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
	050075	A. BUILDING _____ B. WING _____	06/24/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPITAL - OAKLAND/RICHMOND	280 WEST MACARTHUR, OAKLAND, CA 94611 ALAMEDA COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00232584 - Substantiated Representing the Department of Public Health: Surveyor ID # 17299, HFES 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. T22 DIV5 CH1 ART3-70213(d) Nursing Service Policies and Procedures. (d) Policies and procedures that require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff. This Statute is not met as evidenced by: Based on observation, staff interview, and record review, the hospital failed to ensure nursing staff followed hospital policy and procedures that required prompt responses to telemetry cardiac paging system alarms in order to provide appropriate cardiac care interventions and		Kaiser Foundation Hospital Oakland/Richmond presented a corrective action plan related to the entity reported event described herein to the CDPH surveyor on June 17, 2010 in order to respond to the surveyor's declaration of immediate jeopardy. Attached in this plan of correction are the actions that the hospital presented to the surveyor on June 17, 2010 in addition to a status report of where the hospitals is with the actions. RECEIVED JAN 09 2012 Licensing & Certification East Bay District Office	6/25/10

Event ID: 6XLN11 12/14/2011 9:22:25AM

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Sr. V.P. & Area Manager 1/9/12

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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continuous cardiac monitoring of patients. Patient A's cardiac monitor sent alarms to the nurse's paging system device which indicated rapid heart rates above 120 beats per minute and an notification of a low battery, neither of which was responded to after repeated alarm warnings. Patient A was found pulseless, unresponsive and in cardiac arrest. This failure resulted in Patient A sustaining anoxic encephalopathy (brain death) and subsequent death on [redacted]10.

THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ) WHICH PLACED THE LIFE AND SAFETY OF PATIENT A AT RISK WHEN FACILITY STAFF FAILED TO IMPLEMENT POLICIES AND PROCEDURES FOR CONTINUOUS CARDIAC MONITORING OF PATIENT A, RESULTING IN PATIENT A SUFFERING CARDIAC ARREST OF UNKNOWN DURATION PRIOR TO DISCOVERY.

Findings:

Patient A was brought to the hospital emergency department (ED) on [redacted]10 11:09 a.m. by ambulance with a complaint of shortness of breath (SOB). Physical examinations and laboratory test determined Patient A had a diagnosis of pneumonia, sinus tachycardia (heart rate greater than 100), congestive heart failure (inability of the heart muscle to effectively pump blood throughout the body), and cardiomyopathy (enlarged heart muscle). Patient A was admitted to hospital for monitoring of his identified heart condition and treatment of his pneumonia.

Immediate/Systemic Actions

1. KFH Oakland/Richmond has a routine ongoing monitoring program through its' Clinical Technology Department to ensure that the cardiac monitors and alarm paging system are functioning correctly. — 6/25/2010

2. Nursing staff on telemetry units have an ongoing process to test their pagers for response times at the beginning of each shift. The results of the tests are documented in a log on each telemetry unit. — Ongoing

3. An investigation began upon notification of the event.

4. Upon discovery of the event in question, the data for the cardiac monitor and the paging device were preserved and a forensics investigation by the manufacturer was requested.
   a. The forensics data was provided to the facility and demonstrated that the equipment was functioning properly and alarms were appropriately sent regarding weak battery power in the monitoring device.

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The patient was transferred to the telemetry unit on [redacted]/10 at 4:30 p.m. A telemetry nursing unit is staffed with registered nurses (RN) trained to use and read electrocardiogram (EKG) equipment, also known as heart monitors. The nurses on the unit are responsible for observing and interpreting patient EKG heart rhythms. They are also responsible for notifying doctors if cardiac emergencies arise and the initiation of immediate emergency interventions, such as CPR (cardiopulmonary resuscitation).

Patient A's vital signs (blood pressure, pulse) taken on admission to the telemetry unit indicated a blood pressure of 108/73 (normal blood pressure is 120/80) with a pulse of 108. Patient A's cardiovascular assessment indicated his heart rate was tachycardic (rapid heart rate of greater than 100 beats per minute).

