California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFX (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 000 E 000 Initial Comments The following reflects the findings of the California Department of Public Health during the investigation of a complaint conducted from 4/11/17 through 4/12/17. For Complaint CA00529817 regarding State Monitoring, Adverse Events or series of adverse CALIFORNIA DEPARTMENT events, a State deficiency was identified, (See OF PUBLIC HEALTH California Code of Regulations, Title 22, Section 70263(g)(2)). This was a State Immediate Jeopardy Administrative Penalty (AP IJ) Level 4. JUN 2 8 2017 Inspection was limited to the complaint L&C DIVISION investigated and does not represent the findings SAN JOSE of a full inspection of the facility. Representing the California Department of Public Health: 27194. Pharmaceutical Consultant II. Tag E 485 E 485 T22 DIV5 CH1 ART3-70263(g)(2) E 485 A1. The corrective action taken to correct Pharmaceutical Service General Requirements the hospital's failure to administer two immediate (STAT) medications (g) No drugs shall be administered except by per policy are the following: licensed personnel authorized to administer 1. Policy# MED0306 Medication drugs and upon the order of a person lawfully Administration was reviewed and authorized to prescribe or furnish. This shall not determined to be compliant with preclude the administration of aerosol drugs by respiratory therapists. The order shall include the CMS guidance, in terms of time name of the drug, the dosage and the frequency expectations to deliver of administration, the route of administration, if immediate STAT medications. other than oral, and the date, time and signature Further, it was determined that of the prescriber or furnisher. Orders for drugs the policy was inconsistently should be written or transmitted by the prescriber followed by staff (nurses and or furnisher. Verbal orders for drugs shall be pharmacists). 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 Licensing and Certification Division LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE

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California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  CA070000133	A BUILDING		E SURVEY PLETED C 13/2017
	ROVIDER OR SUPPLIER	225 N JAC	KSON AVI	STATE ZIP CODE	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COMPLETE DATE
	Countersign the or (2) Medications are administered as or administered as or administered as or Based on interview hospital failed to a ordered when Pat medications order therapy to prevent medication to prevent medication to prevent delayed for administimely contributed health status and physical impairmed Findings:  A review of Patien indicated he was a brought in by amb (neck brace, a me person's neck) to department (ED) of sustaining a fall at 1's physical exam 3/22/17, the patien	ber or furnisher shall der within 48 hours.  Ind treatments shall be redered.  It met as evidenced by: It wand document review, the idminister medications as itent 1's two immediate (STAT) and (heparin, an anticoagulation blood clot and valporic sodium, went additional seizure) were istration by hospital staff for ours and 1.5 hours. These ister the two critical medications to a rapid decline in Patient 1's may have resulted in significant	E 485	Continued from page 1 – Tag E 485  Revisions to this policy were made under Procedure B, 2, b, "Medications ordered as "STAT" "NOW" shall be administered to the patient within 30 minutes of the order entry and prior to transfer to receiving unit."  (Changes to this section are the italicized portions.) The policy changes were made and approved at the following committees:  Neuroscience Quality Review Committee (QRC)  Pharmacy and Therapeutics (P&T) Committee  Medical Executive Committee (MEC)  Board of Trustees (BOT)  An education module was developed entitled Medication Administration by the Director of Education.  a. Included in the module is the Medication Administration policy with the approved revisions. Educational materials and content were reviewed and approved by the Chief Nursing Officer (CNO).  b. Education commenced on 6/14/17.  c. All nurses will complete the	6/14/17 6/14/17 6/26/17 6/27/17 6/14/17 6/14/17

