These corrective steps were reported through the Medical Staff P&T Committee on 1/26/2017. The Chief Medical Executive made a report to the Medical Staff Safety and Quality Committee on 2/1/2017 and made a report to the Medical Executive Committee on 2/15/2017. The Chair of the Medical Executive Committee, the Chief of Staff, reported the achievements to date to the Governing Body on 3/2/2017. **Title/Position of Individual Responsible for Implementation of Corrective Actions:** Director of Pharmacy Chief Medical Executive Chief of Staff **Completion Date: 3/2/2017** **Implementation Plan:** **E.** Nursing staff, cleared for duty, received the policy and procedure, "Physician's Orders: Receiving, Transcribing, Reviewing (IPPC)" focusing on read back of verbal orders on 4/3/17 (see **Attachment B**).	12/28/16 4/11/17 1/24/17 4/11/17 1/26/17 2/1/17 2/15/17 3/2/17 3/2/17 4/3/17

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	On 12/6/16 at 1 p.m., during an interview, ICU nurse RN 4 stated, after Pt 1 returned to ICU from IR, she "picked up the graft [fistula] arm and found a large pool of blood underneath her arm." Pt 1's clinical record indicated, on 11/22/16 at 7 p.m., ICU nurse RN 5 documented she attempted "to stop her [Pt 1] right arm from bleeding...Gauze and pressure dressing applied... I marked the borders of the hematoma (abnormal collection of blood outside of a blood vessel) ..." Pt 1's clinical record indicated blood tests were done on 11/20/16 at 10:45 p.m. The results indicated her hemoglobin (a protein in the red blood cells that transports oxygen) level was 10 (normal is 12 to 16). Pt 1's Partial Thromboplastin Time (PTT) (a blood test to determine how many seconds it takes for the blood sample to clot) was 32.8 (normal clotting times is 25 to 35 seconds). Pt 1's clinical record indicated blood tests were repeated on 11/23/16 at 12:03 a.m. The results indicated her hemoglobin level was 5.9, indicating a low blood volume in Pt 1's body. Her PTT was greater than 200, indicating the inability of the blood to clot normally. A review of the "Hospital Death Summary," dated 11/23/16 at 8:53 a.m., indicated the causes of death were Hypovolemic Shock (decrease in blood volume) and Iatrogenic (resulting from the activity of a health care provider or institution; said of any adverse condition in a patient resulting from treatment by a physician, nurse, or allied health		**Monitoring and Tracking for Effectiveness:** The Chief Medical Executive and the Chief Nursing Executive reported the findings to the Medical Staff Safety and Quality Committee on 2/1/2017. In addition, the Chief Medical Executive made a report to the Medical Executive Committee on 2/15/2017. The Chair of the Medical Executive Committee, the Chief of Staff, reported the achievements to date to the Governing Body on 3/2/2017. RN employees were electronically assigned to read the updated policy and complete an electronic attestation of understanding the content. An assignment completion report generated on 4/3/17 shows that 910 of 915 assignments were completed—a 99.45% completion rate. The expected compliance rate was 90%. This was a nursing staff one-time requirement. **Title/Position of Individual Responsible for Implementation of Corrective Actions:** Chief Nursing Executive Chief Medical Executive Chief of Staff **Completion Date: 3/2/2017** **Implementation Plan:** **F.** A review of the updated policy and procedure, "Physician's Orders: Receiving, Transcribing, Reviewing (IPPC)" including the following specification: "If the medication is directly controlled by the	2/1/17 2/15/17 3/2/17 4/3/17 3/2/17

