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

- **Complaint Intake Number:** CA00275191 - Substantiated
- **Representing the Department of Public Health:** Surveyor ID # 27533, HFEN
- **Health and Safety Code Section 1280.1(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.
- **Penalty number:** 110009707
- **A001 1279.1(c) Informed Adverse Event Notification**
- **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.**

<table>
<thead>
<tr>
<th>(X4) ID PREFIX</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LGC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>A010 1280.1(a) Health &amp; Safety Code 1280</td>
<td>The following constitutes Marin General Hospital's plan of correction of the alleged deficiencies cited by the California Department of Public Health in the Statement of Deficiencies Form State 2567 dated January 29, 2013. Preparation and/or execution of this corrective action does not constitute admission or agreement by the provider of the truth of the facts or conclusions set forth on the Statement of Deficiencies. It has been prepared and/or executed solely because it is required by federal and state law.</td>
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Immediately after the event of 7/14/2011, an event investigation team convened and completed a Root Cause Analysis.

Hospital management carefully reviewed and documented its review of any allegations made as to employees to determine whether any disciplinary or corrective action was warranted as to acts or omissions by or related to such employees. These reviews were completed as to the RN employee on 7/14/2011. Employee matters are reviewed under the policies and procedures of the Department of Human Resources. These include a system of progressive disciplinary action for which the Executive Director of Human Resources, now titled Chief Human Resources Officer is ultimately responsible. Complete records of any such actions taken at the time are maintained and are available for on-site review.

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 disapprovable 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 disapprovable 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.

State-2587 FAC approved 2/19/13 (Facility notified)
Continued From page 1

(a) Subject to subdivision (d), prior to the effective date of regulations adopted to implement Section 1280.3, if a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

(See E485)

E 485 T22 DIV5 CH1 ART3 - 70263(g) (2)

(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.

The involved RN completed a medication administration competency, which included a medication test and a video presentation. She also completed a literature search on medication error reduction.

On 2/17/2011 the Pharmacy completed an evaluation of the automated dispensing cabinet (ADC) to determine the cause of the medication error. It was determined that the presence of labetalol injection in a multi-pocket drawer and noise and traffic near the ADC may have contributed to the error. The Director of Pharmacy Services determined that injectable beta blocker medications could be moved into a “cubie” drawer containing individual compartments with lids that open only when a specific medication is selected to minimize the risk of selecting a medication from the wrong compartment. The medication Labetalol was identified as one of the medications and was relocated to a “cubie”.

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On 2/17/2011 Pharmacy alerted all clinical units electronically in an e-mail that “Scan on Remove” (a bar code wand, used to read the bar code on the medication to ensure it is the correct medication) attached to the ADC medication stations and refrigerators would be implemented after staff education by demonstration at the ADC.

A one week trial occurred in the ICU starting on 3/23/2011 to identify any issues prior to implementing the change in all clinical units. Just-in-Time education by demonstration at the ADC occurred on all clinical units immediately prior to the implementation. After the successful ICU trial, Scan on Remove was expanded to several other nursing units with appropriate education prior to implementation. This was fully implemented and expanded to all nursing units by 5/12/2011. This was designed as an interim measure until the roll-out of bedside bar code electronic validation and documentation of medication administration.

Pharmacy, Facilities and Nursing identified 7 ADCs out of the total of 25 stations in the hospital as being located in high traffic public areas. All 7 were moved to either a supply room or a more private area out of the hallways. In addition, lighting was improved at 2 ADCs as a result of the evaluation. This was completed in April 2011. Subsequently six more ADCs were identified for relocation. This was completed mid-December 2011.
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normal levels.

Physician Progress Notes, dated [2011 indicated Patient 21 had improved. He was able to maintain a normal blood pressure without medications,

The Intensive Care Flow Record for [2011 indicated that at 3 p.m., Patient 21's blood pressure dropped from 112/65 to 81/42. At 3:30 p.m., Patient 21's blood pressure dropped to 51/30. Patient 21's heart rate also dropped, from the 90's to the 50's (Normal blood pressure range from 90/60-130/80. Severely low blood pressure reduces blood flow which, in turn, reduces the supply of oxygen and nutrients to the brain, kidneys, and other organs.)

Patient 21 was intubated and placed on a ventilator, to support respirations, and medications were restarted to raise Patient 21's blood pressure. Three hours later, at 6 p.m., Patient 21's blood pressure had finally reached 133/82.

During an interview on 07/07/11, Administrative Staff A stated at approximately 7 p.m., on [2011, Licensed Nurse R discovered an empty bottle of Labetalol 100 milligrams, an antihypertensive medication, hanging attached to Patient 21's IV tubing. Administrative Staff A stated Licensed Nurse R had pulled the incorrect medication from the Automated Drug Cabinet. Licensed Nurse R was unavailable for interview.

Physician orders and the Drug Administration

On 9/27/2011 the Pharmacy implemented bedside bar coding and it was decided to continue the process of "Scan on Remove". The policy and procedure for Medication Administration was revised to reflect this change. Nursing staff education by demonstration at the ADC on removing and scanning the drugs occurred prior to the roll-out on 9/27/2011. Nursing staff received education on the revised Medication Administration policy.