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California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION DENTIFICATION NUMBER COMPLETED A BUILDING: C B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 485 Continued From page 2 E 485 Continued from page 2 - Tag E 485 he had a history of left frontal meningioma Validation of education is the (tumors that develop in the cells of the membrane that surrounds the brain and spinal cord) and the successful completion of a tumor was surgically removed at a hospital in post-test. Remediation will 2003. About 2 months after the surgery, he had be provided to those nurses generalized seizures and he was placed on who are unsuccessful with Dilantin (medication to control seizure) for about 5 passing the post-test. years. He had no further seizures and after Monitoring of completion follow-up, the Dilantin was discontinued about 3 rates of this education is or 4 years ago. occurring daily and reported Further review of Patient 1's medical record dated to the CNO. 3/22/17 revealed, shortly after his arrival to the d. Those nurses that are away ED, he was taken to the radiology department for on Medical Leave will not be his initial computed tomography (CT) scan (a allowed to return to work series of X-ray images taken from different until the successful angles and uses computer processing to create completion of the cross-sectional images, or slices, of the bones, educational module and blood vessels and soft tissues inside one's body) of the head and cervical spine to determine the post-test. extent of the injury and to determine if surgery 3. Additional education has been 6/15/17 was needed. At 7:50 a.m., the CT scan findings provided to all nursing staff at were communicated to Physician 1. The results Regional Medical Center of San showed evidence of a cervical vertebrae C7 Jose (RMCSJ) by the CNO, in a (spinal segment located towards the bottom of letter dated 6/15/17, related to the cervical spine which helps provide the neck Medication Administration, with structural support) fracture. Handoff Communication and During a telephone interview with Physician 1 on Neurological Assessment. 4/14/17 at 11:31 a.m., he stated the close Informal education has been 6/8/17 proximity of the main artery to the fractured area provided at change of shift of the neck was one of his concerns and he huddles to all working nurses ordered a CT angiogram or CTA (a CT imaging regarding medication test that looks at the arteries and tissues in administration of STAT various parts of the body) with contrast to study orders and the significance the nearby blood vessels to determine if there of handoff communication was any injury done to the artery. and neurological Review of the CT angiogram results on the assessments. diagnostic imaging report dated 3/22/17 at 9:45

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A. BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) DATE TAG TAG DEFICIENCY) E 485 Continued From page 3 E 485 Continued from page 3 - Tag E485 a.m. revealed evidence of left vertebral artery Developed a daily auditing report 6/14/17 dissection in addition, to C7 fracture. to identify STAT medications During a telephone interview with Physician 1 on administered > 30 minutes. This 4/14/17 at 11:31 a.m., he confirmed he requested data is analyzed daily by the Chief a neurosurgery consultation to determine the next Quality Officer (CQO) and CNO, course of treatment after Patient 1's CTA to identify barriers that created a diagnostic imaging results. delay. Immediate process improvements are implemented, A review of the neurosurgery consultation report dated 3/22/17 at 12:02 p.m. by Physician 2 as delays are identified. indicated "Neurologically, Patient 1 has no focal Immediate coaching is provided deficit. His fracture is generally considered to staff involved. stable. I will keep him in a cervical collar for now; however, I am more concerned about his B1. The title or positon of the person who vertebral artery injury. If this truly has a clot, he will monitor the corrective action and may need to be anticoagulated. I recommend we the frequency of monitoring: get IR involved. needs to have better Responsibility for compliance to imaging study like an MRI scan of his head just to make sure there is no sort of contusions or injury the administration of immediate to his brain that would preclude him from having (STAT) medications per policy will anticoagulation therapy..." be the CNO and the Chief Medical Officer (CMO). A continued review of Patient 1's diagnostic imaging reports included the magnetic resonance A2. The corrective action taken to imaging or MRI (a non-invasive imaging prevent medication order entry errors technology that produces three dimensional detailed anatomical images without the use of are the following: damaging radiation) of his head taken on 3/22/17 1. The Cardiovascular Accident and it was documented at 1:25 p.m. the results (CVA) Heparin protocol was revealed this patient has "no acute infarcts or reviewed and revised. There was hemorrhage." clarity made to the section containing the Heparin bolus On 4/11/17 at 1:30 p.m. an interview with dosage order. This section now Physician Assistant 1 (PA1) was conducted. PA1 has a "hard stop" not present at stated she was working in the interventional radiology department of the hospital on 3/22/17. the time of this event. This will Patient 1 was referred to her for follow-up care allow the prescriber to bypass and treatment. A MRI diagnostic imaging study of the dosage and thus complete Patient 1's head was ordered to determine

