California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000063	A. BUILDING: _____ B. WING _____	C 11/13/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HENRY MAYO NEWHALL HOSPITAL	23845 MCBEAN PKWY VALENCIA, CA 91355

(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
E 000	Initial Comments The following reflects the findings of the Department of Public Health during an Entity Reported Incident (ERI) investigation. ERI number: CA00543798 Representing the Department of Public Health: Surveyor ID #: 31333, RPH, Pharmaceutical Consultant The inspection was limited to the specific entity reported incident investigation and does not represent the findings of a full inspection of the facility. Health and Safety Code 1280.3 (g) for purposes of this section, "Immediate Jeopardy" means a situation in which one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.	E 000		
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs 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	E 485		

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E 485	Continued From page 1 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. (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: Based on interview and record review, the facility failed to ensure an intramuscular (IM - given by needle into the muscle) medication, epinephrine (generic for Adrenalin, an injection used to treat severe allergic reactions [anaphylaxis]) was administered as prescribed. Patient 1 received a concentrated dose of epinephrine via intravenously push (IVP - rapid injection of medication directly into a vein/bloodstream). Epinephrine for IM/SQ had concentration of 1:1000 [1.0 milligram (mg) per 1.0 milliliter (ml)] and IV administration had concentration of 1:10,000 (1 mg per 10 ml, which is equivalent to 0.1 mg per 1.0 ml). Epinephrine for IM or SQ (subcutaneous, a method of administering medication under the skin) administration is ten times more concentrated than Epinephrine for IV administration. As a result Patient 1 experienced a STEMI (ST-Elevation Myocardial Infarction, serious type of heart attack), a cardiac (heart) catheterization procedure was completed (a procedure used to diagnose and treat heart conditions; during cardiac catheterization, a long thin tube called a catheter is inserted in an artery or vein in a groin,	E 485		

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neck or arm and threaded through a blood vessels to the heart), and required admission to the Intensive Care Unit (ICU).

Findings:

On 9/14/17, an unannounced visit to the facility was conducted to investigate an Entity Reported Incident (ERI) regarding a medication error that occurred on 7/4/17. According to Patient 1's clinical records, the patient presented to the emergency department (ED) for allergic reaction on 7/4/2017 at 7:54 p.m.

According to Patient 1's ED Patient Records under Physical Assessment, Medical Notes, dated 7/4/17, at 8:15 p.m., RN 2 noted that patient came in for an allergic reaction after eating ice-cream. Patient 1 was complaining of itchiness and some tightness to the throat, swollen eyes, head pain and some shortness of breath. Patient 1 had redness and swelling around the eyes and wheezing (when a person breathes with a whistling or rattling sound in the chest, as a result of obstruction in the air passages) during breathing.

On 9/14/17 at 11:14 a.m., during an interview, Staff 1 stated that Patient 1 arrived in ED complaining of an allergic reaction to food and Epinephrine IM was ordered. However, Epinephrine was administered IV, opposed to IM, as ordered and shortly after the Epinephrine was administered IV Patient 1 had symptoms of a heart attack.

On 9/19/2017 at 9:38 a.m., during a telephone interview Physician 1 stated, "Patient 1 had an allergic reactions in the past and needed anaphylactic treatment. An IM medication

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Epinephrine was given to Patient 1 intravenously. I expected the medication orders to be carried out as ordered; within a minute after the administration of the Epinephrine by IV, Patient 1 began experiencing chest pain. Patient 1 had EKG changes, became hypotensive, cardiologist was called and Patient 1 was taken to the Cardiac Catheterization laboratory for STAT cardiac angiogram. Patient 1's adverse reaction was due to the administration of Epinephrine by the wrong route and wrong dose."

On 11/3/2017 at 9:30 a.m., during a telephone interview RN 2 stated, the medication error occurred shortly after he came on duty on 7/4/17. RN 2 stated he saw RN 1 was having difficulty starting an IV line on Patient 1 and he went to assist RN 1. While he was setting up the IV line, RN 1 came back into the room and stated, "Here are your IV medications. I just pulled it for you" and placed the three medications along with the syringes for the medications on Patient 1's bedside table. Then RN 1 left to attend to her assigned patients. RN 2 stated, "I quickly looked at Patient 1's MAR to verify ordered medications, however I missed that Epinephrine was to be administered IM and not IV. Right after administration of the medication Patient 1 became more anxious, nervous, could not breath, and was wheezing. I quickly put Patient 1 on oxygen. RN 4 was making her rounds and saw that Patient 1 was in distress and came to assist me." RN 2 further stated he called Physician 1 right away and RN 4 took over the care of Patient 1. "I was too devastated to continue."

