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
	CA230000013	A. BUILDING _____ B. WING _____	C 08/08/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENLOE MEDICAL CENTER	1531 ESPLANADE CHICO, CA 95926

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E 000	Initial Comments [redacted] 2/17/09 The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident on August 6, 2008. Entity reported incident: 159362 The inspection was limited to the specific entity reported incident and does not represent the findings of a full inspection of the facility. Representing the California Department of Public Health: [redacted], RN, HFES II [redacted], PharmD, Pharmaceutical Consultant II [redacted], RN, HFEN A deficiency was written including E 275, E 475, and E 485.	E 000		
E 275	T22 DIV5 CH1 ART3-70214(a)(2) Nursing Staff Development (2) All patient care personnel, including temporary staff as described in subsection 70217(m), shall be subject to the process of competency validation for their assigned patient care unit or units. Prior to the completion of validation of the competency standards for a patient care unit, patient care assignments shall be subject to the following restrictions: This Statute is not met as evidenced by:	E 275	**Corrective Actions Taken:** • Medication delivery device (i.e. IV pumps, PCA pumps-including Dilaudid/"other" specific, epidural, etc) return demo competency and training will be alternated approximately every six months as to achieve a semi-annual return demo competency on medication delivery devices for appropriate personnel. After 3 years, training will be continued annually. All licensed staff (as appropriate to job requirements) will complete the following: **Continued on page 2**	8/08 & Ongoing

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E 475	Continued From page 1	E 475	**Corrective Actions Taken Cont.**	
E 475	T22 DIV5 CH1 ART3-70263(c)(1) Pharmaceutical Service General Requirements (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. This Statute is not met as evidenced by:	E 475	○ Annual skills fair with hands on demo competency validation for medication delivery devices. This training will include: ▪ Medication administration policy and procedures ▪ Guardrails and override alerts ▪ Independent double check requirements ○ Medication Management training program with hands on return demo as well as didactic. This training will include: ○ Medication administration policy and procedures ○ Guardrails and override alerts ○ Independent double check requirements ○ Simulation/case study scenarios ○ Automated medication dispensing devices ○ Securing medication devices (i.e. keys and security features)	8/08 and Ongoing Ongoing
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: The above regulations were not met as evidenced by: Based on interview and record and facility policy	E 485	○ Policy updated to require an independent double check by two licensed staff for identified double-check medications ○ A list of guardrails is readily available on both the pump and Formulary web page in the "Nursing Toolbox" **Continued on Page 3**	10/31/08 9/31/08

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E 485	Continued From page 2 review, the facility failed to provide licensed staff with ongoing training to ensure competency in the use of medication administration devices. The lack of competency validation resulted in Patient 1 receiving an excessively high dose of heparin (a blood thinner standard concentration is 25,000 units in 250 milliliters [mL] of solution for a dose of 100 units per mL). The excessive dose of heparin resulted in Patient 1 developing a right sided intracranial hemorrhage with subsequent left sided paralysis. Additionally, based on observation, interview, and record review the facility failed to implement policies and procedures intended to minimize medication errors and/or adverse drug events; failed to identify the loss of the pharmacy's software system's ability to automatically access critical drug related laboratory values following a software update. The cumulative effects of these systemic problems resulted in the pharmacy's inability to provide pharmaceutical services and care in a safe and effective manner resulting in serious injury to Patient 1 and posed a significant risk for injury or death to other patients. These violations, both individually and collectively, caused or were likely to cause serious injury or death to a patient(s). Findings: A record review conducted on 8/6/08, revealed that Patient 1 was a 82 year old woman admitted to the hospital on 7/31/08, with an admission diagnoses that included peripheral artery disease with a complete obstruction of the superficial artery in the right leg. On 7/31/08 at 10:42 am, Patient 1 was taken to	E 485	**Corrective Actions Cont.** • OCAT (Orientation Competency assessment tool) has been updated to list specific medication delivery devices to ensure compliance. • All nursing staff caring for patients utilizing an infusion device was required to perform hands on return demonstration competency validation prior to delivering patient care. • All nursing staff given education regarding Guardrail safety alerts prior to delivering patient care. Education validated by signature of staff member upon completion. • High-Risk Medication Policy updated to require an independent double check by two licensed staff for identified medications • Standardization of the process to track competency completion in inpatient units to eliminate variability in documentation and to clarify the individual competency of staff. • Education to staff completed via 5 minute meeting and will be introduced/reinforced at the comprehensive medication administration training program for all appropriate licensed personnel with hands on return demo as well as didactic related to medication management practices. **Continued on page 4**	11/08 8/4/08 8/1/08 11/7/08 11/30/08 11/30/08

