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	(X3) DATE SURVEY COMPLETED
	050360	A. BUILDING _____ B. WING _____	06/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Marin General Hospital	250 Bon Air Rd, Greenbrae, CA 94904-1702 MARIN COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00269065, CA00276079, CA00274284 - Substantiated Representing the Department of Public Health: Surveyor ID # 27294, 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 1280.1(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: 110009908 A 001 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. A 010 1280.1(a) Health & Safety Code 1280		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 from State 2567 dated 5/29/2013. Preparation and/or execution of this evidence of corrective action does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. It has been prepared and/or executed solely because it is required by State law. Immediately after the event an investigation commenced. The involved Registered Nurses (RN) and Respiratory Therapist (RT) were interviewed for their accounting of the event. 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 employees on 5/11/2011 and the RT on 5/12/11. Employee matters are reviewed under the policies and procedures of the	7/14/11

Event ID:LHIM11 5/29/2013 3:21:27PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Joan L. McCready RN, Director, Quality Mgmt Svcs TITLE (X6) DATE 6/25/13

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s) 1 thru 9

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.

Plan of Correction reviewed & accepted. Facility informed - 6/27/13 B Nelson, HFEN

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	(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. This RULE is not met as evidenced by: E 1156 T22 DIV5 CH1 ART6 70493(a) Intensive Care Services General Requirements (a) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Policies and procedures shall include, but not be limited to: This RULE is not met as evidenced by: See Tag 1159, 1160, and 1164. E 1159 T22 DIV5 CH1 ART6 70493(a) (3) Intensive Care Services General Requirements (3) Routine procedures.		Department of Human Resources. These include a system of progressive disciplinary action for which the Executive Director of Human Resources is ultimately responsible. As required by the Respiratory Care Board the RT was reported to the licensing agency. Complete records of any such actions taken at the time are maintained and are available for on-site inspection in the Office of the Executive Director of Human Resources. In addition, management conducted an overall review of the applicable policies, procedures, bylaws and rules and regulations and any amendments thereto undertaken by the Department of Human Resources to ensure that the allegations contained in the deficiency report were adequately addressed by these policies. The policy and procedure entitled Patient Care Protocol Intubation, Assisting with, was revised to include time frames for assessment and reassessment of the patient during the intubation process by nursing and respiratory therapy. The policy was revised further to include a time-out procedure and assurance of adequate ventilation post-intubation. The time-out process includes documenting the	9/1/11

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	This RULE is not met as evidenced by: See Tag 1156, 1160, and 1164. E 1160 T22 DIV5 CH1 ART6 70493(a) (4) Intensive Care Services General Requirements (4) Emergency procedures. This RULE is not met as evidenced by: See Tag 1156, 1159, and 1164. E 1164 T22 DIV5 CH1 ART6 70495(a) (1) Intensive Care Service Staff (a) A physician with training in critical care medicine shall have overall responsibility for the intensive care service. This physician or his designated alternate shall be responsible for: The hospital violated the regulation by failing to implement intensive care policies and procedures when the respiratory therapist and three registered nurses did not provide reassessment and did not provide continued ongoing assessments with documentation of respiratory care given; including the intubation procedure, and Patient 11's response to the procedure according to the acute care hospital's policies and procedures. These failures contributed to Patient 11's death. These failures of the violations of Section, 70493(a), 70493(a) (3), 70493(a) (4) and 70495(a) (1) of Title 22 of the California Code of Regulations and was a deficiency		size and placement of the endotracheal tube, securing the endotracheal tube, connecting the patient to the ventilator, observations of pulmonary, cardiovascular and neurological status (e.g., observing the patient flow loop, chest rise, bilateral breath sounds, patient volume, and peak inspiration pressure, verifying pulse oximetry), observing heater settings and humidification, setting alarms, documentation and labeling of documents. The policy was approved by Nursing on 8/5/2011, the Medical Executive Committee on 8/15/2011 and the Quality and Patient Safety Committee on 8/23/2011. It is approved by the Board of Directors on 9/1/2011. The ventilator flow sheet was revised to include the RT and RN signature verifications of participation in the time-out checklist. This checklist is currently incorporated into the electronic health record (HER). The time-out process includes noting the size and placement of the endotracheal tube, securing the endotracheal tube, connecting the patient to the ventilator, observing pulmonary, cardiovascular, and neurological status (e.g., observing the patient flow loop, chest rise, bilateral	7/14/11