RN 2 further stated, it was not unusual in the ED for one nurse to pull the medication from the ADC and another to administer especially during a trauma or a Code situation. However, RN 2

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stated this was not initially a Code situation for Patient 1; Physician 1 inputted the medication orders into the CPOE, the information was sent to the pharmacy for review and the medications specific for Patient 1 was added to the ADC for the nurse to remove medications from the machine. RN 2 stated, hearing from RN 1, 'Here are your IV medications,' and the distress of Patient 1 may have contributed to the medication error; and cannot explain how it happened and hope it will never happen again. RN 2 stated usually the nurse that pulls the medication from the ADC is the same nurse that administers the medication to the patient. RN 2 stated he was not aware of any facility's policy regarding handing off medication that was pulled from the ADC by one nurse and administered by a different nurse when a Code has not been called.

A review of Patient 1's clinical record indicated that on 7/4/17 at 8:01 p.m., an emergency room physician 1 (Physician 1) entered orders for Patient 1 through computerized physician order entry (CPOE) to receive the following medications for treatment of an allergic reaction:

1. Epinephrine [(Adrenalin) medication is used in emergencies to treat very serious allergic reactions to insect stings/bites, foods, drugs, or other substances. Epinephrine acts quickly to improve breathing, stimulate the heart, raise a dropping blood pressure, and reduce swelling of the face, lips, and throat] 0.5 milligram (mg) IM one time dose only.

2. Benadryl [(Diphenhydramine) is an antihistamine (a drug to treat allergic reactions and colds) used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, itching, watery eyes,

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E 485	Continued From page 5 itchy eyes/nose/throat, cough, runny nose, and sneezing. It is also used to prevent and treat nausea, vomiting and dizziness caused by motion sickness] 25 mg intravenous push (IVP) one time dose only. 3. Solu-Medrol [(Methylprednisolone succinate) is a steroid medication used decrease inflammation. One of the conditions in which it is used include allergies] 125 mg IVP one time dose only. A review of the facility's Automatic Dispensing Cabinet (ADC) transaction report indicated an emergency room registered nurse 2 (RN 2) removed all three ordered medications from the cabinet on 7/4/17 between 8:10 p.m., to 8:11 p.m. According to the Medication Administration Record (MAR) dated 7/4/17 at 8:22 p.m., RN 2 documented administering to Patient 1 Benadryl and Solu-Medrol. However there was no documentation on the Medication Administration Record (MAR) that the epinephrine had been given by RN 2. A review of the ED Patient Records under Physical Assessment, Medical Notes, dated 7/4/17 at 8:24 p.m., indicated RN 2 documented that Patient 1 was accidentally given Epinephrine 0.5 mg through IV. RN 2 documented Patient 1 was complaining of shortness of breath, feeling like she cannot catch her breath, feeling anxious, dizzy, and complaint of tightness to the chest. According to MAR, dated 7/4/17, RN 3 from ICU, documented that Epinephrine was administered in the ED.	E 485		

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E 485	Continued From page 6 On 9/14/2017 at 11:36 a.m., during an interview and record review, in the presence of Staff 1, the director of pharmacy (DOP) confirmed RN 1 documented to remove ordered medications from the ADC and RN 2 administered medications to Patient 1 and documented. DOP stated, in the presence of Staff 1, that the form of Epinephrine available in the emergency room's ADC were undiluted ampules intended for IM or subcutaneous (SQ, injection under the skin) administration only. DOP stated the emergency department's ADCs allowed a practitioner to select a drug from a patient-specific list on the ADC screen and obtain a medication only after the order has been verified by a pharmacist. The licensed nurse pulling the medication from the ADC would see the physician's order. DOP stated the facility does not have a policy or system in place as to how the ADC's cautions, instructions, warnings, and overrides should be communicated from one nurse to another when the nurse removing the medication from the ADC and the nurse administering the mediation to the patient were two different nurses. Staff 1 acknowledged the facility do not have any policy or procedure to guide medication handoff between nurses to minimize or prevent medication errors. DOP stated, "Best practice were for the nurse to pull own medications and administer to the patient. There is a safety gap, there are no bar code scanning (information encoded in barcodes allows for the comparison of the medication being administered with what was ordered for the patient.) at the bedside in the ED. Right now it is a human error. The bar code scanning happens in all areas of the facility except the ED." Concurrently, during an interview, in the presence of DOP, Staff 1 stated the nurse administering	E 485		

