CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CJA IDENTIFICATION NUMBER:
052033

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
05/29/2018

NAME OF PROVIDER OR SUPPLIER
Vibra Hospital of Sacramento
STREET ADDRESS, CITY, STATE, ZIP CODE
330 Montrose Drive, Folsom, CA 95630-2720 SACRAMENTO COUNTY

(X4) ID
PREFIX
TAG

(X5) ID
PREFIX
TAG

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LEG IDENTIFYING INFORMATION)

The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA00424314 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 2204, HFEN

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.

Health and Safety Code Section 1280.3(g): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

Health and Safety Code 1279.1 Medication Error
(b) For purposes of this section, "adverse event" includes any of the following:
(4) Care management events, including the following:
(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

The facility detected the Adverse Event on 12/14/14. The facility reported the Adverse Event to the Department on 12/19/14.

The following plan of correction is intended to demonstrate the facility's commitment to compliance with applicable state and federal regulations. The statements set forth below shall not be construed as an admission or constitute agreement with the deficiencies alleged. The facility has taken the actions set forth in the following plan of correction by the dates indicated.

Event ID:6DNL.11
7/25/2018 2:53:12PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
By signing this document, I am acknowledging receipt of the entire citation packet.

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.
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X4) PROVIDER/SUPPLIER CLIA IDENTIFICATION NUMBER: 052033

05/29/2018

STREET ADDRESS, CITY, STATE, ZIP CODE
330 Montrose Drive, Folsom, CA 95630-2720 SACRAMENTO COUNTY

NOMINEE OF PROVIDER OR SUPPLIER
Vibra Hospital of Sacramento

SUMMARY STATEMENT OF DEFICIENCIES
Each deficiency must be preceded by full regulatory or LSC identifying information.

The facility notified the patient/responsible party on 12/14/14.

Adverse Event Notification - Informed
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 1279.1: (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 2 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

The Department verified the facility reported the adverse event to the Department within the mandated time frame.

Health and Safety Code 1280.3: (a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a
deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars ($75,000) for the first administrative penalty, up to one hundred thousand dollars ($100,000) for the second subsequent administrative penalty, and up to one hundred twenty-five thousand dollars ($125,000) for the third and every subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.

T22 DIV5 CH1 ART3 702363(c) Pharmaceutical Services General Requirements

(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.

T22 DIV5 CH1 ART3 702363 Pharmaceutical
Services General Requirements

(g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient’s medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours.

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

An unannounced visit was made to the facility on 12/20/2014 to investigate complaint number CA00424314, The Department determined the facility failed to administer medications as prescribed by the physician and in accordance with facility policy. It also failed to develop and implement policies and procedures for establishment of a safe and effective system for the storage, dispensing, and use of drugs when:

1) Patient A was given 1500 - 4000 micrograms (unit
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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Vibra Hospital of Sacramento

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330 Montrose Drive, Folsom, CA 95630 2720 SACRAMENTO COUNTY

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1. **Summary Statement of Deficiencies**

   of measure) of undiluted Levophed by direct injection into the vein at a strength of 3000-8000 times the ordered dose. (Levophed is a common name norepinephrine bitartrate, a medicine used to treat a patient with low blood pressure resulting from shock; it is delivered with an infusion pump through a vein.) Both the physician order and facility policy required Levophed to be administered diluted using an IV continuous drip infusion.

2. The facility administered Levophed without determining the patient's MAP (mean arterial blood pressure - an average blood pressure present in the arteries) prior to administration. The physician order required Levophed to be administered when Patient A's MAP was 65 or below.

3. The facility failed to follow its policy and procedures for administration of Levophed when it failed to conduct concentration, dosing, and administration monitoring and verify that the pharmacy label described the correct medication and amount, type and amount of diluent, date and time prepared and initials/name of the person preparing the solution.

