CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION
	050145	A. BUILDING _____ B. WING _____

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMMUNITY HOSPITAL OF THE MONTEREY PENINSULA	23625 Holman Hwy, Monterey, CA 93940-5902 MONTEREY COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	CALIFORNIA DEPARTMENT OF PUBLIC HEALTH APR 11 2014 L & C DIVISION SAN JOSE The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident conducted on 11/13/13 through 11/19/13. For Entity Reported Incident CA00375500 regarding State Monitoring, Medication Error, a State deficiency was identified (see California Code of Regulations, Title 22, Section 70263(g)). Inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the hospital.		A) Main OR/PACU Hand-off Monitor-Tool created and will be completed on patients where IV medication drips are utilized. The form requires confirmation of the following activities: * Anesthesiologist-physical activity stops * Surgeon identified * Procedure stated * Intra-op medications reviewed * IV infusions labeled * Labels and clamps checked * Medication orders entered * Opportunity provided for questions * Patient Label attached. Responsible Person: Director, Main OR/PACU	12/18/13
			B) Medication Added Labels and Medication Added infusion label reminder posted in all OR Suites and placed on all Pyxis machines within the 8 Operating Rooms. Medication labels ordered for IV medication tubing labeling and their use has been implemented. The following information is required: * Patient/Room Number * Drug - Amount - Base Solution * Start Time-Date-Flow Rate * Expiration Date	10/17/13 11/16/13

Event ID:GS1B11 2/18/2014 10:58:16AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Jessie Lowe TITLE VP Nursing (X5) DATE 4/9/2014

By signing this document, I am acknowledging receipt of the entire citation packet. Pages 1 thru 12

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	Representing the California Department of Public Health was 27000, Pharmaceutical Consultant II. Health and Safety Code Section 1279.1(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made. The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. Health and Safety Code Section 1280.1(c) (c) For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY. California Code of Regulations, T22 DIV5 CH1, ART3, Section 70263(g) (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.		* Added By_____ Responsible Person: Director, Main OR/PACU C) Memo sent to Anesthesia Services in reference to utilization of IV medications and application of medication labels. 12/2/13 Subject: Standardization of protocols on vasoactive medications for Carotid Endarterectomy Operations at Community Hospital. Responsible Person: Anesthesia Clinical Director D) Review of the first 15 out of 20 MOR/PACU Hand-Off Monitoring checklists have been completed. Data collected will be submitted and monitored by Quality Management. 12/18/13 Responsible Person: Director/Assistant Director MOR/PACU	

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	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. Based on interviews and medical record and document review, the hospital failed to provide safe medication use for one sampled patient (1) when a medication was administered without an order. Patient 1 was given Neo-Synephrine (generic: phenylephrine; a medication to immediately increase blood pressure in critical care settings) intravenously (IV, directly through the vein) without a physician order, resulting in a medication error. The medication error contributed to the significant medical complications the patient experienced during the recovery period after a carotid endarterectomy (a surgery to remove plaque build-up in the large artery on the side of the neck to prevent strokes). The complications included a "blown patch" (a patch sewn on the artery during surgery that was blown off), profuse bleeding, requiring tracheostomy (surgical opening through the neck into the trachea), one-hour code (an emergency situation where immediate medical attention was required) with cardiopulmonary resuscitation (CPR, emergency procedures to revive unresponsive patient), and a return to surgery. Consequently, the patient suffered from anoxic brain injury (injury caused by lack of oxygen			

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to the brain), loss of consciousness, and never regained consciousness. Patient 1 died 11 days after surgery.

Findings:

On 11/1/13, the California Department of Public Health received a report from the hospital indicating a potential care management event related to a patient's death associated with a medication error.

Patient 1 was admitted to the hospital on [redacted] for an elective carotid endarterectomy. Her diagnoses included high blood pressure (BP), a 30-year history of smoking, kidney cancer, and carotid artery stenosis (constriction of the inner surface of the large artery in the neck). The medical record indicated the surgery was conducted on [redacted] She was transferred to the post anesthesia care unit (PACU) at 9:48 a.m.