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E 485	Continued From page 3 the operating room where she underwent a laser atherectomy (the removal of plaque from the artery). At the end of the surgical procedure a stent was placed (device used to keep the artery open) and tPA (potent blood clot dissolving agent) was infusing into the stent to keep the artery open and maintain blood flow. At 1:38 pm, following the surgical procedure, Patient 1 was transferred to the post anesthesia care unit (PACU) where she received continued monitoring. A review of the nursing note dated 7/31/08 at 1:38 pm, read that Patient 1 was in bed, awake, and talking. A review of the physician order sheet dated 7/31/08 at 1:30 pm, read for Patient 1 to receive heparin 600 units at 6 mL per hour to run into the sheath (stent). Further orders included a partial thromboplastin time (PTT-the PTT is a test used to monitor heparin therapy) to be drawn in PACU and every six hours thereafter. During an interview with Staff Member (SM) I on 8/6/08 at 11:20 am, she stated she received Patient 1 in the PACU. SM I stated that prior to starting the heparin infusion, she ordered the PTT to be drawn by the lab, as per the physician order sheet. SM I received the results of the PTT that showed a level greater than 200 seconds, (normal is 24 to 36 seconds). SM I notified the surgeon and received new orders to hold the heparin infusion for now and start the infusion at 4 pm at a lower dose of 500 units or 5 mL per hour. SM I stated that at 4 pm, after verifying the pharmacy labeled information on the bag of heparin and in the presence of SM J, she thought she programmed the Alaris intravenous (IV)	E 485	**Corrective Actions Continued**: • High risk and double check medication policies undergoing complete review and revision o Existing high risk and double check medications are being re-evaluated by P&T o ISMP High Alert medication list undergoing evaluation by P&T to determine if additional items should be added to the organization's high risk or double check medication lists. This will be reevaluated in P & T at least annually. • Mandatory Education module for nursing staff : o Medications shall be administered as ordered including the importance of administering medications with food as ordered. o Pharmacy shall assign standard administration times (including those with meal considerations) to medications per the "Medication: Timing of" policy. o Medications will be given at the routine times unless considerations (defined in policy) apply. **Continued on page 5**	11/30/08 11/30/08

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E 485	Continued From page 4 pump using the guardrails (a feature on the infusion pumps that allowed the nurse to program specific high risk medications so that only the ordered dose was administered) so that it would administer the ordered dose of 500 units or 5 mL of heparin an hour. SM I stated that she asked SM J to verify the infusion pump settings as heparin is a high risk drug that requires a second licensed nurse to check prior to administration. At 12:56 pm on 8/6/08, an interview was conducted with SM J who confirmed that she was the second nurse to verify the dose for the heparin infusion. SM J stated that upon seeing the ordered heparin dose, she calculated it in her head and concluded that Patient 1 should have received 500 units or 5 mL of heparin an hour. SM J stated that she checked the heparin settings entered into the Alaris pump by SM I to ensure they showed the correct dose of 500 units an hour. SM J stated that upon verifying the settings on the Alaris pump she pushed the start button to begin the infusion. At that time, SM J stated she and SM I, "Hesitated because the pump asked for the dose in milligrams (mgs) per kilogram (kg) per hour (a weight based dose) and the (physician's) order was not in kg." SM J stated that at that point, she and SM I cleared the pump and started over. SM J stated that both she and SM I overlooked the option for a non-weight based dose that was ordered by the physician. After several attempts to enter the information into the infusion pump, SM J stated that she and SM I used the option that required a weight. SM J stated that a weight of 59 kgs was entered into the infusion pump. A collaborative review of the Anesthesia Pre-op Note dated 7/31/08 with SM J revealed Patient 1 weighed 49 kgs not 59 kgs, (a	E 485	**Corrective Actions Taken:** o Staff re-educated to medication administration and documentation policy with a specific focus on: • Appropriate documentation of medication administration is done on the MAR after medications are administered. • Appropriate steps to take when medications are unavailable • Notification to pharmacy when medications are unavailable. o Expanded multidisciplinary medication safety rounds to include the following: ▪ Accuracy of pump programming ▪ Guardrail use ▪ Orders implemented appropriately ▪ High risk/double check medication documentation is appropriate. • "Medication Error Reporting" policy has been reviewed and updated to include • Immediate notification to pharmacy for any medication error level D or higher. • Upon notification, the pharmacist will assess the severity of the medication error and take appropriate action. • Any intervention performed by pharmacy will be documented and reviewed by the Medication Management Committee and reported up to P & T Committee **Continued on page 6**	11/30/08 12/08 11/30/08