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	that caused, or was likely to cause, serious injury and death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1(a). Findings: A medical chart review was conducted on 06/30/11 that indicated Patient 11 was a 52 year old female admitted to the facility on [redacted]11, with diagnoses including respiratory failure due to pneumonia, kidney failure, seizure disorder, and sepsis. She required a ventilator (a mechanical device used to provide artificial ventilations breaths) as Patient 11 was unable to breathe on her own. During an interview on 06/30/11 at 10:45 a.m., Licensed Nurse L stated Patient 11 had been in the Intensive Care Unit (ICU) since [redacted]and had been on a ventilator most of that time. There had been a few attempts to wean Patient 11 from the ventilator without success. She stated on [redacted]11, the decision was made to try again to wean Patient 11 off the ventilator. Patient 11 was extubated around 10 a.m., and placed on bi-pap (a non-invasive form of breathing assistance) but continued to have difficulty breathing throughout the day. The decision was made to re-intubate Patient 11 and put her back on the ventilator. Licensed Nurse L stated Respiratory Therapist K and Physician I (who performed the intubation) and herself were present in the room. The whole procedure took about 5 minutes and was completed at 5:08 p.m. The intubation procedure went well and Licensed Nurse L gave report to Licensed Nurse N. Licensed Nurse		breath sounds, patient volume, and peak inspiration pressure, verifying pulse oximetry), observing heater settings and humidification, setting alarms, documentation and labeling of documents. All respiratory therapists were trained on the time-out checklist and Ventilator Flow sheet revision by 5/19/2011. Ventilator competency for RT's is done at hire and each time a new ventilator series is purchased or leased. Competencies are filed in the employee's personnel file. The competency requires a sign-off by the RT Manager or designated RT evaluator. All RNs in ICU complete a ventilator competency on hire. The competency includes a case study, written test questions and the time-out checklist. When the time-out procedure was developed RNs in ICU, ED, NICU, and Nursing Supervisors completed a competency. The competency requires a sign-off by the nurse evaluator. A time-out tool was developed to perform on the intubated patient after connection to the ventilator. The tool consists of 12	7/14/11

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	L stated when she left the room Respiratory Therapist K was taping the endotracheal tube (ET) and then connected the ventilator to the ET tube. She stated at that point the x-ray technician had arrived to do a chest x-ray, so they left the room including Respiratory Therapist K. Licensed Nurse L stated she did not know where Respiratory Therapist K went, and she did not see him again until 5:20-5:24 p.m., when they called the code. Licensed Nurse L stated she had not looked at the ventilator monitor until she returned to the room at 5:20 p.m. She stated it was then she looked at the monitor and saw no respiratory wave forms. The monitor read "waiting to be connected to patient." She also stated none of the ventilator alarms had sounded which indicated to her that the ventilator was not working. Licensed Nurse L stated the respiratory therapists are responsible for the functioning of the ventilators, including setting the alarms. Patient 11's cardiac monitor alarmed at 5:20 p.m. The monitor indicated Patient 11's heart rate to be low, in the 40's (normal range 60 - 80's) and her oxygen levels were about 60% (normal range- 95%-100%). Licensed Nurse L and Physician I, who were at the desk ran to the room and noted the ventilator monitor screen read "waiting to be connected to patient," which meant the ventilator was on "stand by" mode and was not providing breaths to Patient 11. Physician I immediately disconnected the ventilator from the endotracheal tube and initiated bag/mask manual breathing, and a chemical code was called (only emergency medications were given). The code was started at 5:24 p.m. and ended at 5:37 p.m. resulting in Patient 11's death. When Licensed		assessment items to ensure proper oxygenation of the patient. The time-out checklist was laminated and placed on every ventilator by 5/19/2011. The RT completes the time-out verification process using the checklist immediately after the patient is attached to the ventilator. The time-out checklist and signature verification for RT and RN's was implemented starting on 6/1/11 by Respiratory Therapy. Staff received education on the new requirements, including, assessments and reassessments time frames and documentation (RNs in ICU on 6/17/2011, RNs in NICU and ED by 7/14/2011.) RNs and RTs were educated to the practice change prior to the approval of the policy due to the significance of the event. Documentation of signature verification of the checklist process by both RT and RN's is in the HER. "Critical Care Services-Patient Care Protocol – Respiratory Care Standards" and ICU Plan of Provision of Care" documentation requirements were also covered. Responsible Person Vice President, Nursing Services	7/14/11 7/14/11