During an interview on 11/13/13 at 11 a.m. in the presence of the operating room (OR) director and the risk management director (Admin A), the PACU nurse (RN A) said she was the nurse assigned to care for Patient 1 after the surgery. She said when she received Patient 1 from the OR, there were two IV bags hanging on the IV pole: a big bag of Nipride (nitroprusside, medication for immediate reduction of blood pressure in hypertensive crises or to lower blood pressure to reduce bleeding during surgery) and a small bag (100 milliliters) of Neo-Synephrine. RN A said she did not know the small bag contained Neo-Synephrine because, she was told

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	later, it had a small white tape label and was facing the wall, so she did not see it. The Neo-Synephrine bag was not in use (meaning not running or run by the pump), however, the IV tubing was still connected to the patient. During this interview, RN A said the anesthesiologist (MD A) had mixed (prepared the medications) the Nipride and Neo-Synephrine bags in the OR and was administering the medications during the surgery. When the patient was transferred to the PACU, the Nipride was still running, and the Neo-Synephrine was turned off. The Nipride was later turned off due to BP being below the prescribed parameters. She said typically, in her 10-year experience in the PACU, patients coming from the OR would not have orders for Nipride or Neo-Synephrine. RN A said during the hand-off (process of passing patient-specific information from one caregiver to another, or from one team of caregivers to another), it was not communicated to her there was a bag of Neo-Synephrine. During the same interview above, RN A said post surgery, the patient was able to communicate with her, and complained about headache and tingling of the hands. RN A said these complaints were prior to the medication error. RN A said shortly after the Nipride was turned off, the BP started going up. She said she gave the patient two doses of labetalol (to treat high BP) 2.5 mg each but they did not help. The medical record showed the labetalol doses were given at 10:15 a.m. and 10:20 a.m.			

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	During the same interview as above, RN A explained that the IV tubing for Neo-Synephrine had two clamps: the safety clamp (which was located above, closer to the IV bag, the one to be inserted into the pump when in use) and the roller clamp (located below the safety clamp). When the IV tubing was disconnected from the IV pump, its safety clamp was automatically put in the closed position (a safety mechanism to prevent inadvertent free flow when the infusion set is removed from the pump). RN A said she was "keeping an eye out on the patient constantly" and at the same time trying to "clean up" the IV tubing to get the patient ready for transfer to the Intensive Care Unit (ICU). By doing this, RN A said she returned the safety clamp to its open position without ensuring the roller clamp was closed. RN A said she did not realize the roller clamp was in open position. Consequently, the Neo-Synephrine was allowed to free-flow through the IV tubing into the patient. RN A said at approximately 10:40 a.m., the patient complained of pain at the surgical site. She then came to the bedside to look at the dressing and noticed blood on the outside of the bandage. The patient's systolic blood pressure at the time went up to 214 mmHg (millimeters of Mercury; unit of measure; expected range was from 130 - 140 mmHg). RN A said she immediately applied pressure to the surgical site and called for help. MD A and the surgeon along with other caregivers immediately rushed in. When asked how long the Neo-Synephrine was accidentally infused, RN A and the OR director said that could not be			

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	determined. RN A said, "It was just a matter of seconds." The manufacturer of Neo-Synephrine (phenylephrine) indicates it is a powerful vasoconstrictor, a drug that causes the blood vessels to constrict, which causes an increase in arterial blood pressure. It is intended for the treatment of severe hypotension (low blood pressure), shock, and for the maintenance of an adequate level of blood pressure during spinal and inhalation anesthesia (www.dailymed.nlm.nih.gov; accessed 11/19/13). In the 2012 List of High-Alert Medications, the Institute for Safe Medication Practices (ISMP), a nationally recognized organization focusing on safe medication practices, listed phenylephrine as one of the high-alert medications, those that bear a heightened risk of causing significant patient harm when they are used in error. On 11/13/13 at 1:05 p.m., in the presence of Admin A and a medical record staff, MD A said he mixed the Nipride and Neo-Synephrine bags for patient use in the OR (medication vials were added to a base solution; all were obtained from the automated dispensing cabinet, not pharmacy-delivered). The Neo-Synephrine was 10 milligrams in 100 milliliter solution (10 mg/100 ml) bag. MD A said he did not label the Nipride bag. As for the Neo-Synephrine bag, MD A said he used a marker pen to label directly on the bag with its name and concentration after he mixed it. He said he did not use the hospital sticker to label the bag. MD A stated he			