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the medication should have checked for the five rights which are the main safeguards for the patient even when medication that was pulled by one nurse was provided to another nurse for administration to a patient. Staff 1 stated the five rights included: Right patient, Right medication, Right dose, Right time, and Right route of administration.

According to ED Summary Report Patient 1's vital signs on 7/4/17 were as follows:

1. At 7:56 p.m., right after admission to ED, pulse 65, blood pressure 127/87.

2. At 8:05 p.m., pulse 84, blood pressure 133/93.

3. At 8:27 p.m., after administration of Epinephrine through IV, pulse 84, blood pressure 94/70 (adult normal BP range is below 120/80 millimeters of mercury [mm Hg] or above 90/60) and respirations 26 (adult normal respiration rate is 12-20, a respiration rate under 12 or over 25 breaths per minute while resting is considered abnormal).

4. At 8:31 p.m., blood pressure 61/49.

5. At 8:32 p.m., Patient 1's blood pressure (BP) was documented at 60/46.

At 8:56 p.m., a Code STEMI (procedure that allows for rapid opening of a blocked artery to abort a heart attack) was called.

A review of Patient 1's ED Physician Documentation, dated 7/4/17, at 8:56 p.m., indicated, Patient 1 required critical care due to the inherent instability and or potential for instability. Patient 1, who presented with

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E 485	Continued From page 8 anaphylactic reaction (a sudden, widespread, potentially severe and life-threatening allergic reactions; a person rapidly develops severe symptoms, including generalized itching and hives, swelling, wheezing and difficulty breathing, fainting, and/or other allergy symptoms) then became hypotensive (experiencing abnormally low blood pressure) after inadvertently receiving intramuscular Epinephrine through an IV and then required intravenous Dopamine (a medication used to treat certain conditions, such as low blood pressure, that occur when a patient is in shock, which may be caused by heart attack, trauma, surgery, heart failure, kidney failure, and other serious medical conditions) for blood pressure control. Patient 1 was ordered IV fluids, Aspirin (medication to relieve mild or chronic pain and to reduce fever and inflammation), Morphine (narcotic drug obtained from opium and used medicinally to relieve pain) and Nitroglycerin (a drug used to relax and dilate the blood vessels (vasodilator), improving blood flow to the heart). A cardiologist, Physician 2, evaluated Patient 1 at the bedside and Patient 1 was sent to receive a CT scan (computed tomography, a procedure that uses a computer linked to an x-ray machine to make a series of detailed pictures of areas inside the body) prior to catheter lab. According to cardiologist's Brief Note, dated 7/4/17 at 10:32 p.m., Patient 1 received a dose of Epinephrine in ED and had sudden onset of an acute chest pain and continued to exhibit hypotension (low blood pressure) and chest pain. Based on Patient 1's symptoms a STAT (emergent) echocardiogram (a test of the action of the heart using ultrasound waves to produce a visual display, used for the diagnosis or monitoring of heart disease) was requested and Cardiac Catheterization laboratory (an	E 485		

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E 485	Continued From page 9 examination/procedure room with equipment to visualize the arteries of the heart and the chambers of the heart and treat any abnormality found) was activated. Patient 1 was emergently taken to the Cardiac Catheterization laboratory while the patient was continuing to complain of chest pain and shortness of breath. Cardiac catheterization was then performed revealing patent coronary arteries without any evidence of dissection (tear) or occlusion. In a Brief Note, the cardiologist documented STAT echocardiogram that was performed exhibiting mild stunning of basal lateral wall, consistent with spasms in area of EKG changes with ejection fraction [(EF) - a measurement of the percentage of blood leaving your heart each time it contracts] of 50 percent (normal EF is 50 to 75 percent). The plan to move patient (Patient 1) to ICU for monitoring. A review of Stat Transfer Summary Report, dated 7/6/17 and completed by Physician 3, indicated Patient 1 was transferred to a GACH for further care with a final diagnosis of severe anaphylactic shock, secondary to ice cream. Physician 3 documented Patient 1's coronary angiogram was negative for any thrombus or occlusion or dissection. "Abnormal electrocardiogram with normal coronary, most likely Epinephrine induced coronary spasm." According to DailyMed, "Common adverse reactions to systemically (medication administration into the circulatory system so that the entire body is affected) administered Epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and respiratory difficulties. Premature ventricular contractions (occur before	E 485		

