

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA220000009	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/09/2009
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NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO	STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL SOUTH SAN FRANCISCO, CA 94080
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E 000 Initial Comments

The following reflects the findings of the California Department of Public Health during a survey on 12/09/09.

Representing the California Department of Public Health:

██████████ Pharmacy Consultant II

Health and Safety Code Section 1280.1(c). For the purpose of this section, "Immediate Jeopardy" means a situation in which the licensee's non compliance with one or more requirements of licensure has caused, or likely to cause an immediate jeopardy or death to the patient.

E 000

Tag 000 - Introduction

Kaiser Foundation Hospital South San Francisco has taken the findings from the Medication Error Reduction Program survey and the issues cited in this "Statement of Deficiencies" very seriously and has taken both immediate and systemic actions to ensure that such medication errors do not occur again. This "Plan of Correction" outlines these actions in the areas of:

- (1) Medication Storage to ensure that vaccinations, PPDs and all medications are safely stored.
- (2) Medication Error Recognition which includes:
 - identification, screening for follow-up care and notification of the patients specifically affected by this situation;
 - improvements made to ensure that the potential for vaccination and PPD administration errors are reduced, and
 - an expansion of the definition of "medication error" with revisions to policies, procedures and tools to ensure that medication errors of all types are better identified, reported and analyzed so that opportunities for improvements can be identified and acted upon.

E1900 T22 DIV5 CH1 ART7-70701(a)(5) Governing Body

(a) The governing body shall:
(5) Take all reasonable steps to conform to all applicable federal, state and local laws and regulations, including those relating to licensure, fire inspection and other safety measures.

This RULE: is not met as evidenced by:
Based on observation, interviews, and policy and document review, the hospital failed to maintain the temperature in the pharmacy's refrigerator in accordance with the manufacturer's recommendations, state regulations and hospital policy to ensure stability, potency and safety of refrigerated medications. Medications were stored at below freezing temperatures (as low as minus 8 degrees Centigrade) for a 32 month period. This resulted in the administration of improperly stored vaccines which resulted in unknown or ineffective vaccination status of

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Linda V. Jensen

SR-VP, Area Manager

2/31/10

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3,921 patients.

The facility's failure to maintain refrigerator temperatures at 2-8 C in accordance to hospital policy and the manufacturer's recommendation is a deficiency that has 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.

Findings:

The facility's failure to maintain refrigerator temperatures at 2-8 C in accordance to hospital policy and the manufacturer's recommendation is a deficiency that has 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.

The above indicated over a 32 month period the majority of the lowest weekly temperatures were at freezing temperatures (0 C or below) in the inpatient refrigerator. The inpatient refrigerator was used to store the majority of the hospital's refrigerated medications. The failure of the facility to maintain appropriate refrigeration temperatures was identified during a California Department of Public Health Medication Error Reduction Plan (MERP) Survey started on August 12, 2009.

According to Lexi-Comp Online, a nationally recognized drug information resource indicated, "do not freeze" for the following medications:
 Insulin-used for diabetes
 Diltiazem Injectable-used to treat heart problems
 Rocuronium- adjunct to general anesthesia
 Tuberculin Skin Test- skin test in diagnosis of

E1900 (3) Focused education through "Patient Safety University" to create and sustain a culture of patient safety throughout the hospital that includes a culture where errors and issues can be safely reported, escalated and addressed to further promote a safe patient care environment.