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	determined Patient 1 may need the Nipride and Neo-Synephrine in the PACU, therefore, did not disconnect the IV lines from the patient when the patient left the OR. MD A further explained when he was later called in for immediate help, he discovered the Neo-Synephrine bag was running. He immediately threw the bag to the floor to stop the infusion and disconnected the IV tubing from the patient (the bag was later tossed away). When asked if the Neo-Synephrine administration error played a role in the complications the patient experienced, MD A said, "Certainly. It increased the blood pressure. That's what caused the problem." On 11/13/13, a review of an anesthesia note addendum, dated 11/13/13, indicated MD A "discovered the medication bag labeled Neo-Synephrine 10 mg/100 ml open to patient. Infusion discontinued and disconnected from pt (patient)." During an interview on 11/13/13 at 1:50 p.m., Admin A said when RN A "tried to clean up" she put the safety clamp back into the open position, she should have closed the roller clamp to prevent accidental free-flow. Admin A said on 11/4/13, the hospital conducted the root cause analysis (a method of problem solving to identify the root causes of faults or problems). She explained the patient's condition was already compromised before the medication error happened by her BP already going up, and she was complaining of headache, sore throat, and tingling in the hands. Admin A acknowledged the medication error contributed to			

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the increase in the patient's BP, but whether it was the only factor causing the complications, she said the hospital could not make that determination.

During the interview above, Admin A provided the 8.5 x 4.75 inch Instruction Sheet, which came with every IV tubing set (SmartSite Infusion Set, made by CareFusion, used to deliver Neo-Synephrine for Patient 1). It had a clearly written all-caps instruction under Warning: "TO PREVENT FREE-FLOW, CLOSE SET CLAMP WHEN SAFETY CLAMP ON PUMP SEGMENT IS OPEN."

A review of 10/2011 CareFusion's publication online titled "Alaris Pump module FAQs" on 11/18/13 reflected that the set roller clamp is the primary safety mechanism to regulate the infusion rate and to prevent or stop flow to the patient. The safety clamp is the secondary safety mechanism. (http://www.carefusion.com/pdf/Infusion/clinical_documentation/faq_tip_sheets/IF0898-02_Alaris_Pump_module_FAQ.pdf; accessed 11/18/13).

The PACU record indicated the following of Patient 1's BP (obtained from arterial line) and other assessments during the PACU stay on [redacted]

Time	BP	Assessments
9:58 a.m.	138/51	asleep, sedated
10:00 a.m.	133/52	patient states no signs of pain
10:05 a.m.	135/44	patient more awake; able to cough
10:10 a.m.	146/55	patient reports headache; weak movement

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	10:15 a.m. 152/57 patient states moderate pain headache; awake, conversant; oriented to person, place, situation 10:30 a.m. 157/56 patient states moderate pain headache 10:40 a.m. 161/56 patient states moderate pain headache; medication; effective for short intervals 10:45 a.m. 214/96 patient states severe pain right neck surgical site During a review of the above information with the OR director on 11/13/13 at 4:45 p.m., he said he thought the medication error happened sometime between 10:40 a.m. to 10:45 a.m. (on [redacted] as the blood pressure increased significantly during that period. Lexi-Comp online, a nationally recognized drug information resource, indicates Neo-Synephrine has an immediate effect when given intravenously. On 11/13/13, a review of Patient 1's medical record revealed there was no physician order to administer Neo-Synephrine post-surgery. This was confirmed with Admin A and OR director on 11/13/13 at 4:50 p.m. The first Operative Report (the report from the surgeon after the first surgery), dictated [redacted], indicated the incision was made in the common carotid artery (large blood vessel in the neck) to remove the plaque and a Hemashield patch (an ultra-thin patch used for cardiac and vascular patch			

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grafting) was sewn in place. It indicated the patient had a successful surgery, was awakened in recovery room in good condition.