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the order

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION DENTIFICATION NUMBER COMPLETED A BUILDING \_ C B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (X5) COMPLETE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC DENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 4 Continued from page 4 - Tag E485 suitability for initiation of anticoagulation therapy. Further, an evidence based guideline Upon release of the MRI findings at 1:25 p.m. and recommended dose now appears in the "clean MRI" results, PA1 stated this was the confirmation that she needed to proceed with this section off to the side of the heparin anticoagulation protocol. The PA1 dosage. The provider, now, must further stated she went into the hospital's free text in a dose for Heparin bolus Meditech (electronic health record system) or cannot proceed to the completion system and ordered both the heparin bolus (a of this order. Revisions were made by single dose of drug given all at once) dose and Pharmacists in collaboration with the the heparin infusion or drip to be immediately Medical Director of Neuroscience administered. Department. The order set was According to Patient 1's medical record, both the reviewed and approved at the heparin bolus and heparin drip orders were following committees: entered at approximately 1:53 p.m. on 3/22/17. 4/2017 Computer Physician Order Entry However, neither of the heparin orders were (CPOE) administered by nursing staff to Patient 1 until 5/24/17 **Neuroscience Operations** approximately 6:00 p.m. or 4 hours after the Improvement Committee (OIC) medications were ordered. 4/12/17& Pharmacy & Therapeutics 6/14/17 When the PA1 was asked when she would expect Committee (P&T) the medication to be administered to Patient 1 on 6/26/17 Medical Executive Committee 4/11/17 starting at 1:30 p.m., she said "this is a (MEC) STAT order; the medication should be given right 6/27/17 Board of Trustees (BOT) away." She further stated that she even went to 6/26/17 a. Education of the corrective the inpatient pharmacy and informed one of the actions was provided to all pharmacists about her new heparin orders. medical staff at RMCSJ, via In an interview with the pharmacy manager the CMO Newsletter. (Pharm 1) on 4/12/17 at 3:30 p.m., she stated the 6/14/17 2. Medical Staff Peer Review was verification of these two heparin orders was completed on this case at May assigned to a clinical pharmacist (Pharm 2) on and June 2014 Neuroscience QRC the 2 East floor. According to pharmacy record with case review concluding on and Pharm 1, the Pharm 2 acknowledged the 6/14/17. receipt of the heparin orders in about a minute a. It was determined that there after they were entered into the system. However, Pharm 1 stated the original heparin were many system issues bolus order was put into the Meditech system with that ultimately led this no dosage entered, and thus Pharm 2 was negative patient outcome. unable to complete the verification process until

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**FORM APPROVED** California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING C B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X5) COMPLETE (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 6 Continued from page 6 - Tag E485 RN3, he recalled about 5 to 10 minutes after the 3. The second STAT medication start of his shift in the ICU, Patient 1 complained error (Depakote) occurred when of feeling sick and then vomited in bed. RN3 said "it took about 15 to 20 minutes to clean up" as the provider entered the drug, this patient was still in C-Spine precaution dose and route of the medication (patients with spinal precautions are turned very on the order set but did not carefully to prevent flexion or movement of the provide the par fill solution to vertebrae). RN3 stated a dose of Zofran mix the medication in. This (medication to prevent nausea and vomiting) was required the pharmacist to clarify administered to Patient 1 to control his vomiting. the order with the provider. A Review of Patient 1's pharmacy record confirmed a dose of ondansetron (generic drug of Zofran) 4 new order was generated by the mg was administered intravenously (IV) at 3:55 pharmacist, which included the p.m. on 3/22/17. drug, dose, rout and par fill solution; however, the However, according to RN3, after administration pharmacist failed to re-enter the of Zofran IV medication, Patient 1 experienced order as a STAT medication. To another episode of a seizure, and Physician 3 prevent this from occurring in the from the ED was brought in to the ICU for emergent treatment. According to the pharmacy future, revisions to the order set record, two separate doses of lorazepam 2 mg IV have been made. There is now a were administered at 4:43 p.m. and 4:44 p.m. section included to assist the provider in the selection of a par Review of the Patient 1's clinical notes dated fill solution along with the range 3/22/17 by Physician 4 indicated "called at 1630 of Depakote orders. Revisions to for pt seizing, had recently vomited and the order set were made by the maintained in C spine precautions. Seizure continuing and gave Ativan 2mg times 2 doses Pharmacy Department in without resolution of seizure ... Anesth called and collaboration with the Medical intubated at 1650 with glidescope and maintained Director of the Neuroscience in C collar. Physician 3 called and recommended Department. The order set was Propofol and EEG" Continued review of the reviewed and approved at the patient medication records indicated at 4:44 p.m. following committees: Physician 3 had ordered valproate sodium 4/2017 Computer Physician Order Entry (medication to prevent seizure) 1500 mg IV STAT (to be given immediately). However, review of (CPOE) 5/24/17 the record indicated the valproate sodium order **Neuroscience Operations** 