**Tag E 1900
Governing Body**

**Immediate Action -
Medication/Vaccination Storage:**

- All medications, vaccines and PPD skin tests that were stored in the Pharmacy refrigerator and in the medication refrigerators on the nursing units were immediately sequestered on August 13, 2009. August 13, 2009
- All medications, vaccines and PPD skin tests products were replaced with new stock on August 13, 2009. August 13, 2009
- An immediate preventive maintenance review was conducted on the Pharmacy refrigerator on August 13, 2009 and it was found to be functioning correctly. August 13, 2009
- A manual temperature monitoring system was immediately implemented within Pharmacy on August 13, 2009 to ensure that the refrigerator was maintained within appropriate temperature ranges. August 13, 2009

California Department of Public Health

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tuberculosis
 Filgrastim-used for low white blood cell count (impaired immune function)
 Healon 5-Used in eye surgery
 Abciximab-Used to prevent heart complications during surgery
 Antihemophilic Factor-treatment for hemophilia
 Calcitonin-treatment for Osteoporosis
 Crotalidae Polyvalent-rattlesnake bite antidote
 Drotrecogin-treatment for bacteria blood infections (sepsis)
 Epoetin Alfa-treatment of anemia secondary to renal failure, HIV
 Etanercept-treatment of Rheumatoid Arthritis
 Hyaluronidase-Increases absorption of injected medications
 Michrogam-Used in blood transfusions
 Oprelvekin-Used to treat blood problems after chemotherapy
 Peginterferon-treatment for hepatitis
 Rabies Immune Globulin-rabies prophylaxis
 Rabies Vaccine-prevent rabies
 Rhogam-used in blood transfusions
 Sargramostim-help prevent life threatening infections after chemotherapy
 These medications were all found in the inpatient refrigerator and stored at freezing temperatures according to the inventory list provided by the hospital.

In addition to the medications listed above the following vaccines/skin test were stored in the inpatient pharmacy refrigerator and exposed to freezing temperatures:
 Diptheria tetanus(dT) vaccine- used to prevent diphtheria and tetanus
 Diptheria tetanus and pertussis (Tdap) vaccine-used to prevent diphtheria, tetanus, and pertussis
 Hepatitis B Vaccine- prevent hepatitis
 Pneumococcal Vaccine - used to prevent

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- Temperature monitoring oversight has been and continues to be conducted by Pharmacy Management.
- All medication refrigerators throughout the hospital were systematically reviewed and found to be appropriately maintained and in range. This was completed on September 3, 2009.
- All Pharmacy staff were re-educated on policies and procedures related to medication storage and appropriate escalation processes when refrigerator temperature issues were identified. This was completed on August 31, 2009. For Pharmacy staff who were on leave, education was completed on September 2, 2009

September 3, 2009

August 31, 2009

September 2, 2009

Systemic Actions – Medication Storage:

- The Pharmacy refrigerator was replaced with a new refrigerator on October 26, 2009. The manual temperature monitoring system, including Pharmacy Management oversight, continues.
- Engineering staff was in-serviced by the manufacturer to ensure that preventive maintenance activities were accurately set-up in the Engineering work order system. (October 26, 2009)

October 26, 2009

October 26, 2009

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pneumonia
Tubersol skin test - used to aid in the detection of infection with tuberculosis

A review of the document entitled "Number of Patients Who Received Vaccines and Insulin Products, MERP Survey Request Follow Up Letter and Drugs Dispensed from Inpatient Pharmacy" indicated that over 5000 patients received refrigerated medications that were stored at freezing temperatures.

According to the Centers for Disease Control publication titled Morbidity and Mortality Weekly Report, Dec 8, 2006 indicated the following medication storage recommendations:

- *Diphtheria tetanus or pertussis-containing vaccines: Do not freeze (Aluminum adjuvant -- irreversible loss of potency with exposure to freezing temperature)
- *Hepatitis B vaccines: Do not freeze (Aluminum adjuvant -- irreversible loss of potency with exposure to freezing temperature)
- *Pneumococcal conjugate or polysaccharide vaccine: Do not freeze (re: conjugate vaccine, Aluminum adjuvant -- irreversible loss of potency with exposure to freezing temperatures)

According to the World Health Organization (WHO), an internationally recognized health organization in the document titled, "Temperature Sensitivities of Vaccines" indicated, "More than two million deaths were averted by immunization, as well as an additional 600,000 hepatitis B related death that would otherwise have occurred in adulthood...However, despite this, more deaths could be prevented and illnesses avoided, if vaccines which are sensitive both to excessive heat and excessive cold, were transported and stored correctly...Liquid formulations of vaccines

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- The hospital reviewed all policies and procedures related to equipment and device maintenance and failures to ensure that appropriate reporting occurs. (August 2009)

August 2009

- Any policies requiring amendment were reviewed and approved by the appropriate committees. (November 2009)

November 2009

- All appropriate staff were re-educated to any new or amended policies by August 2009 - ongoing.