The second Operative Report, dictated [redacted] indicated the surgeon was called emergently to the recovery room because of respiratory (breathing) distress. It indicated "the patient had suffered an episode of severe hypertension (high blood pressure), followed by massive rapid bleeding into the neck, requiring an attempt at intubation (a tube inserted into the trachea (windpipe) to maintain an open airway to aid breathing), which was not successful, requiring opening the wound and tracheostomy," and, "the patient was also undergoing cardiopulmonary resuscitation, which was continued for close to an hour." The patient was transported back to the OR for a second surgery to remove the Hemashield patch and to close the wound.

The Discharge Summary, dated [redacted], indicated Patient 1 suffered from "anoxic brain injury after prolonged hypotension due to a cardiac code," respiratory failure, "pulseless electrical cardiac arrest following a right carotid endarterectomy on [redacted], unconscious, and "status post right endarterectomy with complications with a blown patch and profuse bleeding, hypotension requiring a tracheostomy, and 1-hour code with CPR."

The medical record revealed Patient 1 was transferred to the ICU after the second surgery on [redacted], was put on comfort care on [redacted] and

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	she died on [redacted], 11 days after surgery. RN A's administration of Neo-Synephrine to an already hypertensive patient with a fresh carotid artery patch without an order has caused, or was likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the California Health and Safety Code Section 1280.1(c). This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).			

MOR/PACU Hand-off Monitoring

Date:_____

Time:_____

- ☐ Anesthesiologist-physical activity stops
- ☐ RN- physical activity stops
- ☐ Surgeon identified
- ☐ Procedure stated
- ☐ Intra-op meds reviewed
- ☐ IV infusions labeled
- ☐ Labels and clamps checked
- ☐ Medication orders entered
- ☐ Opportunity provided for questions

"Do you have any questions before I go?"

Place Patient Label Here

[redacted]

PURPOSE

To support the organization's goal of improving patient safety by limiting the use of verbal orders.

DEFINITION

Verbal orders for patient care are those orders that are oral, spoken communications, transmitted face-to-face, by telephone or other auditory device.

POLICY

A. Verbal orders should be limited to situations where immediate written or electronic communication is not feasible. Verbal orders are not accepted when the prescriber is present, unless it is impossible for the order to be written down or entered electronically by the prescriber.

B. Verbal orders can only be given by a member of the medical staff, including allied health professionals such as physician assistants and nurse practitioners, credentialed by the facility in which the care will be provided (CHOMP and it's satellite facilities, Westland House, Hospice of the Central Coast) and those authorized by medical staff physician order protocols (pharmacists and respiratory therapists).

C. Verbal orders must be within the scope of practice of the person receiving the order.

D. Read-back is required for all verbal orders.

E. All verbal orders require review and signature (including electronic) by the prescriber within a designated time frame based on the facility in which the care is being provided. If necessary, another physician assuming responsibility of the patient's care may electronically sign the verbal medication order in the absence of the prescriber. This signature indicates that the covering physician assumes responsibility for his/her colleague's order as being complete, accurate and final.

   1. CHOMP: within 48 hours
   2. Westland House: within 72 hours
   3. Hospice of the Central Coast: within 30 working days.

Verbal Orders for Tests, Procedures, or Care

A. Within the scope of their practice, persons authorized to accept verbal orders include:

   1. registered nurses (RN)
   2. licensed vocational nurses (LVN)
   3. registered pharmacists (RPh)
   4. respiratory therapists (RCP)
   5. licensed psychiatric technicians (LPT)
   6. registered dietitians (RD)

[redacted]

7. occupational therapists (OTR/L)
8. speech therapists (ST)
9. physical therapists (PT)
10. sonographers

B. A complete verbal order includes:

1. name of patient
2. test/procedures or care to be provided
3. medical necessity or diagnosis for outpatient tests/procedures
4. date and time order is to be completed or frequency/duration
5. patient specific instructions if applicable

C. Persons receiving verbal orders will enter them directly into the patient's record using the Order Source *Verbal Order or Telephone Order*, if appropriate.