Admission physician orders dated [redacted]/10 indicated the following:

1. Call physician if heart rate greater than 120 and any sustained ventricular tachycardia (an abnormal heart rhythm that is rapid, irregular and is most commonly associated with heart attacks and are considered life-threatening).

2. Call physician for heart rate greater than 120 and less than 50 beats per minute.

Review of the hospital's policy and procedure, "Patient Care Services: Nursing Cardiac

5. An enhanced practice of daily monitor battery changes and pager battery changes at every shift was implemented on June 4, 2010. The previous practice had been to change the batteries upon alarm notification. — Ongoing

a. Telemetry RNs received an immediate communication regarding this practice enhancement.
b. A second written education and attestation was provided to the Telemetry RNs on June 16 thru July 24, 2010.

6. The "Cardiac Monitoring" policy and procedure was revised to reflect this practice change. The policy was reviewed and approved by the Medical Executive Committee on June 17, 2010 — 6/25/2010

7. Beginning June 14, 2010, Monitor Technicians were assigned to each shift on the 8th and 9th floor telemetry units. The processes are fully implemented into the work flows and are sustained. — 6/25/2010

Accountable Party: Chief Nursing Officer (CNO).

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	Continued From page 3 Monitoring", indicated, "Critical behaviors and skills performed by the registered nurse [RN] caring for cardiac monitored patients on the telemetry unit include setting the paging alarm device parameters based on a patient's medical condition and physician orders." The telemetry unit RNs were expected to respond quickly and effectively to all cardiac alarms and implement emergency procedures as needed for patients. The telemetry unit cardiac monitoring procedures required all RNs assigned to the unit to pass a telemetry competency examination and sign a "Telemetry Attestation" form. The signed attestation form indicated that the RN acknowledged understanding of their accountabilities to patients on telemetry cardiac monitoring and the responsibilities to implement hospital cardiac telemetry policy and procedures. The Telemetry Attestation indicated: "The following actions are requirements for monitoring of all telemetry patients by the assigned cardiac competent RN": 1. All telemetry pagers must be set to "AUDIBLE" not vibrate. 2. At the start of the shift, the RN responsible for the patient must test the pager to assure it is on AUDIBLE alert status. 3. Each RN is individually responsible for telemetry monitoring.		Monitoring Plan: 1. Beginning immediately of the event Telemetry unit logs were reviewed by management on daily basis to ensure that the alarms tested correctly and the logs were properly completed. 2. If any issues were identified during the review, staff was immediately re-educated to proper processes. 3. The results of the monitoring were reported to the Medical Executive Committee on 10/06/2010. 4. Upon four (4) months of monitoring that demonstrated sustained compliance, the monitoring practice returned to its usual time frame.	10/06/2010

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Vigilance in responding to alarms is REQUIRED.
RED (immediately respond to patient bedside) potentially lethal arrhythmias. All RN's on the team are responsible in responding.
YELLOW (assess arrhythmias and then assess patient as indicated) Irregular rhythms occasional PVC (premature ventricular contractions)
INOP (immediately assess patient and trouble shoot telemetry electrodes/transmitter). Usually leads off.

The telemetry cardiac monitor system on the eighth floor telemetry nursing unit was observed on 6/24/10 with hospital administrative and biomedical staff. There were three cardiac information monitor screens noted. One cardiac monitor screen was located in the center of the unit at the nurses' station. The other two cardiac monitor screens were located at opposite ends of the unit and were visible and audible to all RNs and physicians on the unit. One of the cardiac monitor screens was located immediately outside of Patient A's room (Room 832 A).

A simulation of the cardiac alarm notification system was demonstrated at the unit located at the nurses' station. A low battery indication is "visually" displayed on the central monitor as a yellow bar with the printed statement indicating "battery low" with the patient's initials and room location.

In conjunction with central cardiac monitoring system the telemetry unit utilized the Emergin Paging System. This paging system is designed to ensure that arrhythmias or equipment failures are

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promptly detected whenever the nurse is on the unit. The Emergin System has a "battery low" alert which indicates when the telemetry transmitting device worn by the patient needs a battery replacement.