4. The facility failed to have policies and procedures preventing storage of Levophed in the concentrated form in a vial in the Medication Dispense Machine (MDM) without added physical safeguards commonly used for a High Alert Medication warning label. A high alert medication is a drug that has a heightened risk of causing significant patient harm when used in error. LN 1 administered this vial rather than the diluted IV continuous drip infusion placed in the refrigerator by the pharmacy.

The medication error caused Patient A's heart to

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**Corrective Action**

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<td>Vasoactive Drip Policy reviewed with current ICU RN's.</td>
<td>RN Educator</td>
<td>1/26/2015</td>
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<td>ICU RN competencies reviewed and approved.</td>
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<td>Added to automated dispensing system an alert for Levophed: MUST BE DILUTED IN 250ml For IV Infusion Only. Not for IV push.</td>
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**Event ID:**8DNL11

**7/25/2018 2:53:12PM**

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**Page 5 of 13**
immediately stop beating effectively and caused Patient A's subsequent death.

Findings:

Patient A was admitted to the hospital in October 2014 and was transferred to the intensive care in early December 2014 when his heart started beating rapidly. According to a physician progress note dated 12/11/14, Patient A's heart rate was controlled (within normal limits). Review of Patient A's Interdisciplinary Team Meeting Care Conference record dated 12/10/14 indicated the discharge plan was to send Patient A to a Skilled Nursing Facility.

A review of Patient A's clinical record revealed a document titled All Orders Report - Detail, which noted the following physician order dated 12/10/14 at 9:14 [a.m.]: "Norepinephrine Bitartrate 1MG [milligram - unit of measure] Dose: 4MG Dextrose 5% SOLN [Solution] Dose: 250 ml [milliliter - unit of measure] Drip Rate: 1ML Per: HR [hour] IV...CONC [concentration]= 16 mcg/ml RATE: 0.5 mcg/min [micrograms per minute] or as prescribed my [sic] MD [Medical Doctor]...as directed by MD until target BP [blood pressure] reached...Keep MAP > 65...High Alert Medication [a high alert medication is a drug that has a heightened risk of causing significant patient harm when used in error]." The physician ordered patient A to receive diluted Levophed at an IV drip rate of 1 ml per hour (0.5 microgram/minute) when patient MAP was below 65.

Review of Patient A's documented vital signs

Event ID:8DNL11

7/25/2018 2:53:12PM
(recorded 16 times) from 12/13/14 at midnight through 12/14/14 at 0742 (7:42 a.m.) indicated Patient A's MAP (normal range is 70-110 and a map below 60 is unsafe) ranged from 61-91. The last recorded MAP at 7:42 a.m. on 12/14/14 was documented as 78.

A review of Patient 1's Medication Administration Record (MAR) indicated Levophed 4 mg (4000 mcg) was given IV on 12/14/14 at 08:47 (8:47 a.m.) by Licensed Nurse (LN) 1. There was no documented evidence that LN 1 assessed or otherwise determined that Patient 1's MAP was below 65 prior to administration.

During an interview with LN 2 on 12/20/14 at 3:22 p.m., she stated she was in the med room while LN 1 was retrieving the meds [for Patient A] and she verified that she was the cosigner for LN 1 on 12/14/14. LN 2 stated she was not aware that LN 1 drew up a vial of Levophed to give IVP (rapid direct injection directly into the vein) and that she never looked at the medication being given.

During an interview with LN 1 on 1/14/15 at 3:25 p.m., she stated she pushed the touch screen for each of Patient A's meds due at 9 a.m. and did not read the touch screen instructions written for Levophed to be diluted in 250 ml of D5 and given as a drip. LN 1 stated she was not paying attention to the charted vital signs prior to her shift where the patient was within parameters and did not need Levophed per physician's order (Patient A's MAP was not below 65, which was the physician criteria for administration of Levophed). LN 1 stated she had
never given Levophed and did not research it or
double check with the co-signer about the
medication administration. LN 1 stated that Patient
A "coded" (Patient A's heart stopped) during
administration of the Levophed before she gave the
full volume she had drawn up. LN 1 stated she
realized what had happened afterwards when she
saw the mixed IV bag with Levophed for Patient A in
the refrigerator in the medication room.