Verbal Orders for Medication

A. Within the scope of their practice, persons authorized to accept verbal medication orders include:

1. registered nurses (RN)
2. licensed vocational nurses (LVN)
3. registered pharmacists (RPh)
4. respiratory therapists (RCP)
5. licensed psychiatric technicians (LPT)
6. registered dietitians (RD)

B. A complete verbal medication order includes:

1. name of patient
2. age and weight of patient, when appropriate
3. drug name, dosage form, strength and concentration
4. dose, frequency and route
5. quantity and/or duration
6. purpose or indication for as needed (PRN) medications
7. name of prescriber
8. date and time of order

C. Persons receiving verbal medication orders will enter them directly into the patient record using the Order Source *Verbal Order* or *Telephone Order*, if appropriate.

[redacted]

D. Read back of medication orders should include verbalization of:

1. the name of the drug and spelling if it is a Look Alike/Sound Alike Drug (e.g. spell back "GLIPIZIDE")
2. verbalization of the dose such as 50 mg as "That's fifty milligrams, five zero milligrams"
3. instructions for use without abbreviations (i.e. 1 tab TID should be "Take/give one tablet three times daily"

E. Special circumstances:

1. verbal orders **WILL NOT** be accepted for antineoplastic agents; the preprinted chemotherapy order form must be used
2. verbal orders **WILL NOT** be accepted for investigational drugs
3. clarification of an original medication order can be verbal.

CONTENTS	DESCRIPTION
Submitted by:	Mariann Novarina, RPh, Director, Pharmacy Services
Next review date:	2013
Effective date:	2010
Applicable to:	All CHOMP departments
Approved by:	Interdisciplinary Quality Committee August, 2010 Medical Executive Committee September 2010
Reviewed by:	Patient Care Committee August, 2010
Replaces:	November 21, 2006 version
References:	CMS interpretive guidelines, TJC RC02.03.07, MM04.01.01, PC02.01.03
Key Words:"	verbal orders, verbal medication orders
Distribution:	CHOMP Intranet – Clinical Department manual
Additional information:	
Related policies or programs:	Acceptable medication orders 3.1

I. Post anesthesia assessment is a systematic and continuous process performed by a Registered Nurse.

II. The initial assessment begins prior to admission to PACU by utilizing data documented in SCM by the admitting RN. This date, in conjunction with the type of anesthesia, surgical procedure, patient age and cultural preferences, allow the PACU RN to formulate a preliminary plan of care and determine the level of post procedure care.

III. At the time of admission to PACU the patient's response to the procedure and other pertinent data to include vital signs, medications, IV fluids given during procedure, and fluids and medications to be continued post operatively is communicated to the PACU RN by the anesthesiologist and by the written intraoperative record. This data in conjunction with the PACU RNs initial assessment is analyzed and the plan of care is modified as appropriate.

IV. On admission to and discharge from the post anesthesia recovery are the post operative status of the patient is assessed using an anesthesia approved scoring system. The patient is monitored continuously during the post operative period and discharged from the post anesthesia recovery area by physician order.

V. Patients are assessed at regular intervals during care to determine the patient's response to care. A significant change in the patient's condition or diagnosis results in reassessment.

VI. Staff base patient care decisions on identified patient needs and priorities utilizing patient assessment information. Assessment data is documented in SCM and communicated to appropriate clinical disciplines as needed.