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	Nurse L was asked what the nurses' responsibilities were post-intubation, she stated the primary nurse should make sure the chest rises and falls, listen to the lung sounds, observe the ventilator monitor to make sure it is providing ventilations to the patient, observe respiratory wave forms on the monitor, make sure ET tube is secure, make sure oxygen levels are within normal limits. During an interview on 06/30/11 at 10:15 a.m., Physician I stated that after Patient 11 was intubated, he and Respiratory Therapist K checked the lung sounds and checked the carbon dioxide (CO2) monitor and everything was okay so he instructed Respiratory Therapist K to connect the ventilator to Patient 11's ET tube. Physician I stated he then left the room, and went back to the desk to complete his charting. Physician I stated he did not look at the ventilator monitor at that time. He stated usually the respiratory therapist stays in the room to make sure the ventilator is functioning properly. During an interview on 07/05/11 at 2 p.m., Licensed Nurse M stated that he was helping Licensed Nurse N reposition Patient 11 on [redacted]11 after the post intubation chest x-ray. Licensed Nurse M was asked if he had looked at the ventilator monitor or checked to see if Patient 11 was breathing he stated he had not, until Physician I and Licensed Nurse L came back into the room. When asked what were nurses' responsibilities post-intubation, Licensed Nurse M stated to listen to the patients' breath sounds, make sure the ventilator is giving ventilations to the patient, observe the patient's		Monitoring The Manager, Respiratory Care or designee is auditing all ventilator cases for RT and RN compliance with signature verification of the time-out checklist. Immediate action is taken by the nurse manager and the respiratory manager with non-compliant staff, including appropriate re-education or discipline. Data is analyzed and reported to the Performance Improvement Committee quarterly or more frequently if indicated for action of any identified trends. The respiratory therapists were re-educated regarding charting on all respiratory patients and the need to monitor closely for respiratory failure according to department policy "Respiratory Care Services Manual for Critical Care Department" page 4; and the new requirements for the Ventilator Flow Sheet on 6/15/2011. Charting is done at least every 2 hours on all ventilated patients, or any time the RT has an encounter with the patient and when any change in patient status occurs. Information Systems collaborated with nursing and respiratory	7/14/11 9/26/11

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	chest for rise and fall, look at the ventilator monitor for respiratory waves, and monitor blood pressure, heart rate, respiratory rate, and oxygen levels. During an interview on 07/25/11 at 2:45 p.m., Licensed Nurse N stated she had not assessed Patient 11's breathing after the ventilator was connected, but she had listened to Patient 11's lung sounds immediately following the intubation while Respiratory Therapist K was still providing manual breathing for Patient 11. During additional interview on 08/30/11 at 10:00 a.m., Administrative Staff A stated Respiratory Therapist K no longer worked at the hospital. Several attempts (06/30/11, 07/05/11 and 07/22/11) were made by telephone to contact Respiratory Therapist K without success. Administrative Staff A stated that on [redacted]11 the ventilator in question was examined by the hospital's biomedical engineers and the company who serviced the ventilators and was found to be in good working condition. During an interview on 07/06/11 at 2:45 p.m., Administrative Staff J stated their own investigation revealed the thermometer probe had been removed from the ventilator and the tubing had not been recapped which alerted the ventilator to go on stand-by mode. During observation on 07/06/11 at 3:00 p.m., Administrative Staff J demonstrated how the ventilators are checked for proper functioning. It was noted that when the cap was open on the		therapy staff to help facilitate documentation with the new electronic medical record by building screens that include all required documentation for the time-out procedure and documentation on the ventilator flow sheet to reduce inconsistencies. The implementation of an electronic health record for nursing and clinical ancillary services was completed 9/26/2011. In the interim (July 2011 until 9/26/11 a monitoring process was established (see below "Monitoring") and feedback and/or disciplinary action forthcoming to clinicians who are deficient on this standard. Responsible Person Manager, Respiratory Care Monitoring The Manager, Respiratory Care or designee is auditing all Ventilator Flow Sheets and counsels respiratory staff for compliance. Disciplinary action and/or education will be taken for repeated episodes of non-compliance. Data is analyzed and reported to the Performance Improvement Committee quarterly	9/26/11