The facility policy titled Vasoactive Drips
Norepinephrine dated 7/27/09 indicated the
following: "Obtain prepared IV solution from the
pharmacy... Verify the Pharmacy label correct
medication and amount, type and amount of diluent,
date and time prepared and initials/name of the
person preparing the solution... Do not infuse
Levophed above 20 mcg/min unless specified by the
physician... Check the concentration of each new
bag to verify that the same concentration is being
added... Document the dose (in micrograms per
minute) and the infusion rate..."

The facility policy titled Restrictive Guidelines for
I.V. Infusion Medications Which Registered Nurse
May Administer revised 5/2012 indicated the
following: "This list is provided to serve as a
guideline for the use of intravenous infusion
medications: Ordered for Continuous infusion... With
significant side effect profiles. It is required that
these I.V infusion drugs be administered by a
controlled infusion device, i.e. I.V. pump. Maximum
concentrations are given for use in fluid restricted
patients... Norepinephrine... Drug Classification and
Use... Temporary blood pressure control for acute
### REVIEW OF THE DOCUMENT TITLED PATIENT CARE NOTES

Review of the document titled Patient Care Notes dated 12/14/14 included the following nursing note at 0904 (9:04 a.m.): "...heart rhythm converted and patient went into vfib [ventricular fibrillation - a serious cardiac rhythm disturbance which causes the heart to quiver and not pump any blood, resulting in cardiac arrest]."

The document titled Full Disclosure Zoom in Report in Patient A's clinical record, dated 12/14/14 at 0900 (9 a.m.), included an electrocardiogram (ECG - a record of the electrical activity of a person's heart) that displayed the onset of vfib.

Further review of Patient A's clinical record included a document titled Emergency Cardiopulmonary Record dated 12/14/14 which indicated the following entries:

<table>
<thead>
<tr>
<th>Time</th>
<th>ECG Rhythm</th>
</tr>
</thead>
<tbody>
<tr>
<td>0902 (9:02 a.m.)</td>
<td>vfib</td>
</tr>
<tr>
<td>0906 (9:06 a.m.)</td>
<td>vfib</td>
</tr>
<tr>
<td>0907 (9:07 a.m.)</td>
<td>vfib</td>
</tr>
<tr>
<td>0909 (9:09 a.m.)</td>
<td>vfib</td>
</tr>
<tr>
<td>0910 (9:10 a.m.)</td>
<td>vfib</td>
</tr>
<tr>
<td>0911 (9:11 a.m.)</td>
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### SUMMARY STATEMENT OF DEFICIENCIES

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<tr>
<td></td>
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<td>hypotensive states [sudden onset low blood pressure]. Concentration, Dosing, and Administration Information. Standard Concentration: 4mg/250mL D5W or NS (16mcg/ml). Dosing information: Initial Dose: 0.5-1 mcg/minute. Titrated to maintain SBP [systolic blood pressure] of 90-100mmHg. Monitoring Parameters: Blood Pressure, ECG, Heart rate, Arrhythmias. Cautions: Arrhythmias. VFib.</td>
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<td>Event ID:8DNL11 7/25/2018 2:53:12PM</td>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

052033

A BUILDING

05/29/2018

NAME OF PROVIDER OR SUPPLIER

Vibra Hospital of Sacramento

STREET ADDRESS, CITY, STATE, ZIP CODE

330 Montrose Drive, Folsom, CA 95630-2720 SACRAMENTO COUNTY

SUMMARY STATEMENT OF DEFICIENCIES

ID

PREFIX

TAG

0913 (9:13 a.m.) Ecg rhythm...vfib
0914 (9:14 a.m.) Ecg rhythm...vfib
0916 (9:16 a.m.) Ecg rhythm...vfib
0926 (9:26 a.m.) Ecg rhythm...asystole of electrical activity.