Submitted by:	K. Burke, RN Asst. Director PACU, T. Housen, RN Director PACU
Next review date:	6/2016
Effective date:	12/2013
Applicable to:	PACU
Approved by:	2/95
Reviewed by:	1998, 2001, 2006, 2009, 12/2013
Replaces:	2009
References:	
Key Words:	Scope of Assessment
Distribution:	PACU P&P
Additional information:	P&P/PACU/COP\ScopeOfAssessment
Related policies or programs:	Post Anesthesia Patient Assessment

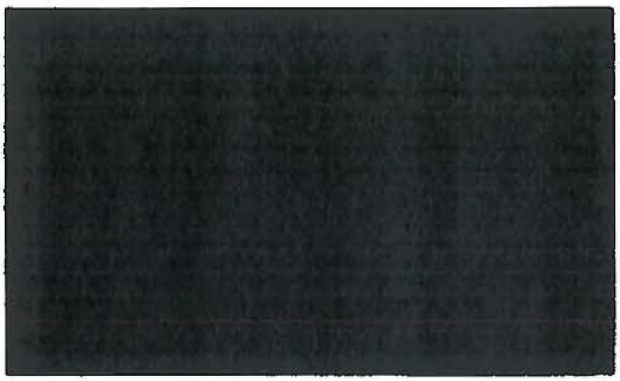
[redacted] | [redacted]

EPHEDRINE EPHEDRINE

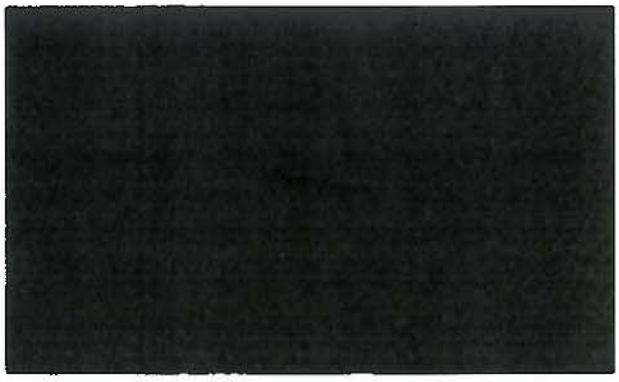
[redacted]

[redacted]

Label all medication infusion bags with the following information:



Label all medication infusion bags with the following information:



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Community Hospital
of the Monterey Peninsula
MEDICAL STAFF SERVICES

MEMORANDUM

TO: All Members of the Division of Anesthesiology; Ventana Anesthesia

FROM: Matthew Fritsch, MD – Division Chair

DATE: 12/02/2013

SUBJECT: Standardization of protocols on vasoactive medications for Carotid Endarterectomy operations at Community Hospital

The plan of correction from the recent Root Cause Analysis meeting with the quality management department of Community Hospital and the members of Ventana Anesthesia Associates have agreed that for all CEA cases in the future, an infusion pump will be present in the operating room with the pharmacy standard nitroglycerin infusion. No other standard infusions will need to be pre-ordered. Should another vasoactive medication infusion be needed during the operation, the anesthesiologist will order the **pharmacy standard** infusion if there is enough time before administration. If there is not enough time or if the concentration of the infusion that the anesthesiologist wants is different than the pharmacy standard, then the anesthesiologist will make their own infusion. However, this infusion will be discontinued and/or switched to the **pharmacy standard prior to transferring care in the PACU**. Any "handmade" infusion will be labeled with drug name, total bag dosage, and dosage per milliliter on an orange adhesive drug label provided in all anesthetizing locations. Signing and dating the label is preferred but not necessary. The OR staff have agreed to have these adhesive labels readily available in all operating locations. In addition, PACU sign-out will be a more formal process. The accepting PACU nurse must stop all activities and listen solely to the anesthesiologist during the sign-out. The PACU has agreed to supply a second nurse to attend to the patient while the primary nurse is receiving sign-out. All vasoactive medications in line to the patient will be explicitly pointed out to the accepting nurse. Lastly, over then next month, M. Fritsch will be having all PACU nurses sign-off on completing a tutorial on vasoactive infusions. They must complete this with Fritsch and be cleared by Kathleen Burke.

Thank you for your compliance on this.

Sincerely,

Matthew Fritsch