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E 485	Continued From page 5 10 kg or 22 pound difference). SM J confirmed that the weight had been entered incorrectly. SM J stated that after entering the information into the infusion pump SM I pushed the start infusion button. SM J stated that at that point the override screen (a built-in safety alert) appeared and both SM I and SM J decided to push the override button allowing the infusion to begin. SM J stated that once the infusion was initiated she failed to perform the final step as indicated on the side of the pump, to review the infusion screen to ensure the correct dose would infuse. SM I stated that after the heparin infusion was initiated, she had to leave and reported off [duty] to SM J. SM J stated that approximately 30 minutes after starting the heparin infusion, the pump alarmed to indicate the infusion was complete. SM J stated that it was at that moment she realized they had set the wrong dose to infuse. As a result of the pump being incorrectly programmed, Patient 1 received 25,000 units of heparin over 30 minutes, an infusion that should have run over 50 hours. Once SM J realized the mistake, the physician was notified at 4:45 pm and orders were received. At 7:35 pm, Patient 1 was transferred to the Neuro Trauma Intensive Care Unit (NTICU) for further care and monitoring. The nurse's note dated 7/31/08 at 8 pm, indicated that Patient I's blood pressure dropped as low as 66/44 and Patient 1 required IV fluids to increase her blood pressure. At that time it was also noted that Patient 1 developed swelling in her abdomen. The physician was notified and orders were received for Patient 1 to receive a Computerized Axial Tomography (CAT) Scan to determine the cause of the abdominal swelling. While Patient 1 was in the radiology department undergoing the	E 485	**Corrective Actions Continued:** • High risk and double check medication policies undergoing complete review and revision o Existing high risk and double check medications have been re-evaluated by Sub P&T and P&T o ISMP High Alert medication list undergoing current evaluation and at a minimum an annual reevaluation by P&T to determine if additional items should be added to the organization's high risk or double check medication lists. o Double check medication list has been updated to include thrombolytics. **Monitoring:** Random unannounced Medication Management Rounds to be completed on a monthly basis. Focus of these rounds will include: • Adherence to policy and procedures for pump programming • Procedures for pump programming, guardrail utilization, as well locking (where applicable) as medication administration specifically focusing double check/high risk medication process. All fallouts are reported to the Manager for staff follow up per EMC progressive disciplinary process. • Compliance with educational module will be forwarded weekly to the Quality Management Department to track completion of mandatory module **Continued on page 7**	11/08

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E 485	Continued From page 6 CAT scan, she began to complain of a headache. Patient 1 immediately underwent a CAT scan of the head which the radiologist read as a large right intracerebral hemorrhage or bleeding into her brain. During further interview with SM J, she revealed that she was not familiar with the use of the built-in safeguards on the Alaris IV pump or with the facility policy and procedure for operating the safeguards on the infusion pumps. A collaborative review of the Alaris Pump history provided by SM H on 8/6/08, revealed that at 4:05 pm, the pump was set at a dose that the internal safety feature recognized as too high. Despite this warning, SM I and SM J overrode the warning and administered the heparin. An interview was conducted with SM H on 8/6/08 at 4 pm, to discuss the process for training and competency verification with the various medication administration pumps. SM H stated that when a licensed nurse is first hired they go through nursing orientation which included a review of all of the medication administration pumps used. SM H added that there was no ongoing or annual training to ensure continued competency with the medication administration equipment. As a result of the medication error, Patient 1 sustained an "extensive right-sided intracerebral (within the brain) hemorrhage" as determined by computerized tomography (CT) brain scans on 7/31/08, 8/1/08, and 8/3/08; and as reported by the radiologist. These findings were confirmed by Patient 1's primary care physician (MD 1) in review of his progress note entries on 7/31/08 at 9:50 pm, " ...CT [of] brain shows large right	E 485	**Monitoring Continued:** • The Medication Management and P&T committees will review all significant medication errors in the organization associated with medications identified in policy as high risk and/or requiring double checks and actions taken when applicable • The P&T committee will evaluate new medications being considered for addition to high risk/double check medication list at least annually. • P & T will consider deleting any medication from the formulary based on safety concerns including medication error potential, literature/alert information, and packaging/labeling information. • Quality Management will review all entries into the electronic incident reporting system (Midas) with a focus on identifying high-risk, high-volume, and problem-prone areas. • Entries will be aggregated by incident and severity type for early identification and process improvement. • Compliance with educational module was tracked on all appropriate units. Nursing staff had to complete mandatory training before they were allowed to care for patients. **Continued on page 8**	