August 2009

- To ensure consistent Preventive Maintenance oversight, Engineering provides copies of all Preventative Maintenance performed on the refrigerators in the Pharmacy to the Pharmacy Director or Manager. The Pharmacy Director/ Manager have kept and continues to keep these records archived in the department to show that Preventative Maintenance was performed regularly and on time.
- Medication storage and temperature monitoring has been and continues to be a part of orientation for new Pharmacy staff and annual training for all Pharmacy staff.

Accountable Party – Medication

Storage:

Medication Storage: Inpatient Pharmacy Director

Refrigerator Preventive Maintenance: Support Services Assistant Administrator

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containing diphtheria, pertussis, tetanus, hepatitis B, Hemophilus influenzae type b, IPV and their combinations should not be frozen...When a vaccine containing an antigen adsorbed to an aluminum adjuvant (e.g. hepatitis B, tetanus toxoid,...) is damaged by freezing, the loss of potency can never be restored; the damage is permanent...Freezing affects the adsorbed vaccines through changing their physical form...Freezing brings changes in the structure and morphology of the adsorbed vaccines...ice crystals formed during freezing force aluminum particles to overcome repulsion, thereby producing strong interparticle attraction resulting in aluminum particle coagulation/agglomeration.... The size of the granules seems to increase on repeated freezing and thawing cycles."

In an interview on 12/09/09 at 1:45 p.m. Administrator 1 stated after reviewing patients' charts the estimated number of patients that actually received ordered vaccines or skin tests (Tubersol) stored at freezing temperatures from 11/16/06 to 08/13/09 were as followed:
dT and Tdap-2727
Hepatitis B vaccine-12 patients
Pneumococcal vaccine-1034
Tubersol-148 patients

A review of Patient 48's clinical record indicated that this patient was one of the 1034 patients that received compromised Pneumococcal vaccine. Patient 48 had a past medical history of lung cancer, diabetes mellitus, and splenectomy (surgical removal of the spleen). Patient 48's vaccine and pneumonia history were as followed:
[REDACTED]/07 Physician ordered Pneumococcal vaccine
[REDACTED]/07 Received compromised Pneumococcal vaccine was age 52 at the time of vaccination

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Monitoring – Medication Storage:

- On a monthly basis, the inpatient pharmacy vaccine refrigerator manual log has been audited to ensure that temperatures were taken on a twice daily basis and that any temperatures that were out of range shows documentation of actions taken.
- Any identified issues would have been immediately addressed with the Inpatient Pharmacy Director/Designee.
- The results of the audit were reported to the Medication Safety Committee, P&T Committee, Integrated Safety Committee and Medical Executive Committee on a routine basis for six months to demonstrate a sustained performance.
- If performance did not meet expectations, any committee would have made recommendations for further action and monitoring.
- On a monthly basis, all scheduled preventive maintenance orders for Pharmacy equipment from the previous month have been audited to ensure that they were completed in a timely manner.
- Any orders that were not completed in a timely manner were immediately remediated.
- The results of the audit were reported to the Medication

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[REDACTED] 08 Admitted into hospital for Pneumonia and Candidemia (Fungus in the blood)
 [REDACTED] 09 Admitted into the hospital for Community Acquired Pneumonia
 [REDACTED] 09 Blood culture gram positive Pneumococcal pneumonia (bacteria in the blood)