Box marked which read "Expired [Patient died]."

Review of the document titled Certificate of Death issued on May 30, 2016, indicated the immediate cause of death was noted to be cardiac arrest.

During a tour of the Intensive Care Unit (ICU) on 12/20/14 at 11:13 a.m., the MOM was located behind a locked door at the back of the nurse's station.

Further observations of the medication room included a refrigerator on one side of the room, directly across from that was the MDM. The refrigerator contained premixed IV medications dated and labeled by the pharmacy. On the wall above the MDM there were postings of a variety of medications and the method they were to be administered. The medication Levophed was on one of the documents posted and was dated 2011. There were policy manuals and resource drug books in the medication room.

On 12/20/14 at 11:40 a.m. the Pharmacist (Pharm 1) demonstrated the use of the MDM in the ICU. Pharm 1 stated the laptop computer on the top of the machine controlled the drawers which dispensed the medications. Pharm 1 demonstrated the process for retrieving Levophed for Patient A from the MDM. Pharm 1 stated as the touch screen...
appeared on the laptop, "The nurse needs to touch the screen on the medications to be given at the time they are ordered to be given." Levophed had drop down information regarding its use. On the first drop down page the information presented as the following: "High Alert Medication: CONC [concentration] =16 mcg/ml [micrograms per milliliter - unit of measurement], Rate: 0.5mcg/min or as prescribed by MD [Medical doctor] Titrate [adjust to effect] increase by 2 mcg/min q [every] 5 min or as directed by MD until target BP [blood pressure] reached...High Alert Medication."

On the second touch screen drop down page the following information appeared: "Norepinephrine Bitartrate 1 MG/ML [milligram per milliliter - unit of measure] IV Check Order #0048851...Levophed in Dextrose 5, in Water [5% sugar water]...Do not administer undiluted solution. Requires infusion control device..."

On the third touch screen drop down page the following information appeared: "Norepinephrine Bitartrate 1 MG/ML SOLN [solution] 250 ML.
Ordered Route: IV scheduled time 12/14/14 0900 [9 a.m.], Order comments: High Alert Medication...Administration Detail: 12/14/14 0647 [8:47 a.m.] Nurse (LN) 1 and LN 2 electronic signatures."

Pharm 1 stated, "Now the drawer opens and medication can be obtained by the nurse." Pharm 1 further stated the MDM does not stay locked when Levophed is selected, or have any warning or reminders in place or any mechanism to prevent
removal of the concentrated vial from the drawer, even though the pharmacy premixed IV infusion of Levophed for Patient A was stored in the refrigerator.

Concurrent to the observations of touch screens, Pharm 1 said, "The nurse had three screens to tell her about the medication and there was a co-signature [from another LN] for the medication prior to administration."

Continuing the interview with Pharm 1 about the method of medication preparation for patients, he stated in this case, the Levophed was already mixed in a solution and stored in the refrigerator in the medication room in the ICU. The nurses have to dilute their own medications during afterhours such as during the night shift when new orders are given or in case of emergencies. Pharm 1 stated Patient A's infusion was ordered during the day shift. Pharm 1 added there was a vial of Levophed in the MDM in the concentrated form and there was no D5 [dextrose] solution attached to it for dilution. Nor was there a reminder or warning advising similarly, as is usually provided with high alert medications and attached to the vial itself.

According to Lexicomp online (retrieved 1/21/15), Levophed Dosage and Administration:
"...administered by IV infusion using an infusion pump or other apparatus to control the rate of flow...Prior to administration, the commercially available concentrate for injection must be diluted with 5% dextrose."

The Department determined the facility failed to
administer a medication as prescribed by the physician or in accordance with facility policy. It also failed to develop and implement policies and procedures for establishment of a safe and effective system for the storage, dispensing, and use of drugs. These failures, jointly, separately, or in any combination, resulted in non-compliance with one or more requirements of licensure and caused or was likely to cause serious injury or death.