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E 485	Continued From page 7 hemisphere hemorrhage ..."; and at 11:12 pm, when he documented having a discussion with Patient 1's family "informing them of the error with [the] heparin dose that she received." At approximately 12 noon, on 8/6/08, SM G stated that MEDITECH was the computerized health care information system in use, facility-wide. He indicated that MEDITECH's pharmacy application featured the ability to concurrently access laboratory data during drug order processing. When processing orders for heparin, the most recent PTT results were to automatically appear ("pop-up") on the computer display. This acts as an alert for the pharmacist's review. SM G was unable to demonstrate this feature for Patient 1, or any other patient on heparin; i.e., no PTT laboratory data popped up on the computer's display. Up until this time, SM G was unaware of this malfunction and unable to provide any explanation as to why this feature was inoperative. At 2:30 pm, SM G indicated that he had learned that the computer software had been updated "the latter part of June" and these "pop ups" were inadvertently eliminated since then. SM G confirmed that the software update was completed on 6/23/08. He further indicated that the facility's IT (information technology) person was now working on correcting the problem. On 8/8/08 at 7:55 am, SM G stated that, "MEDITECH confirmed there's a glitch on their side related to their software update involving heparin and [the] drug with lab test view [PTT display screen feature]." On 8/6/08 at approximately 12:30 pm, SM R was interviewed. SM R confirmed that on 7/31/08 at 3:30 pm, he had processed Patient 1's 3:09 pm heparin order which read, "Hold heparin; start heparin at 500 units/hr at 4 pm." When asked to	E 485	**Monitoring Continued:** • 100% review of all medication errors level D or higher will be reviewed by the interdisciplinary Medication Management Committee to ensure pharmacy notification of medication error. All fallouts are reported to the Manager for staff follow up per EMC progressive disciplinary process. • Alaris SE infusion pump Guardrail Suite software data reviewed quarterly to ensure appropriate pump programming, use of the guardrail features, and identify outliers. • Data will be reviewed in the Medication Management Committee. Outliers for specific profiles will be investigated and data will be referred to the corresponding department manager(s) for appropriate action. • Aggregate data of outliers and trends will be reported to the Performance Improvement /Patient Safety Committee for recommendations on global corrective actions. **Responsible for Action Plan:** Chief Operating Officer Vice President of Nursing Services	

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describe how he processed intravenous heparin orders at the time of order entry he stated, "I check the dose, rate ...look at the hemoglobin, hematocrit [types of blood tests] and the PTT." When asked how he checks drug related lab values he stated, "Well usually ...for Coumadin (an oral blood thinner) a screen pops up. I'm not sure [if] one for heparin does. I'm not sure." SM R did not recall checking the PTT for Patient 1. He hadn't noticed that the heparin linked screen pop-up lab data function was disabled since late June, stating, "I guess it hasn't been working." When asked what he would do if the reported lab PTT level was greater than 100 seconds (the facility established critical lab value) he stated, "I would contact the physician for [order] clarification." He did not recall contacting the physician for Patient 1. No further documentation was provided indicating that the pharmacist had contacted Patient 1's physician concerning the patient's critically elevated PTT (reported as > 200 seconds); or that he requested clarification on continuation of heparin as ordered, in light of the critically elevated PTT level.

Review of the facility policy, "Medication Order Processing," revised 3/08, indicates, "To delineate safety procedures designed to assure patient safety." Under policy item 4, it reveals the following, "Orders will be processed with a patient-centric approach, focused on patient safety and satisfaction." Under procedure item 2, "A pharmacist will review all medication orders and address all concerns, issues or questions (including ...adverse drug event potential) with the individual prescriber before a medication will be dispensed or made available for administration. Orders will be reviewed for: ...appropriateness of the drug, dose ...laboratory values and potential impact ... [and] variation from the organization's

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E 485	Continued From page 9 criteria for use." On 8/6/08, at 3:41 pm, SM G stated these polices should have been followed and added, "We failed." Review of the facility drug utilization statistics for heparin 25,000 units 250 mL premix (the standard concentration that Patient 1 received in the PACU) revealed that between 6/23/08 (date of the MEDITECH pharmacy software upgrade), and 8/8/08 (when it was identified that the "pop-up" PTT laboratory display was not functioning), that 24 orders for this drug product were processed by the pharmacy, for a total of 18 different patients. SM G confirmed this data on 8/8/08, at 1:50 pm. When asked if all of these premixed heparin orders were processed by pharmacy staff without the benefit of the automatic pop-up display of the heparin linked PTT lab value for the pharmacist's review, he responded, "[You could] bet money on it." As a result of this investigation, it was determined that the following regulations were violated: (1) § 70214 of Title 22; by not providing ongoing education to ensure proficiency among the licensed staff in the safe use of medication administration equipment; (2) § 70263(g)(2) failing to ensure that medications are given as ordered; (3) and § 70263(c)(1) failing to implement policies and procedures to minimize medication errors. The facility's failure to comply with these regulations both individually and collectively has caused or is likely to cause serious injury or death to a patient(s).	E 485		

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