Physician 3.

was not verified by the pharmacy until 6:23 p.m.,

one and half hours after it was ordered by

Improvement Committee (OIC)

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION DENTIFICATION NUMBER COMPLETED A. BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 Continued From page 7 E 485 Continued from page 7 - Tag E485 During an interview with Pharm 1 on 4/13/17 at Pharmacy and Therapeutics 4/12/17& 2:49 p.m., she stated the original valproate (P&T) Committee 6/14/17 sodium order had a data entry error and the 6/26/17 Medical Executive Committee verifying pharmacist attempted to correct it by (MEC) creating a new order of the same medication 6/27/17 Board of Trustees (BOT) while discontinuing the old one. However, the 6/26/17 Education of the corrective pharmacist did not make the new valproate actions made to the order sodium order as an immediate order in Meditech. As the result, Pharm 1 confirmed the verification set was provided to all of the valproate sodium and printing of its label in medical staff at RMCSJ, via pharmacy did not take place until approximately the CMO Newsletter. 6:23 p.m. on 3/22/17, and the subsequent IV 4/2017 b. Education concerning order administration of the medication to Patient 1 did set revisions was provided to not take place until 7:09 p.m. all pharmacists by the Director of Pharmacy. Review of the hospital policy dated 2/23/16 entitled, "Prescribing, Verification and Clarification of Medication Orders" on page 2 under B2. The title or positon of the person who "Prescribing and Verification of Medication will monitor the corrective action and Orders" it read "13. The medical staff approves the frequency of monitoring: turnaround times for processing medication Responsibility for compliance to orders. The turnaround times for this hospital are correct medication order entry as follows: a. STAT medications: 15 minutes ..." will be the Director of Pharmacy and the CMO. During an interview with RN3 on 4/12/17 at 2:20 p.m., he stated he did not know there were heparin "STAT" orders written by PA1 earlier that A3. The corrective action to be taken to afternoon on 3/22/17. He also stated he could prevent the transfer of patients from not recall a hand off during the shift change or one unit to another without any discussion of the pending heparin STAT order administration of STAT medications: between the RN2 and him on 3/22/17 at 3:00 p.m. He further stated he first learned of the heparin orders when he was in the patient's room while assisting Physician 3 with the EEG (electroencephalogram; a test that measures and records the electrical activity of your brain) procedure and Physician 3 asked him to start administering heparin to Patient 1 as soon as possible.

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY STATE, ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY E 485 E 485 Continued From page 8 Continued from page 8 - Tag E 485 Further review of the Patient 1's medication 1. Policy# MED0306 Medication administration record (MAR) indicated the heparin Administration was reviewed and "STAT" order was not administered until determined to be compliant with approximately 6:00 p.m. Review of Patient 1's CMS guidance, in terms of time medical record did not find any hand off expectations to deliver documentation between RN2 and RN3 during the immediate STAT medications. p.m. shift change at 3:00 p.m. on 3/22/17. Further, it was determined that the policy was inconsistently Review of the hospital document dated 4/2015 entitled, "Intensive Care Unit Standards of Care" followed by staff (nurses and on page 4 under "I. Assessment and pharmacists). Revisions to this Reassessment," it read "7. Change of shift policy were made under hand-off will include on-coming and off-going RN Procedure B, 2, b, "Medications doing a bedside double-check of patient status to ordered as "STAT" "NOW" shall include: review of all IV infusions/rates, be administered to the patient assessment of skin, verification of relevant within 30 minutes of the order assessment findings (IE: neurological status, entry and prior to transfer to IABP settings, etc.) receiving unit." (Changes to this On 4/13/17 at 3:24 p.m. during an interview with section are the italicized Pharm 1, she confirmed the first dose of heparin portions.) The policy changes orders written by PA1 was administered at were made and approved at the approximately 6:00 p.m. on 3/22/17, 4 hours following committees: after they were ordered by PA1. 6/14/17 Neuroscience Quality Review Committee (QRC) Review of the hospital policy dated 6/28/16 6/14/17 entitled, "Medication Administration" on page 4 Pharmacy and Therapeutics under procedure; it read "2. b. Medication ordered (P&T) Committee as "STAT" "NOW" shall be administered to the 6/26/17 Medical Executive Committee patient within 30 minutes of the order entry." (MEC) 6/27/17 Board of Trustees (BOT) On 3/23/17, additional MRI and neurological An education module was assessment of Patient 1 were conducted. 6/14/17 developed entitled Medication Review of the MRI findings dated 3/23/17 revealed large pons (area of the brain that serves Administration by the Director of as a message station between several areas of Education. the brain) infarct (a small localized area of dead tissue resulting from failure of blood supply) with

extensive blockage of the left vertebral artery.