A review of Patient 42's clinical record indicated that this patient was one of the 1034 patients that received compromised Pneumococcal vaccine. Patient 42 had a past medical history of dementia, diabetes mellitus, and hyperlipidemia. Patient 42's vaccine and pneumonia history were as followed:

[REDACTED] 08 Admitted into hospital and physician ordered Pneumococcal vaccine
 [REDACTED] 08 Received compromised Pneumococcal vaccine was age 87 years old at the time of vaccination
 [REDACTED] 09 Death certificate lists pneumonia as the only cause of death

A review of Patient 51's clinical record indicated that Patient 51 was one of the 1034 patients who was administered compromised pneumococcal vaccine. Patient 51 had a past medical history of diabetes mellitus and end stage renal (kidney) disease. Patient 51's vaccination record and pneumonia history were as followed:

[REDACTED] 98 Received Pneumococcal vaccine
 [REDACTED] 09 Admitted to intensive care unit (ICU) for pneumonia/sepsis
 [REDACTED] 09 Physician ordered Pneumococcal vaccine
 [REDACTED] 09 Received compromised Pneumococcal vaccine
 [REDACTED] 09 Admitted to hospital for pneumonia/sepsis

A review of Patients 152's clinical record, on 12/9/2009, indicated that Patient 152 was one of the 1034 patients who was administered

Safety Committee, P&T Committee, Integrated Safety Committee and Medical Executive Committee on a routine basis for six months to demonstrate a sustained performance.

- If performance did not meet expectations, any committee would have recommended further action and monitoring.

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compromised pneumococcal vaccine. Patient 152 vaccination record and pneumonia history were as followed:
 [REDACTED] 2008 Received compromised Pneumococcal vaccine was age 75 years old at the time of vaccination.
 [REDACTED] 2009 Admitted to ICU for pneumonia/sepsis

A review of Patient 153's clinical record, on [REDACTED] 2009, indicated that Patient 153 was one of the 1034 patients who was administered compromised pneumococcal vaccine. Patient 153's had a past medical history of hypertension, right renal transplant, congestive heart failure and placement of pacemaker. Patient 153's vaccination record and pneumonia history were as followed:
 [REDACTED] 1993 Received Pneumococcal vaccine
 [REDACTED] 2001 Received Pneumococcal vaccine
 [REDACTED] 2007 Received compromised Pneumococcal vaccine was age 69 years old at the time of vaccination.
 [REDACTED] 2009 Admitted to hospital for sepsis/urinary tract infection/pneumonia

A review of Patient 151's clinical record, on 12/9/2009, indicated that Patient 151 was one of the 1034 patients who was administered compromised pneumococcal vaccine. Patient 151's had past medical history of aortic stenting, coronary heart disease, atrial fibrillation and anemia. Patient 151's vaccination record and pneumonia history were as followed:
 [REDACTED] 1999 Received Pneumococcal vaccine
 [REDACTED] 2009 Received compromised Pneumococcal vaccine was age 80 at the time of vaccination.
 [REDACTED] 2009 admitted to hospital for pneumonia. Patient died approximately two hours after admission.
 Physician note dated [REDACTED] 2009 at 3:08 p.m.

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indicate, "Death pronounced at 2:25 PM ... Presumed cause of death is pneumonia. Unable to rule out CNS (central nervous system) event since patient was to unstable for head CT."

2. A review of QA data provided by the hospital indicated within just less than a 3 year period the majority of the lowest weekly refrigerator temperatures were at freezing temperatures (0 C or below). The DOP was not aware of these zero and subzero temperatures.

According to Lexi-Comp Online, Centers for Disease Control, manufacturer's package inserts indicates "do not freeze" for medications that were stored in the inpatient pharmacy refrigerator. For some medications there would be a loss of potency when stored at freezing temperatures.