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E 485	Continued From page 10 the regular heartbeat) may appear within one minute after injection ...Myocardial ischemia (reduced blood flow and oxygen to the heart), myocardial infarction (heart attack, occurs when blood flow decreases or stops to a part of the heart, causing damage to the heart muscle) and cardiomyopathy (abnormal heart muscles) have been noted in the literature following overdose of Epinephrine. A review of the facility's policies and procedures titled, "Medication Administration, Preparation, Control, Distribution and Documentation - Medication Management," dated 11/1/1995, indicated: a. Medications will be dispensed and safely administered to patients ... as prescribed by the physician. The medication order is received by Pharmacy and entered onto the patient's eMAR profile. The order is then available for nursing review and if correct, is acknowledged by the nurse. Medications are dispensed in the most ready-to-administer form to minimize opportunities for error. As each medication is prepared for administration, check label three (3) times: (1) As it is removed from the automated dispensing cabinet or cassette; (2) As it is placed in the medication cup or drawn into the syringe; and (3) When unit dose is opened at bedside or after being drawn into the syringe. Prior to administration of all medications, the nurse will: Confirm that the medication selected matches the order and is properly labeled. b. Prior to administration of high alert medication, the amount ordered and amount prepared must be checked by two (2) Licensed Nurses or two (2) Registered Nurses as indicated by the policy.	E 485		

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E 485	Continued From page 11 c. For areas utilizing bar code scanning, the licensed practitioner will then proceed to identify the patient and medication by scanning each with the hospital bar code scanning system. In all cases, the 'Five Rights of Medication Administration' will be observed and carried out: Right Patient, Right Medication, Right Dose, Right Route, Right Time d. To the maximum extent possible, drugs are to be administered by the person preparing the dose ...Patient medication must be given and charted by the person administering it. A review of the facility's policies and procedures titled, "Medication-High Alert," with an approved date of 2/10/2016, indicated, "High-Alert Medication List ...Use warning labels in medication storage areas or on the medications themselves ... Epinephrine - High risk, Problem Prone ..." The facility's failure to ensure consistent implementation and establishment of current policies and procedures for the safe and effective use of IM Epinephrine is a deficiency that has caused, or is likely to cause, serious injury or death to Patient 1, and therefore, constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3 subdivision (g).	E 485		

POC Acceptable 12/18/18 LPE

Henry Mayo Newhall Hospital

Addendum to Plan of Correction for State Deficiencies for ERI Number: CA00543798

Plans for Monitoring Continued Compliance:

1. Bar code scanning rates in the Emergency Department will be audited monthly until 95% compliance is achieved for four months. In order to address 100% of patients, the remaining 5% refers to the outliers where patient and medication scanning may not be feasible. These are in times of emergent and "code" situations where very often there is a physician and a pharmacist at the patient bedside during the medication administration by the nurse. These situations will be monitored for verbal verification with verbal repeat back of the order, and the five rights. This will be verified and documented by the scribe, as applicable to the patient scenario. Any medication hand-offs from one staff member to another requires verification of the medication order, with repeat back, and verification of the five rights. Compliance will be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.

2. The education module "Epinephrine Administration" completion will be audited until 100% is achieved. Staff members returning from leave of absence will be required to complete the module within the first 30 days of their return. This will be monitored by the Education staff who will resume the staff member's access to the hospitals online learning system. The pharmacy department will have a component in new hire nursing training to address the five rights of medication administration, as well as the process of administering "high risk" medications, such as Epinephrine. The organization-wide policy titled "High Risk Medications" has updated the verbiage for Epinephrine from "problem prone" to "high risk" medication. Compliance will be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.