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California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY IDENTIFICATION NUMBER AND PLAN OF CORRECTION COMPLETED A BUILDING CA070000133 B WING 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 9 – Tag E 485 Review of the neurological assessment dated Included in the module is the 6/14/17 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in Medication Administration a decreased level of consciousness) off since policy with the approved 8:15 a.m. Pt. opens eyes spontaneously, but revisions. Educational does not track. Gaze in midline." And materials and content were subsequent consultation dated 3/23/17 concluded reviewed and approved by the patient likely had Locked-in syndrome (a the Chief Nursing Officer condition in which a patient is aware but cannot (CNO). move or communicate verbally due to complete 6/14/17 b. Education commenced on paralysis of nearly all voluntary muscles in the body except for vertical eye movements and 6/14/17. blinking) with prognosis for functional recovery is All nurses will complete the 7/7/17 poor. Health Stream module by 7/7/17. Validation of A 014 A 014 1280.1(c) HSC Section 1280 education is the successful completion of a post-test. For purposes of this section "immediate jeopardy" Remediation will be provided means a situation in which the licensee's to those nurses who are noncompliance with one or more requirements of unsuccessful with passing licensure has caused, or is likely to cause, the post-test. Monitoring of serious injury or death to the patient. completion rates of this education is occurring daily and reported to the CNO. d. Those nurses that are away on Medical Leave will not be allowed to return to work until the successful completion of the educational module and post-test.

Licensing and Certification Division STATE FORM

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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

JUN 2 8 2017

L & C DIVISION SAN JOSE

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING B WING CA070000133 06/13/2017 STREET ADDRESS, CITY STATE ZIP CODE NAME OF PROVIDER OR SUPPLIER 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 10 - Tag E 485 Review of the neurological assessment dated 3. Additional education has been 6/15/17 3/23/17 indicated "Neuro exam is very limited provided to all nursing staff at today, despite propofol (medication that results in a decreased level of consciousness) off since Regional Medical Center of San 8:15 a.m. Pt. opens eyes spontaneously, but Jose (RMCSJ) by the CNO, in a does not track. Gaze in midline." And letter dated 6/15/17, related to subsequent consultation dated 3/23/17 concluded Medication Administration, the patient likely had Locked-in syndrome (a Handoff Communication and condition in which a patient is aware but cannot Neurological Assessment. move or communicate verbally due to complete 6/8/17 paralysis of nearly all voluntary muscles in the Informal education has been body except for vertical eye movements and provided at change of shift blinking) with prognosis for functional recovery is huddles to all working nurses poor. regarding medication administration of STAT A 014 A 014 1280.1(c) HSC Section 1280 orders and the significance of handoff communication For purposes of this section "immediate jeopardy" and neurological means a situation in which the licensee's assessments. noncompliance with one or more requirements of 4. Developed a daily auditing report 6/14/17 licensure has caused, or is likely to cause, to identify STAT medications serious injury or death to the patient. administered > 30 minutes. This data is analyzed daily by the Chief Quality Officer (CQO) and CNO, to identify barriers that created a delay. Immediate process improvements are implemented, as delays are identified. Immediate coaching is provided to staff involved.