A review of the document entitled Number of Patients Who Received Vaccines and Insulin Products, MERP Survey Request Follow Up Letter and Drugs Dispensed from Inpatient Pharmacy indicated that over 5000 patients received refrigerated medications that were stored at freezing temperatures.

According to the hospital policy and procedures titled Storage and Disposition of Medications indicated "Medication Storage and preparation areas throughout the hospital shall be under the responsibility of the Inpatient Pharmacy Director or designee... Medications are stored under necessary conditions to ensure stability ...refrigerator 36 to 46 F (2 to 8 C)"

During an interview on 12/02/09 at 3:00 pm the Director of Pharmacy (DOP) stated that the inpatient pharmacy's medication refrigerator was

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where most of the refrigerated medications were stored in the hospital. The DOP said there was no designee that was responsible for monitoring refrigerator temperatures.

The above indicated that since there was no designee that was assigned responsibility, based on the hospital policy and procedures, the DOP was responsible for monitoring refrigerator temperatures.

3. A review of the document entitled Medication Error Reduction Program Survey indicated " Technology regarding the refrigerator temperature sensor ...The sensor mechanism can be set in freezer or refrigerator mode ... The designated mode tells the sensor which Celsius scale to use ... There are two types of paper wheels on which the sensor stylus records: freezer and refrigerator. Both are similar in color and gross visualization and resemble graph paper ...The sensor has been set in freezer mode since its installation. Temperatures recorded on the freezer wheels are accurate. "

During an interview on 08/21/09 at 3:00 pm the Regional Director stated that the temperature wheel used graphing paper to record temperatures on a weekly basis. He said that the pharmacy would accidently use the wrong graph paper and the temperatures would be recorded incorrectly. He also said that he was able to obtain accurate temperatures after contacting the manufacturer and then converting the incorrect recorded temperatures to correct recorded temperatures.

4. The interview on 08/17/09 at 11:35 am the Engineer 2 stated that the Inpatient Pharmacy Refrigerator should, based on manufacturer recommendations, have an annual preventative

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maintenance (PM) check although he recommended a PM every 3 months for a refrigerator that stored medications. He also stated that by mistake they had scheduled the PM every 3 years instead of every 3 months. The last PM was in November 2006 and the next scheduled was November 2009.

A review of the PM work order dated 11/01/06 indicated that the last PM check was done on 11/16/06. The work order also indicated the next scheduled PM would be in 3 years.

The violation has caused or likely to cause serious injury or death to patients. An immediate jeopardy was called on 08/24/09 at 10:00 am. The immediate jeopardy was abated on 12/09/09 at 5:00 pm.

**Tag E 1944
Patient Rights**

Immediate Action - Patient Identification and Notification:

- Kaiser Foundation Hospital South San Francisco immediately began a series of actions to ensure that any patients who might have been impacted by compromised vaccinations and PPD testing were identified, screened for necessary follow-up, and contacted.
- A review of literature began immediately on August 13, 2009 to determine what vaccines/PPD skin tests might have had potency impact if held outside the recommended temperature range.
- A risk stratification of patients was conducted by the Infectious Disease physician specialist. This was based on the review of literature and consultation with the San Mateo County Health Officer, the Clinical Branch of CDPH and Kaiser Permanente vaccine experts.

August 13,

E1944 T22 DIV5 CH1 ART7-70707(a) Patients' Rights E1944

(a) Hospitals and medical staffs shall adopt a written policy on patients' rights.

This RULE: is not met as evidenced by:
Based on observation, interview, and record review, the facility failed to provide the patients the right to be notified of the outcome of care as soon as the facility discovered that vaccines, medications, and biologicals that were exposed to freezing temperatures were administered to the patients.

Findings:

On 08/13/09 the hospital had been informed of a

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large number of improperly stored medications that were identified during a Medication Error Reduction Plan (MERP) survey that began on 8/12/09. These improperly stored medications were related to vaccinations and other related biological agents (tuberculin skin test material and interferon) that had been stored in an improperly maintained inpatient pharmacy refrigerator. The medications were exposed to freezing temperatures that made them ineffective or compromised their potency.