Review of the operator manual for the Emergin Paging System indicated the Emergin System acquires patient alarm data from the patient's telemetry transmitter device and relays the alarm to the paging device and central monitors on the unit. Alarms are sent out in the order in which they are received. Red and yellow alarms are sent to the pager worn by the RN responsible for monitoring the cardiac rhythm status of the patient.

Red alarms are of critical importance. It would indicate asystole (no heart beat) and life threatening arrhythmias such ventricular fibrillation (rapid irregular contraction of the heart which can lead to asystole). The device will also send notification as a red alarm to the pager worn by the RN when the battery in the transmitting device worn by the patient is low and the signal strength is below 10%, which requires immediate battery replacement. Yellow alarms are indicative of rapid heart rates and prolonged irregular rhythms that need to be closely monitored. A "battery low" alarm means the cardiac monitor will lose the ability to monitor an assigned patient's cardiac rhythm if not corrected by replacing the battery. If the battery is not replaced, the patient's cardiac rhythm status and potential threatening cardiac arrhythmias would not be visible on the central monitor screens. A "replace battery" alarm means "No monitoring is

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occurring" and the battery should be replaced immediately. In addition, there would be no alarm indicator transmitted to the Emergin Paging device worn by the RN.

During a telephone interview on 6/29/10 at 8:05 a.m., RN 2 said she had reported to work on the night shift (11:15 p.m. to 7:45 a.m.), [redacted]/10. It was after 11:00 p.m. and RN 1 (Patient A's primary nurse on the evening shift, 3:15 p.m. to 11:45 p.m.) had begun the change of shift report with other night nurses who had already reported to work. When RN 2 said she arrived on the telemetry unit at approximately 11:15 p.m. and noted a "replace battery" indication for Patient A in Room 832 bed-A was alarming on the central cardiac monitor screen. RN 2 responded to the alarm and went to Patient A's room to replace the battery.

RN 2 said that when she entered the room, Patient A appeared to be sleeping. Upon further assessment, Patient A was found to have no pulse and unresponsive. RN 2 immediately called an emergency code at 11:26 p.m., on [redacted]/10. The code team responded immediately and performed CPR (cardiopulmonary resuscitation) for approximately 40 minutes. Patient A was intubated (breathing tube inserted into the windpipe for mechanical ventilation) during the emergency code and was eventually transferred to the Intensive Care Unit (ICU).

Review of post cardiac arrest evaluation written by Physician A, dated [redacted]/10 at 7:24 a.m., indicated: "Patient's [Patient A] AMS [altered mental state] is

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likely 2/2 [secondary two] PEA [pulseless activity] with post anoxic encephalopathy [brain death]."

(A patient in cardiac arrest will generally present in pulseless ventricular tachycardia [VT], ventricular fibrillation [VF], or pulseless electrical activity [PEA]. Because pulseless VT and VF are both rhythms that still have electrical activity, although chaotic they are treated the same with defibrillation and medication. By the same token, asystole (the absence of detectable ventricular electrical activity) and PEA won't respond to electrical shock, and are treated with medication only. American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care)

On [redacted]10, RN 1's Emergin Paging device recorded 80 unanswered cardiac monitor alarms between 3:47 p.m. and 8:50 p.m. Seventy five (75) of these text alarm messages were indication of a heart rate abnormality, two of which indicated a potential heart arrhythmia of ventricular fibrillation or ventricular tachycardia (red alarms). Patient A's heart rate exceeded 120 and was in the range of 141 to 153 on several occasions. There was no documentation found in the medical record which indicated RN 1 notified Patient A's physician of the numerous yellow alarms which indicated that Patient A had heart rates greater than 120 beats per minute.