Licensing and Certification Division STATE FORM

MQ1611

If continuation sheet 10 of 10

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETE DATE (X4) ID PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 11 - Tag E 485 Review of the neurological assessment dated 3/23/17 indicated "Neuro exam is very limited B3. The title or positon of the person who today, despite propofol (medication that results in will monitor the corrective action and a decreased level of consciousness) off since the frequency of monitoring: 8:15 a.m. Pt. opens eyes spontaneously, but Responsibility for compliance to does not track. Gaze in midline." And the administration of immediate subsequent consultation dated 3/23/17 concluded (STAT) medications per policy will the patient likely had Locked-in syndrome (a be the CNO and the Chief condition in which a patient is aware but cannot Medical Officer (CMO). move or communicate verbally due to complete paralysis of nearly all voluntary muscles in the body except for vertical eye movements and A4. The corrective action to be taken to blinking) with prognosis for functional recovery is prevent Pharmacy delays related to difficulty in contacting providers are the following: A 014 A 014 1280.1(c) HSC Section 1280 4/7/17 1. Education was provided to all Pharmacists by the Director of For purposes of this section "immediate jeopardy" Pharmacy, on the Provider means a situation in which the licensee's Phone/Contact list, located in noncompliance with one or more requirements of Meditech system. Pharmacist 2 licensure has caused, or is likely to cause, serious injury or death to the patient. was unaware that physician assistant's phone numbers are located I this repository. She instead thought it was a list for physicians only and spent a considerable amount of time attempting to locate the PA by telephoning the units she believed the PA to be at.

Licensing and Certification Division STATE FORM

MQ1611

CALIFORNIA DEPARTMENT If continuation sheet 10 of 10 OF PUBLIC HEALTH

California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY IDENTIFICATION NUMBER AND PLAN OF CORRECTION COMPLETED A BUILDING C B WING CA070000133 06/13/2017 STREET ADDRESS, CITY STATE ZIP CODE NAME OF PROVIDER OR SUPPLIER 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID ID (X5) COMPLETE (EACH CORRECTIVE ACTION SHOULD BE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 12 - Tag E 485 Review of the neurological assessment dated Monitoring will include 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in random observational audits a decreased level of consciousness) off since performed by the Director of 8:15 a.m. Pt. opens eyes spontaneously, but Pharmacy to ensure does not track. Gaze in midline." And Pharmacist compliance to subsequent consultation dated 3/23/17 concluded the process. Immediate the patient likely had Locked-in syndrome (a coaching will be provided for condition in which a patient is aware but cannot non-compliance. Further, move or communicate verbally due to complete paralysis of nearly all voluntary muscles in the this education will now be body except for vertical eye movements and part of the new hire blinking) with prognosis for functional recovery is orientation for Pharmacists. poor. 2. While the physician assistant had the medication order screen A 014 1280.1(c) HSC Section 1280 A 014 open on her computer the pharmacist was not able to For purposes of this section "immediate jeopardy" complete the verified Heparin means a situation in which the licensee's bolus order. Again, the noncompliance with one or more requirements of pharmacist did not contact the licensure has caused, or is likely to cause, serious injury or death to the patient. PA (did not have her phone number) to close the order so it could be completed. After several minutes, the PA did close the medication order and the pharmacist was able to complete the order. This problem could have been remedied by calling Information Systems (IT) to close the order to prevent further delays.

Licensing and Certification Division STATE FORM

6899

MQ1611

If continuation sheet 10 of 10



JUN 2 8 2817

L & C DIVISION SAN JOSE California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY **IDENTIFICATION NUMBER** AND PLAN OF CORRECTION COMPLETED A BUILDING C B WING CA070000133 06/13/2017 STREET ADDRESS CITY STATE ZIP CODE NAME OF PROVIDER OR SUPPLIER 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID PREFIX ID (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 13 - Tag E 485 Review of the neurological assessment dated a. This education was provided 4/7/17 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in to all pharmacy staff by the a decreased level of consciousness) off since Director of Pharmacy. 8:15 a.m. Pt. opens eyes spontaneously, but Monitoring will include does not track. Gaze in midline." And random observational audits subsequent consultation dated 3/23/17 concluded performed by the Director of the patient likely had Locked-in syndrome (a Pharmacy to ensure condition in which a patient is aware but cannot Pharmacist compliance to move or communicate verbally due to complete the process. Immediate paralysis of nearly all voluntary muscles in the body except for vertical eye movements and coaching will be provided for blinking) with prognosis for functional recovery is non-compliance. Further, poor. this education will now be part of the new hire A 014 A 014 1280.1(c) HSC Section 1280 orientation for Pharmacists. For purposes of this section "immediate jeopardy" B4. The title or position of the person means a situation in which the licensee's who will monitor the corrective action noncompliance with one or more requirements of and the frequency of monitoring: licensure has caused, or is likely to cause, Responsibility for compliance to serious injury or death to the patient. the prevention of pharmacy delays related to difficulty in contacting providers will be the Director of Pharmacy. A5. The corrective action to be taken to improve handoff communication (both verbal and written) between nurses at change of shift/location are the following: 6/14/17 An education module titled Handoff Communication was developed by the Director of Education.