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	professional) Massive Bleed status post (after) Fistulagram Declot. According to the Food and Drug Administration (a federal agency within the United States Public Health Services that monitors to ensure drugs are safe and effective), a continuous intravenous infusion of 20,000 to 40,000 units of heparin should be diluted in 1,000 milliliters of saline and given over a 24 hour period. A document from the Food and Drug Administration titled, "APP 451209D - Heparin Sodium" dated 9/2011, indicated "...OVERDOSAGE: Symptoms - Bleeding is the chief sign of heparin overdose.. ADVERSE REACTIONS: Hemorrhage is the chief complication that may result from heparin therapy ...METHOD OF ADMINISTRATION: Continuous Intravenous Infusion - 20,000 to 40,000 units/24 hours in 1,000 ml of ...Sodium Chloride..." The hospital policy and procedure which applies to the use of heparin to keep an AV fistula open titled, "IV Medication - Heparin Sodium Non-Cardiac Patients" dated 11/19/2014 indicated, "POLICY: E. Documented double check of IV heparin dose is required by two qualified health care professionals ... PURPOSE: A. to provide direction in the safe and effective administration of intravenous heparin. PROCEDURE: B. Dosage (Adult): NOTE: A second Registered Nurse should validate and document the correct dosage of ...infusion dosages... 2. Initial Infusion: a. ...After loading dose start heparin infusion at 18 units/kg [a unit of mass equal to 1,000 grams]/hr ... (Maximum of 1000 units/hr. or		physician due to variable dose/frequency, the order must include medication concentration", was completed with the Angio Lab nurses, through email dissemination and one–to-one (1:1) meetings with the Department Manager on 1/25/2017 (see **Attachment C**). **Monitoring and Tracking for Effectiveness:** The review process, initiated on 1/10/2017, was documented through the email dissemination and by employee signature on attestation sheets verifying the review was completed by 1/25/2017. All Angio Lab nurses, cleared for duty, completed the review. The process will also be included in departmental new hire orientation of Angio Lab nurses beginning 1/25/2017and will be ongoing. The Manager of AMDC will report the findings to the Medical Staff Imaging Department, Medical Staff Safety and Quality Committee and the Medical Executive Committee. **Title/Position of Individual Responsible for Implementation of Corrective Actions:** AMDC Manager **Completion Date: 1/25/2017 & ongoing.** **Corrective Action/Improvement Plan:** **G.** Addition to the process of new physician onboarding.	1/25/17 1/10/17 1/25/17 1/25/17 1/25/17 and ongoing

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	infusion as ordered by physician.. The Hospital Policy and Procedure titled, "Medication: Administration ..." dated 10/14/16 indicated, "...PROCEDURE: ... I. Before administering a medication, the health care professional does the following: 1. Verifies that the medication selected for administration is the correct one based on the medication order and the product label...W. High risk medications such as heparin... must be checked by two qualified healthcare professionals for the dose... This double check must be documented." The Hospital Policy and Procedure titled, "Medication: High Risk (High Alert)" dated 7/15/16 indicated, "...POLICY: G. High risk medication such as...heparin...must be checked by two qualified healthcare professionals..." The hospital failed to follow its policies and procedures related to the administration of high risk medications which led to Pt 1 receiving an overdose of IV heparin, leading to internal blood loss, and her ultimate death. The hospital's failure to follow its policies for high risk medication administration led to the licensee's noncompliance with one or more requirements of licensure. 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).		**Implementation:** All physicians, including all locum tenens physicians, new to Memorial Medical Center, prior to any clinical duties, during pharmacy orientation, will review the policy and procedure "Physician Orders: Receiving, Transcribing, Reviewing (IPPC)" that includes, "If medication is directly controlled by the physician due to variable dose/frequency, the order must include the medication concentration". This information was included in the new physician onboarding starting 12/31/2016 and ongoing (see **attachment D**). **Monitoring and Tracking for Effectiveness:** Evidence of participation in new physician onboarding is documented through signed orientation agenda and is tracked by the Medical Staff Services office for completion and compliance. New physician orientation by Pharmacy was provided for 32 new physicians (100%) from 1/1/2017 to 9/29/2017. Physician orientation will not be signed off as complete until the pharmacy component of physician orientation is completed. Two Pharmacists are assigned to present the physician orientation. The goal is 3 months compliance at 100%; then quarterly for 2 quarters at 100%. Results will be reported to Pharmacy & Therapeutics Committee, Safety and Quality Committee, the Medical Executive Committee and Governing Body.	12/31/16 and ongoing 9/29/17

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	infusion as ordered by physician.. The Hospital Policy and Procedure titled, "Medication: Administration ..." dated 10/14/16 indicated, "...PROCEDURE: ... I. Before administering a medication, the health care professional does the following: 1. Verifies that the medication selected for administration is the correct one based on the medication order and the product label...W. High risk medications such as heparin... must be checked by two qualified healthcare professionals for the dose... This double check must be documented." The Hospital Policy and Procedure titled, "Medication: High Risk (High Alert)" dated 7/15/16 indicated, "...POLICY: G. High risk medication such as...heparin...must be checked by two qualified healthcare professionals..." The hospital failed to follow its policies and procedures related to the administration of high risk medications which led to Pt 1 receiving an overdose of IV heparin, leading to internal blood loss, and her ultimate death. The hospital's failure to follow its policies for high risk medication administration led to the licensee's noncompliance with one or more requirements of licensure. 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).		**Title/Position of Individual Responsible for Implementation of Corrective Actions:** Medical Staff Services Coordinator Director of Pharmacy **Completion Date: 8/31/18**	8/31/18