(Ventricular Tachycardia [VT] is a life threatening condition which can lead to the dreaded condition, Ventricular Fibrillation [VF]. In ventricular fibrillation the ventricles beat rapidly in a chaotic, purposeless

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fashion. The heart cannot pump blood effectively to the body. If untreated, ventricular fibrillation can be fatal within minutes, or even seconds. Medicalterms.com)

Three (3) text pager alarm messages received by RN 1 at 3:46 p.m., 4:46 p.m., and 4:50 p.m., indicated, "Battery Low". Failure to response to this alarm can result in the systems inability to analyze and send messages/alarms. (Phillips Emergin System Instructions for Use -pages 5-9)

At 11:20 p.m. the Emergin Paging device memory component indicated the text message, (Red Alarm) sent to RN 1's paging unit indicated technical in-operation "INOP" because the monitoring system could no longer analyze Patient A's cardiac rhythm.

At 11:26 p.m., RN 2 called an emergency code after finding Patient A pulseless and unresponsive when responding to the central monitor "replace battery" alarm. Approximately six minutes passed between when the monitoring system could not analyze Patient A's cardiac rhythm and when RN 2 called the emergency code to attempt resuscitation of the patient.

(Tissue and brain death begin to develop within four to six minutes after patients lose their supply of oxygen due to cardiac arrest. The arrest may be reversible if the patient is defibrillated and successfully resuscitated within a few minutes of the arrest. American Heart Association Scientific Position: Sudden Cardiac Arrest,

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http://www.americanheart.org)

Review of RN 1's personnel file indicated a signed "Telemetry Attestation" form dated 7/7/09. An annual competency review, on 7/8/09, showed that RN 1 passed "Cardiac Monitoring Competency" and demonstrated understanding of the cardiac monitoring standards of practice on the telemetry unit.

During an interview on 6/24/10, RN 1 said he started work at 3:15 p.m. on [redacted]10. After the change of shift report, RN 1 had four assigned patients on cardiac monitoring, including Patient A, which he programed into his Emergin paging device and carried on his person for the entire shift. When asked if the Emergin pager alarms were set on audible, RN 1 confirmed that "audible was on". Shortly after report he made initial rounds on his assigned patients and found Patient A was awake and alert.

RN 1 was aware of the physician's order to be notified if Patient A's heat rate was greater than 120 beats per minute. When asked if he notified the physician of the patient's heart rate that exceeded 120 per minute, RN 1 stated "No" and that he did not notify the physician during his shift because Patient 1 frequently had a high heart rate and seemed to be alright and "always checked out fine".

RN 1 stated that he recalled receiving an alarm on his Emergin Paging device showing that Patient A's telemetry transmitter had a low battery. He said, "I

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did hear it but did not react." When asked if he recalled receiving "Red" alarms to his paging device which indicated technical in-operation because the cardiac monitoring system could no longer analyze Patient A's rhythm, RN1 said, "No". RN1 stated that he had a "heavy assignment" the night of the incident and that other assigned patients needed a lot of assistance. Since he did not have a "buddy" (non-licensed care giver assigned on the unit to assist RNs with patient care) and he had to do all the work alone. He said that he may not have heard all of Patient A's alarms because he was busy providing patient care to his other assigned patients.

RN 1 stated that prior to start of his charting at the end of his shift, he entered Patient A's room at 10:30 p.m., and did a visual check of the patient. He stated he found Patient A was alert and awake at that time. RN 1 stated after change of shift report, at approximately 11:15 p.m., he noted Patient A's cardiac rhythm was a straight line and was alarming "replace battery" on the central station monitor. He stated that RN 2 went to replace the battery for Patient A and that after a few minutes, RN 2 came out of Patient A's room, said the patient was unresponsive and called an emergency code.

The hospital's review of the Emergin Paging device memory component worn by the telemetry unit Assistant Nurse Manager indicated it was not programmed for "RED" alarms on the night of the incident. Hospital policy and procedure required that all telemetry unit Assistant Nurse Manager to

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program their pagers to receive "Red" alarm notifications. The Assistant Nurse Manager did not respond as a backup for RN 1 who had received "Red" alarms for Patient A. This further resulted in Patient A not receiving immediate interventions to ensure appropriate cardiac monitoring and care needs were met.

After being transferred to ICU, Patient A remained in critical condition and sustained two additional cardiac arrest events and expired on [redacted]2010.

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).

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