Licensing and Certification Division STATE FORM

609

MQ1611

If continuation sheet 10 of 10





California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER** COMPLETED A BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) (X4) ID COMPLETE PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 485 Continued From page 9 E 485 Continued from page 14 - Tag E 485 Review of the neurological assessment dated a. Educational materials and 6/14/17 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in content were reviewed and a decreased level of consciousness) off since approved by the CNO. 8:15 a.m. Pt. opens eyes spontaneously, but Content includes, hand-off does not track. Gaze in midline." And communication expectations subsequent consultation dated 3/23/17 concluded for both written and oral the patient likely had Locked-in syndrome (a communication, medication condition in which a patient is aware but cannot reconciliation (IV solutions, move or communicate verbally due to complete STAT medications between paralysis of nearly all voluntary muscles in the body except for vertical eve movements and nurses, physical assessment, blinking) with prognosis for functional recovery is neurological assessments), poor. which commenced on 6/14/17. A 014 A 014 1280.1(c) HSC Section 1280 7/7/17 b. All nurses will complete the Health Stream module. For purposes of this section "immediate jeopardy" Validation of education is the means a situation in which the licensee's successful completion of a noncompliance with one or more requirements of post-test. Remediation will licensure has caused, or is likely to cause, be provided to those nurses serious injury or death to the patient. who are unsuccessful with passing the post-test. Monitoring of completion rates of this education is occurring daily and reported to the CNO. Those nurses that are away on Medical Leave will not be allowed to return to work until the successful completion of the educational module and post-test.

Licensing and Certification Division STATE FORM

MQ1611

If continuation sheet 10 of 10

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING C B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION ID (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) E 485 Continued From page 9 E 485 Continued from page 15 - Tag E 485 Review of the neurological assessment dated 9/30/17 d. Monitoring for compliance to 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in oral and written handoff a decreased level of consciousness) off since communication will occur. 8:15 a.m. Pt. opens eyes spontaneously, but Retrospective chart review does not track. Gaze in midline." And will occur daily (M-F) to subsequent consultation dated 3/23/17 concluded examine the written the patient likely had Locked-in syndrome (a communication of handoff condition in which a patient is aware but cannot communication. Directors move or communicate verbally due to complete will be responsible for these paralysis of nearly all voluntary muscles in the body except for vertical eye movements and audits. blinking) with prognosis for functional recovery is Direct observation audits will 9/30/17 poor. occur daily (M-F) to examine verbal handoff A 014 1280.1(c) HSC Section 1280 A 014 communication at shift change and patient transfers. For purposes of this section "immediate jeopardy" Directors will be responsible means a situation in which the licensee's for these audits. noncompliance with one or more requirements of 6/15/17 2. Additional education has been licensure has caused, or is likely to cause, provided to all nursing staff at serious injury or death to the patient. Regional Medical Center of San Jose (RMCSJ) by the CNO, in a letter dated 6/15/17, related to Medication Administration, Handoff Communication and Neurological Assessment. 6/8/17 Informal education has been provided at change of shift huddles to all working nurses regarding medication administration of STAT orders and the significance of handoff communication and neurological assessments.

Licensing and Certification Division STATE FORM

MQ1611

If continuation sheet 10 of 10

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 16 - Tag E 485 Review of the neurological assessment dated B5. The title or positon of the person who 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in will monitor the corrective action and a decreased level of consciousness) off since the frequency of monitoring: 8:15 a.m. Pt. opens eyes spontaneously, but Responsibility for compliance to does not track. Gaze in midline." And improve handoff communication subsequent consultation dated 3/23/17 concluded (both verbal and written) the patient likely had Locked-in syndrome (a between nurses at change of condition in which a patient is aware but cannot shift/location will be the CNO. move or communicate verbally due to complete paralysis of nearly all voluntary muscles in the body except for vertical eye movements and A6. The corrective action to be taken to blinking) with prognosis for functional recovery is prevent Pharmacy delays when DOOR. verifying a STAT medication order (Depakote) are the following: A 014 A 014 1280.1(c) HSC Section 1280 1. The pharmacist received and acknowledged the STAT order for For purposes of this section "immediate jeopardy" Depakote immediately. means a situation in which the licensee's However, she was not able to noncompliance with one or more requirements of verify the incomplete STAT order licensure has caused, or is likely to cause, within 15 minutes, as per policy. serious injury or death to the patient. The pharmacist was required to contact the provider, obtain the necessary information (par fill order) in order to verify and complete the order. The pharmacist then entered a new order but failed to mark it as STAT medication, causing a delay in administration. This pharmacist was new at the time of the event (two days).