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	thermometer probe tubing, the ventilator stopped and the monitor repeatedly flashed in large yellow letters, "waiting to connect to patient." When Administrative Staff J was asked if there was a ventilator check off sheet used when the ventilators were checked prior to use, she stated before the incident with Patient 11 the check off was done by memory. The Respiratory Therapist flow sheet dated [redacted]11 indicated that Respiratory Therapist K's had only documented on Patient 11 on [redacted]11 at 7:30 a.m. No other documentation was found. During interview on 07/05/11 at 10:00 a.m., Respiratory Therapist O stated they are required to document on the respiratory flow sheet and the ventilator flow sheet every two hours and as needed. This was confirmed also by Administrative Staff J, who stated she did not know why Respiratory Therapist K had only documented once on [redacted]11. The Hospital's Critical Care Services - Patient Care Protocol- Respiratory Care Standards, dated 02/2000; indicated that the RN/RT were to reassess and document lung sounds before and after procedure, patient's skin color before and after the procedure. The Respiratory Care Services Manual for the Critical Care Department dated 03/2008, indicated on page 4, that the patient was to be monitored closely for respiratory failure.		or more frequently by the Manager, Respiratory Care if indicated for action of any identified trends. The Chief Medical Officer met with the involved physician after the event to discuss the ventilator event. As part of the intubation process, the intubating physician will ensure correct tube placement, as well as ventilation and oxygenation of the patient. Following completion of the intubation process, when the patient is immediately connected to a mechanical ventilator, unless called out of the room for an urgent patient care need, the physician will remain in the room during the time-out check list procedure for verification of ventilation and oxygenation of the patient. When a physician is called out for an urgent patient need, the responsible RT or RN will verbally verify post-ventilator patient ventilation and oxygenation to the intubating physician as soon as possible. The RT documents on the ventilator tab in the electronic record that the physician's participation in the time-out or	7/14/11 12/6/11 12/6/11 12/6/11

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	The Hospital's Critical Care Patient Care Protocol for Assisting with Intubation, dated 03/2010; page 2, indicated that pre-procedure and post-procedure assessments should be documented and also the patient's response to the procedure, as well as re-assessments of pulmonary, cardiovascular, and neurological status. No timeframes for re-assessment were specified in the document. The Hospital's ICU Plan of Provision of Care, dated 2001, indicated a RN will complete a patient reassessment at least every 15 minutes and with changes in patient conditions and will assure the patient's safety throughout their stay. Therefore, the hospital violated the regulation by failing to implement intensive care policies and procedures when respiratory therapist and the three registered nurses did not provide reassessment and continued ongoing assessments with documentation of respiratory care given, including the intubation procedure and Patient 11's response to the procedure according to the acute care hospitals? policies and procedures. These failures contributed Patient 11's death. This failure was a violation of Section, 70493(a), 70493(a) (3), 70493(a) (4) and 70495(a) (1) of Title 22 of the California Code of Regulations and was a deficiency that caused, or was likely to cause, serious injury and death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1(a).		verbal communication that the patient is adequately ventilated. A memo from the Chief of Staff went out to all involved physicians on 12/6/2011 listing the changes made to the electronic medical record for the documentation required for physician participation in the time-out process for patient who are immediately connected to mechanical ventilation after intubation. Responsible Person Manager, Respiratory Services Monitoring The Manager, Respiratory Services or designee reviews the checklist on the ventilator tab of the electronic medical record to ensure the physician's participation is documented. Data is analyzed and reported to the Performance Improvement Committee, Chief of Staff, members of the Medical Executive Committee, and Chair, Pulmonary Division for non-compliance. A percentage of compliance is reported to the Medical Executive Committee monthly for action of any identified trends and will be addressed	12/6/11

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	The Hospital's Critical Care Patient Care Protocol for Assisting with Intubation, dated 03/2010; page 2, indicated that pre-procedure and post-procedure assessments should be documented and also the patient's response to the procedure, as well as re-assessments of pulmonary, cardiovascular, and neurological status. No timeframes for re-assessment were specified in the document. The Hospital's ICU Plan of Provision of Care, dated 2001, indicated a RN will complete a patient reassessment at least every 15 minutes and with changes in patient conditions and will assure the patient's safety throughout their stay. Therefore, the hospital violated the regulation by failing to implement intensive care policies and procedures when respiratory therapist and the three registered nurses did not provide reassessment and continued ongoing assessments with documentation of respiratory care given, including the intubation procedure and Patient 11's response to the procedure according to the acute care hospitals? policies and procedures. These failures contributed Patient 11's death. This failure was a violation of Section, 70493(a), 70493(a) (3), 70493(a) (4) and 70495(a) (1) of Title 22 of the California Code of Regulations and was a deficiency that caused, or was likely to cause, serious injury and death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1(a).		The SST is a 6 point check that tests the function of the following: flow sensor; circuit pressure; system leak test; expiratory filter; circuit resistance; and compliance and calibration. The results of the SST are stored in the ventilator's memory. Upon completion of the cleaning, testing, and labeling of the ventilator a plastic cover is placed over the machine. As an additional safety measure, custom plastic covers with locks were obtained. Responsible Person Manager, Respiratory Services Monitoring If a label is not present on a ventilator when the plastic cover is removed, the ventilator is retested before use. A log was developed to ensure all ventilators are cleaned and tested. Data is analyzed and reported to the Performance Improvement Committee quarterly or more frequently if indicated for action of any identified trends.	11/28/11 11/14/11