This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).
<table>
<thead>
<tr>
<th>Corrective Action Taken</th>
<th>Responsible Person</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Added to automated dispensing system an alert for Levophed: MUST BE DILUTED IN DS 250ml. For IV infusion Only. Not for IV push.</td>
<td>Director of Pharmacy</td>
<td>12/14/2014</td>
</tr>
<tr>
<td>Levophed vial removed from automatic dispensing system and made Levophed vial part of a kit which included the medication vial, a 250 ml bag of admixture solution, mixing instructions and a label. (Items included in the label are: Drug Name, Amount of Drug, Type and Amount of Diluent, Concentration, Added By, Date, and Expiration Date). This coupled with the above information alerts will minimize this error from occurring again. This “kit” is only used when pre-mixed bag would not be available.</td>
<td>Director of Pharmacy</td>
<td>12/17/2014</td>
</tr>
<tr>
<td>Medication label inside Levophed kit updated to include “Beyond Use Date”.</td>
<td>Director of Pharmacy</td>
<td>8/3/2018</td>
</tr>
<tr>
<td>Levophed purchased as a premixed bag from pharmaceutical company and placed in ICU automated dispense system and on all Code Carts in hospital.</td>
<td>Director of Pharmacy</td>
<td>1/22/2015</td>
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<tr>
<td>Process changed for new, after hour orders for Levophed, 2 RN’s required to access and sign out Levophed from automated dispensing machine.</td>
<td>Director of Pharmacy</td>
<td>1/26/2015</td>
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<td>Intensive Care Unit closed until further re-education of ICU RN staff was completed.</td>
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<td>Vasoactive drip policy reviewed with ICU RN’s.</td>
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<td>ICU RN Core Competencies reviewed and approved.</td>
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<td>Daily assignment review and approval of ICU RN staff, in addition to review of upcoming schedule for ICU RN staff to ensure only ICU RN’s with current competencies are scheduled to work in the ICU.</td>
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Vibra Hospital of Sacramento  
Facility ID: 030000907  Penalty Number 030014283

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<td>Medication label inside Levophed kit updated to include “Beyond Use Date”.</td>
<td>Director of Pharmacy</td>
<td>8/3/2018</td>
</tr>
<tr>
<td>Single vial of Levophed is not available anywhere in the hospital except the pharmacy. (Now in a “kit”)</td>
<td>Director of Pharmacy</td>
<td>12/14/2014</td>
</tr>
<tr>
<td>Levophed purchased as a premixed bag from pharmaceutical company and placed in ICU and on all Code Carts</td>
<td>Director of Pharmacy</td>
<td>1/22/2015</td>
</tr>
<tr>
<td>Process changed for new, after hour orders for Levophed, 2 RN’s required to access and sign out Levophed from automated dispensing machine.</td>
<td>Director of Pharmacy</td>
<td>1/26/2015</td>
</tr>
<tr>
<td>Total of 29 RN’s and LVN’s received oral training on Verification of Medications.</td>
<td>RN Educator</td>
<td>12/21/2014, 12/22/2014, 12/23/2014</td>
</tr>
<tr>
<td>Vasoactive Drip Policy reviewed with current ICU RN’s.</td>
<td>RN Educator</td>
<td>1/26/2015</td>
</tr>
<tr>
<td>ICU RN Core Competencies reviewed and approved.</td>
<td>Chief Clinical Officer</td>
<td>1/5/2015</td>
</tr>
<tr>
<td>Daily assignment review and approval of ICU RN staff, in addition to review of upcoming schedule for ICU RN staff to ensure only ICU RN’s with current competencies are scheduled to work in the ICU.</td>
<td>Chief Clinical Officer</td>
<td>1/5/2015</td>
</tr>
</tbody>
</table>