According to the Centers for Disease Control publication titled Morbidity and Mortality Weekly Report, Dec 8, 2006; the World Health Organization (WHO), an internationally recognized health organization in the document titled, "Temperature Sensitivities of Vaccines"; and the manufacturers' package inserts of the vaccine/biological agents; collectively indicates that the following vaccines and biological agents should be discarded lose potency when exposed to freezing temperatures Diphtheria tetanus, Hepatitis B, and Pneumococcal. The manufacturers' package insert indicates to discard PPD tests when exposed to freezing temperatures.

A review of the Jewett Polestar Temperatures report listed inpatient pharmacy refrigerator weekly temperatures from 12/26/06 to 08/17/09. The expected refrigerator temperature range is 2.2-7.7 Centigrade (C). The lowest recorded weekly temperatures were not within the expected range. The recorded weekly temperatures were below 1 C and were as low as -8 C for a 138 consecutive week period. The lowest weekly temperatures were 0C or below for 130 weeks.

A review of an inventory list of medications that

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- A clinical review of affected patient populations began with internal and external physician clinical experts determining which patient populations required revaccination.
- Based on the initial clinical review, 2943 patients were determined to need follow-up vaccinations. These patients were mailed letters stating that they may have received compromised vaccines and they were provided with follow-up plans. The letters were in English, Chinese and Spanish and included a dedicated phone number to call for information and assistance. This occurred on October 21 and 22, 2009.
- Kaiser Permanente Primary Care Physicians were notified on October 21, 2009 of the occurrence and were provided a list of their patients who received letters along with information that included suggested responses to anticipate frequently asked questions.
- Dedicated vaccination clinics were held for the identified patients beginning October 26, 2009.
- Throughout this time period, ongoing consultation was held with the Immunization Branch of the California Department of Public Health.

October 21, 2009

October 21, 2009

October 26, 2009

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA220000009	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/09/2009
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NAME OF PROVIDER OR SUPPLIER Kaiser Foundation Hospital - South San Francisco	STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL SOUTH SAN FRANCISCO, CA 94080
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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
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E1944	<p>Continued From Page 11</p> <p>were stored at freezing temperatures in the inpatient refrigerator indicated that there were 78 different types of medications. The inpatient refrigerator was the main hospital medication refrigerator. Some of the medications stored at freezing temperatures were: Diphtheria tetanus(dT) vaccine- used to prevent diphtheria and tetanus Diphtheria tetanus and pertussis (Tdap) vaccine- used to prevent diphtheria, tetanus, and pertussis Hepatitis B Vaccine- prevent hepatitis Pneumococcal Vaccine - used to prevent pneumonia Tubersol skin test - used to aid in the detection of infection with tuberculosis</p> <p>A review of the facility's policy and procedure on "Adverse Outcomes Communication" indicated "Members/Patients, legal representatives, and when appropriate family members have the right to be informed of outcomes of care which may also include unanticipated outcomes. Disclosure of outcomes of care, and especially unanticipated outcomes, should occur as soon as possible following identification."</p> <p>Upon notification on 08/13/09 the hospital agreed to research and identify the number of patients exposed by the improperly stored vaccines/biologicals. As part of the hospital's plan of correction and in accordance to the hospital policy, patients were to be informed of the unanticipated outcome of not being administered properly stored refrigerated vaccines and biologicals.</p> <p>After 78 days from the discovery of the improperly stored vaccines/biologicals the hospital produced a document titled, "Clinical Evaluation of Vaccine/Med/Skin Test Cases"</p>	E1944	<ul style="list-style-type: none"> Beginning on November 19, 2009, and using a rigorous study methodology, repeat patient-level reviews were conducted by clinicians for the populations receiving suspect vaccinations. These reviews were used to clarify the affected patient populations and to drive the decisions around further patient-specific clinical needs and further patient notifications. Kaiser Permanente Primary Care Physicians were notified on November 23, 2009 and requested to conduct an additional clinical review of their patients who had received suspect PPD skin tests, in order to determine additional follow-up care. DPH believed that the first letter that KFH South San Francisco sent to patients notifying them of the vaccination issues did not sufficiently identify for the patients that the medication storage issue was a medication error. DPH was also concerned that the first patient letter was not sent to the entire population of patients affected by the error but only focused on a limited population that KFH South San Francisco believed to be at potential risk. After discussions with DPH, the hospital sent a letter notifying all living patients that the medication storage issue was a medication error. This letter was mailed on December 2 and 3, 2009 and included: 	<p>November 19, 2009</p> <p>November 23, 2009</p> <p>December 2, 2009</p>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA220000009	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/09/2009
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NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO	STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL SOUTH SAN FRANCISCO, CA 94080
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dated 10/30/2009, it lists total patient exposures as 4,895 with the following breakdown by vaccine/skin test:
 Pneumovax 23 - 1875 patients (49 patients expired prior to October 2009)
 Tetanus Diphtheria Pertusis (Tdap) vaccine - 925 patients (4 patients expired prior to October 2009)
 Tetanus Diphtheria (Td) vaccine - 1912 patients (73 patients expired prior to October 2009)
 Hepatitis B - 4 patients
 TB skin test - 179 patients
 The document also indicated that out of 4,895 patients exposed 2,965 would be sent communication offering revaccination. According to the document the hospital would send letters to 2,760 patients who received either Tdap or Td, 201 patients who received Pneumovax 23, and 4 patients who received hepatitis B.