Licensing and Certification Division STATE FORM

MQ1611

CALIFORNIA DEPARTMENT If continuation sheet 10 of 10 OF PUBLIC HEALTH

FORM APPROVED California Department of Public Health STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING \_ B WING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL FACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 17 - Tag E 485 Review of the neurological assessment dated Education was provided to 4/7/17 3/23/17 indicated "Neuro exam is very limited today, despite propofol (medication that results in the entire Pharmacy a decreased level of consciousness) off since Department by the Director 8:15 a.m. Pt. opens eyes spontaneously, but of Pharmacy, on revisions does not track. Gaze in midline." And made to the order set that subsequent consultation dated 3/23/17 concluded will prevent future the patient likely had Locked-in syndrome (a occurrences and an order condition in which a patient is aware but cannot entry of a STAT medication. move or communicate verbally due to complete b. Monitoring will include paralysis of nearly all voluntary muscles in the body except for vertical eye movements and random observational audits blinking) with prognosis for functional recovery is performed by the Director of Pharmacy to ensure Pharmacist compliance to A 014 1280.1(c) HSC Section 1280 A 014 the process. Immediate coaching will be provided for For purposes of this section "immediate jeopardy" non-compliance. Further, means a situation in which the licensee's this education will now be noncompliance with one or more requirements of part of the new hire licensure has caused, or is likely to cause, orientation for Pharmacists. serious injury or death to the patient. B6. The title or position of the person who will monitor the corrective action and the frequency of monitoring: Responsibility for compliance to the prevention of pharmacy delays related to difficulty in contacting providers will be the Director of Pharmacy.

Licensing and Certification Division STATE FORM

MQ1611

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CALIEORNIA DEPARTMENT OF PUBLIC HEAL PORTION sheet 10 of 10

California Department of Public Health (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION IDENTIFICATION NUMBER COMPLETED A BUILDING CA070000133 06/13/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY STATE ZIP CODE 225 N JACKSON AVENUE REGIONAL MEDICAL CENTER OF SAN JOSE SAN JOSE, CA 95116 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL **IEACH CORRECTIVE ACTION SHOULD BE** PREFIX PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) E 485 E 485 Continued From page 9 Continued from page 18 - Tag E 485 Review of the neurological assessment dated A7. The corrective action to be taken is in 3/23/17 indicated "Neuro exam is very limited 7/10/17 today, despite propofol (medication that results in regards to communication to MEC a decreased level of consciousness) off since and Board of Trustees (BOT) of this 6/27/17 8:15 a.m. Pt. opens eyes spontaneously, but Statement of Deficiencies and state does not track. Gaze in midline." And Immediate Jeopardy, as well as a subsequent consultation dated 3/23/17 concluded discussion of the plan of correction. the patient likely had Locked-in syndrome (a Monitoring data will be condition in which a patient is aware but cannot aggregated, analyzed and move or communicate verbally due to complete reported monthly for four paralysis of nearly all voluntary muscles in the body except for vertical eye movements and months to the MEC and BOT. blinking) with prognosis for functional recovery is poor. B7. The title or position of the person who will monitor the corrective action A 014 A 014 1280.1(c) HSC Section 1280 and the frequency of monitoring: 1. Responsibility for compliance to For purposes of this section "immediate jeopardy" reporting the Plan of Correction means a situation in which the licensee's and monitoring data will be the noncompliance with one or more requirements of CQO and CMO. licensure has caused, or is likely to cause, serious injury or death to the patient.

Licensing and Certification Division STATE FORM

6835

MQ1611

CALIFORNIA DEPARTMENT
OF PUBLIC HEALTH

JUN 2 8 2017

L & C DIVISION SAN JOSE