3. RN independent practice of double-checking High Risk Medications, including the five rights, will be audited until 100% compliance is achieved for four months. The auditor will provide direct observation of the two nurse interaction to ensure that that the steps of double checking and double sign off is complete. Compliance to be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.

Ongoing quality assurance is achieved through the removal of all epinephrine 1:1000 ampules and vials from all automated dispensing cabinets and in place stocked epinephrine autoinjectors 0.3 mg and 0.15 mg for IM use throughout the hospital. The Allergic Reaction order set was revised to reflect the addition of the epinephrine pen and removal of the IV and subcutaneous routes. The Emergency Department implemented bar code scanning of both the patient and medications in 11/2017. Once the

medication bar code scanning process is complete the medication administered is documented in the electronic medical record automatically by the system. Bar code scanning has been implemented in acute care nursing units throughout the organization. The data on the scanning rates for each individual nurse, in each patient care department, are collected daily and reported monthly.

Henry Mayo
Newhall Hospital

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California Department of Public Health Request for Plan of Correction for State Deficiencies Letter dated 11/13/2018 and received by Henry Mayo Newhall Hospital on 11/19/2018.

Plan of Correction for State Deficiencies

Title 22 - Division 5 - Chapter 1 - Article 3 - Section 70263 (g)(2): Pharmaceutical Service General Requirements.

(g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory care practitioners. 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.

(2) Medications and treatments shall be administered as ordered.

Process Changes

Immediate and Systemic Corrective Actions:

1. An epinephrine 1:1000 alert was added to the automated dispensing cabinet. The alert states "NOT to be given IVP". Position Responsible for Correction: Director of Pharmacy. Completion date: 07/12/2017.
2. Implemented bar code scanning of medications in the Emergency Department. Once the medication bar code scanning process is completed the medications administered is documented in the electronic medical record automatically by the system. Bar code scanning has been implemented in acute care nursing units throughout the organization. Position Responsible for Correction: Director of Emergency Services. Completion date: 11/07/2017.
3. The Allergic Reaction order set was revised to reflect the addition of the epinephrine pen and removal of the IV and subcutaneous routes. Position Responsible for Correction: Director of Pharmacy. Completion date: 11/28/2017.
4. Removed epinephrine 1:1000 ampules and vials from all automated dispensing cabinets and stocked epinephrine autoinjectors 0.3 mg and 0.15 mg for IM use throughout the hospital. Position Responsible for Correction: Director of Pharmacy. Completion date: 11/28/2017.

Plan for Monitoring Continued Compliance:

1. Bar code scanning rates in the Emergency Department will be audited monthly until 90% compliance is achieved for four months. Compliance to be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.

Education and Training:

Immediate and Systemic Corrective Actions:

1. Medication administration education was provided to the RN administering the epinephrine. Position Responsible for Correction: Emergency Department Navigator. Completion date: 07/14/2017.
2. "Patient Safety Alert" was sent to all areas administering epinephrine. The alert included an overview of the event, direction on how to avoid the error from happening again which specifically stated "do not give epinephrine 1:1000 ampule IV PUSH. It is intended for IM injection only during anaphylaxis. This is a highly concentrated form of epinephrine, 1mg in 1 ml", and processes being revised to prevent reoccurrence. Position Responsible for Correction: Patient Safety Coordinator. Completion date: 09/20/2017.
3. Epinephrine dosing education reviewed with the Emergency Department staff during the daily huddle for 7 calendar days. Position Responsible for Correction: Director of Emergency Services. Completion date: 11/26/2017.
4. A mandatory education module "EpiPen Auto-Injector Module and IV Admixture" was completed by the all nursing staff throughout the organization except the Neonatal Intensive Care Unit. Position Responsible for Correction: Director of Education. Completion date: 11/28/2017.
5. Education regarding High Alert Medications including epinephrine preparation was provided to the nursing staff throughout the organization. Position Responsible for Correction: Chief Nursing Officer. Completion date: 12/13/2018.

Plan for Monitoring Continued Compliance:

1. The education module "EpiPen Auto-Injector Module and IV Admixture" completion will be audited until 90% is achieved. Compliance to be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.
2. RN independent practice of double-checking High Alert Medications will be audited until 90% compliance is achieved for four months. Compliance to be reported to Medication Safety Committee, and Accreditation, Regulatory and Licensing Committee.