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- an acknowledgement of the incident as a medication error related to storage,
- an apology,
- a dedicated phone number for patients to call for questions,
- Instructions to contact their primary care provider to obtain follow-up care through Kaiser,
- confirmation that Kaiser will cover costs of care for any follow-up care for any patient regardless of insurance status.
- Patients were also provided a dedicated Pharmacy call center phone number if they chose to seek further clarification about the letter.
- Patient 151 was not notified due to his death.
- Patient 152 was notified by the physician on February 10, 2010 as noted in EMR.
- Patient 153 was notified by the physician on January 22, 2010 as noted in EMR.
- Kaiser Permanente Primary Care Providers were notified of the medication errors, provided a list of their patients who received letters, of the drug involved in the error and other relevant information. This began on December 4, 2009.
- Medication errors were reviewed by the patients' providers and the following actions were taken:

February 10, 20

January 22, 201

December 4, 2

A review of the patient notification letter sent to the 2,760 patients who were administered either Tdap or Td indicated " During a recent Emergency Department visit at Kaiser Foundation Hospital South San Francisco, you were given a tetanus vaccine ...We have recently discovered that the vaccine was stored at a temperature lower than recommended, which may have reduced the vaccine's strength...Our infectious disease specialists recommend that you return for a repeat vaccination to insure that you are properly protected. " The letter did not indicate accurate information as to what was administered to the patient (Tdap or Td). Instead it simply indicated that the patient received tetanus. The hospital revaccinated with Td for all the patients revaccinated. There were patients that were incorrectly revaccinated with Td when they should have been revaccinated with Tdap.