In an effort to further reduce the risk of medication errors and to enhance our efforts a team consisting of staff from nursing, pharmacy and quality was convened on 8/22/2011. The goal of the team is to identify areas of improvement related to safe medication administration. The team meets monthly.

In October 2011 two medication modules were added to the electronic courseware for RNs and LVNs for completion by December 2011.

Responsible Person

Vice President, Nursing Services

Monitoring

Two medication pass observation tools exist each consisting of 23 items encompassing the medication administration process. Nurse Managers counsel and reeducate staff when trends are identified. Non-
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Record (MAR), for Patient 21, dated prior and up to 07/11/2011, revealed no order for Labetalol, for Patient 21.

Physician progress notes for Patient 21, dated 07/11/2011, indicated the dose of Labetalol caused Patient 21 to develop prolonged low blood pressure and heart rate which resulted in cardiovascular shock. The observation that Patient 21 had stopped making urine, and changes in blood tests, indicated Patient 21 was in acute renal (kidney) failure due to the prolonged low blood pressure.

Physician progress notes, dated 07/11/2011, indicated that Patient 21's liver function blood tests continued to deteriorate indicating his liver had also been affected by the prolonged period of low blood pressure, resulting in ischemic hepatitis (shock liver).

Physicians progress notes, dated 07/11/2011, indicated that hemodialysis was started for continuing renal failure. Hemodialysis is a procedure for removing metabolic waste products from the bloodstream by filtering the blood through a dialysis machine.

A vascular surgery consult note, also dated 07/11/2011, indicated Patient 21 was discovered to have purple to blue discoloration to the base of the toes, approaching mid foot, of both lower extremities. The consultation indicated Patient 21 had only one pulse in the left lower extremity. Additionally, Patient 21 had discoloration in the fingertips of the left hand, all signs of impending ischemia.

compliant staff will be observed again to ensure compliance. If there is further non-compliance disciplinary action will occur such as remediation, counseling or discipline. The Manager, Accreditation and Regulatory Information will report quarterly to the Performance Improvement Committee for action on any identified trends.

The monitoring plan defined above was completed on 12/31/2011 following daily audits that evidenced sustained compliance.

| Event ID: 2HZX11 | 1/28/2013 | 10:27:53AM |

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Gangrene, (death of soft tissue).

A neurology consultation report, dated 11/11, indicated Patient 21 was fully alert but was confused, and had poor attention and concentration, likely due to the lack of oxygen he sustained, and also due to the build-up of toxic elements due to kidney failure and shock liver.

Physician progress notes, dated 11/11 to 11/11, indicated Patient 21's confusion was less, and blood tests indicated liver function was improving. However, Patient 21 continued to require hemodialysis for kidney failure. The discoloration of Patient 21's fingers and toes continued.

Physician progress notes, dated 11/11, indicated that Patient 21 could not bear weight because of the pain in his gangrenous toes.

During a psychosocial assessment dated 11/11, Patient 21 rated his emotional pain as 10, (on a scale of 0-10), about 98% of the time. Physician Progress Notes, also dated 11/11, indicated Patient 21 required intravenous Dilaudid to control the pain of his gangrenous toes and fingers. Patient 21 and his family discussed withdrawal of care with the physician.

Physician progress notes, dated 11/11, indicated Patient 21 expressed the wish to just go to sleep. Faced with a lifetime of continued dialysis, and with increasing pain from gangrenous toes and fingers, Patient 21 and his family decided to stop all treatment. Patient 21 died on 11/11.
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During observation and concurrent interview, on 07/07/11 at 4 p.m., bottles of Labetalol and Ceftriaxone were seen to be approximately the same size. The Labetalol was a liquid and the Ceftriaxone was a powder, which would require mixing with a liquid before administration. The labels were different colors, Labetalol pink, the Ceftriaxone was blue. The Labetalol bottle had the name of the drug clearly printed, as well as the dose, on the left side of the label on a light colored background. The Ceftriaxone name was printed with smaller letters while the dose was printed in larger letters inside a colored circle.

Administrative Staff U stated Labetalol was only given IV in small doses. The Director of Pharmacy concurred and said Labetalol was only given IV push, in small increments, not as a drip, as had been done.

The facility’s House wide Clinical Manual Patient Care Protocol entitled Medication Administration, last revised 8/10, indicated on page 4, step 8 the facility staff would observe the five rights of medication administration: “the right drug to the right patient.”

Licensed Nurse R failed to administer medications in accordance with physician orders, thus failing to ensure that the right medication was administered to Patient 21 and failed to prevent a medication error that resulted in renal failure and dry gangrene of all Patient 21’s toes and two fingers, which contributed to Patient 21’s death. This failure was a


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### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/Clinic Identification Number:** 050360
**Multiple Construction Date Survey Completed:** 07/11/2011

**Name of Provider or Supplier:** Marin General Hospital
**Street Address, City, State, Zip Code:** 250 Bon Air Rd, Greenbrae, CA 94904-1702 MARIN COUNTY

### Summary Statement of Deficiencies
(Each Deficiency Must be Preceded by Full Regulatory or LSC Identifying Information)

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Violation of Section 70263(g)(2) of Title 22 of the California Code of Regulations and was a deficiency that caused, or was likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1.

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).

<table>
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<tr>
<th>(X4) ID Prefix Tag</th>
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<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
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**Laboratory Director's or Provider/Supplier Representative's Signature**

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