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NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO		STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL SOUTH SAN FRANCISCO, CA 94080	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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)
E1944	Continued From Page 13 On 12/01/09, 110 days after the discovery of the improperly stored vaccines and biologicals the hospital had not accurately communicated, or did not have any communication sent to 4,585 of 4,769 patients (4,895 minus patients expired). After 110 days the patients were subsequently notified: *2760 dTap/dT had not been notified *179 PPD had not been notified *1,646 Pneumovax 23 had not been notified The patients were then notified of improperly stored vaccines/biologicals as directed by the California Department of Public Health. There was a sample record review of three out of the 1,646 Pneumovax 23 patients that had not been notified. The results of the sample review indicated three of three patients developed pneumonia and one patient died. a) A review of Patient 151's clinical record, on 12/9/2009, indicated that Patient 151 was one of the patients that were administered compromised pneumococcal vaccine. Patient 151's had past medical history of aortic stenting, coronary heart disease, atrial fibrillation and anemia. Patient 151's vaccination record and pneumonia history were as followed: ██████ 1999 Received Pneumococcal vaccine ██████ 2009 Received compromised Pneumococcal vaccine was age 80 at the time of vaccination. ██████ 2009 admitted to hospital for pneumonia. Patient died approximately two hours after admission. Physician note dated ██████ 2009 at 3:08 p.m. indicate, "Death pronounced at 2:25 PM ...Presumed cause of death is pneumonia." b) A review of Patient 152's clinical record, on 12/9/2009, indicated that Patient 152 was one of	E1944	<ul style="list-style-type: none"> • For patients who received DPT vaccine in the hospital and subsequently received DT as a revaccination, telephone outreach was done by Kaiser Permanente physicians to review each patient's vaccination status and determine any follow up. • Other high risk groups, such as immuno-compromised patients, received calls from Kaiser Permanente Clinicians to discuss follow-up care, which began on December 4, 2009. • For patients who had vaccinations ordered but where administration could not be verified, telephone outreach was done to discuss the error and plans for follow-up care. Patients received calls from Kaiser Permanente Physicians or other Clinicians working under physician protocols began on December 4, 2009. <p style="text-align: right;">December 4, 2009</p> <p style="text-align: right;">December 4, 2009</p> <p>Accountable Party: Chief Operating Officer</p>

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NAME OF PROVIDER OR SUPPLIER WAISER FOUNDATION HOSPITAL - SOUTH SAN FRANCISCO	STREET ADDRESS, CITY, STATE, ZIP CODE 1200 EL CAMINO REAL SOUTH SAN FRANCISCO, CA 94080
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the patients that were administered compromised pneumococcal vaccine. Patient 152 vaccination records and pneumonia history were as followed:
 [REDACTED] 2008 Received compromised Pneumococcal vaccine was age 75 years old at the time of vaccination.
 [REDACTED] 2009 Admitted to ICU for pneumonia/sepsis

c) A review of Patient 153's clinical record, on 12/9/2009, indicated that Patient 153 was one of the patients that were administered compromised pneumococcal vaccine. Patient 153's had a past medical history of hypertension, right renal transplant, congestive heart failure and placement of pacemaker. Patient 153's vaccination record and pneumonia history were as followed:
 [REDACTED] 1993 Received Pneumococcal vaccine
 [REDACTED] 2001 Received Pneumococcal vaccine
 [REDACTED] 2007 Received compromised Pneumococcal vaccine was age 69 years old at the time of vaccination.
 [REDACTED] 2009 Admitted to hospital for sepsis/urinary tract infection/pneumonia

On 12/9/2009 the facility was requested to provide a list of patients who received compromised Pneumovax 23 vaccine and were not notified. Reconciliation of that list with the three patients listed above revealed that Patient's 151, 152, and 153 were not notified by the hospital that they had received compromised Pneumovax 23 vaccine.

The facility's failure to notify patients of their vaccination status is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health

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Monitoring:

- Batches of patient notification letters transported to the United States Postal Service (USPS) were "seeded" with envelopes directed to the homes of some KFH leaders. Monitoring of these envelopes confirmed that the letters were sent by USPS.
- Volumes of calls into the call center were monitored to confirm that the patients were receiving notices.
- Receipt of letters was confirmed during follow-up calls with KP providers.
- Patients receiving follow up care from their primary care providers were tracked via the automated appointment reporting mechanisms.
- Results of monitored outcomes were reported to the Medical Executive Committee for four months from December to March 2009.

December to March 200

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA220000009	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/09/2009
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and Safety Code section 1280.1.

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