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

Complaint Intake Number:
CA00422608, CA00420048 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 2692, HFEN

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

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

Health and Safety Code section 1280.1 (d): This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to one hundred thousand dollars ($100,000) per violation. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to fifty thousand dollars ($50,000) for the first administrative penalty, up to seventy-five thousand dollars ($75,000) for the second subsequent administrative penalty, and up to one hundred thousand dollars ($100,000) for the third and every subsequent violation. An administrative penalty issued after

The plan of correction is prepared in compliance with federal regulations and is intended as Desert Regional Medical Center's (the "hospital") credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.

**Policy & Procedures:**
The Quality Improvement Director, Lab Director, Blood Bank Supervisor, Chief Nursing Officer, ED Director and Chief Medical Officer have reviewed the following without revision with the exception of Administration of Blood Bank Procedures:
- Blood Transfusions (#1054968)
- The Joint Commission/ National Quality Forum Reporting Requirements (#364184)
- Massive Blood Transfusion (#519932)
- Suspected Transfusion Reaction Workup (Lab 30.43)
- Therapeutic Procedures (Lab 30.44)
- Blood Utilization (340793)
- Blood Transfusion and Paul Gann Act Requirements For Elective Procedure /Surgery (700709)
- Antibody Screen (tube) (Lab 30.4)
three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.

A 009 1279.1 (b)(4)(8) HSC Section 1279
(b) For purposes of this section, "adverse event" includes any of the following:
(4) Care management events, including the following:
(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

Title 22 of the California Code of Regulations section: 70215(b):

Planning and Implementing Patient Care

(b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission.

On November 17, 2014, at 9 a.m., an unannounced visit was conducted at the facility to investigate a complaint regarding a patient (Patient

Education/ In-service:
The Quality Improvement Director, Lab Director, Blood Bank Supervisor, Chief Nursing Officer, ED Director and Chief Medical Officer will provide education on the following:

- Physicians, nurses, laboratory technicians and the transfusing staff on transfusion administration process, blood collection, signs and symptom, transfusion reaction and documented communication
- Chief Nursing Officer, Chief Medical Officer and ED Director will educate all RNs, LVNs to complete current.edu course on blood transfusion
- 2 patient identifiers, labeling of specimens, and inappropriately pocketing specimens/placing unlabeled blood on counters
- Blood Transfusion Competency
- Blood specimen drawing and labeling process
- The Hospital Quality Improvement Director (DCQI) provided verbal education to all nursing and lab staff regarding the importance of timely event reporting via eSRM
1. Patient 1 arrived at the emergency room on October 17, 2014, at 11:55 p.m. and was given a blood transfusion. The tube provided to the lab to determine the type of blood to be transfused was mislabeled and Patient 1 was given the incorrect blood type. Consequently, Patient 1 had an adverse reaction to the blood transfusion.

Based on interview and record review, the Department determined that the facility failed to ensure blood transfusions were administered in accordance with its policies and procedures for Patient 1, including but not limited to:

1. The Registered Nurse (RN) failed to correctly label a blood sample prior to sending the sample to the laboratory for testing, pursuant to its policies and procedures, Blood Bank Collect Specimen Collection and Handling.

2. The RN failed to identify the signs and symptoms of an adverse blood transfusion reaction and follow the facility policy and procedure regarding an adverse blood transfusion reaction.

3. The RN failed to notify the laboratory (Blood Bank) and physician of an adverse blood transfusion reaction in a timely manner and follow the policy and procedure titled, Blood Transfusions.

Together these failures resulted in Patient 1 receiving incompatible blood transfusions, which caused kidney failure, multiple medical treatments to include hemodialysis (the use of a special machine to remove harmful wastes and excess fluid...
from the blood), plasmapheresis treatments (separation of the blood components), prolonged hospitalization and had the potential to cause death.

Findings:

A blood transfusion is the transfer of blood or blood products from one person (donor) into another person’s bloodstream (recipient). There are four blood types: A, B, AB, or O (ABO group). Every person has one of these four blood types.

In addition, each person’s blood is either: Rh-positive, or Rh-negative. (RH= Rhesus factor is an inherited protein attached to the blood cell, positive means it is on the cell, negative means it is not). Before undergoing transfusions, a patient undergoes a type and crossmatch (determination of ABO group and Rh type and screening for unexpected antibodies).

Review of Patient 1’s clinical record on February 3, 2015, indicated the following: Patient 1 arrived in the facility’s emergency department on October 17, 2014, at 11:55 p.m., with diagnoses of persistent epistaxis (nosebleed) and anemia (low red blood cell count).

On October 18, 2014, at 1:03 a.m., the physician ordered an immediate blood draw to check Patient 1’s blood levels and type and crossmatch for blood (testing the patient’s blood to ascertain the blood type).

Laboratory results, dated October 18, 2014, at 1:50

Monitoring: Change location

- Observation audit of blood specimen drawing and labeling of 50 observations per month x 4 months with 100% compliance reported to Quality Counsel. If compliance not met observation audits will continued until system has been hardwired.
- Timely reporting is monitored by the occurrence reporting system eSRM on an ongoing basis as well as open reporting by all managers and directors or their designee at the Monday – Friday am Leadership Safety Huddle.

Responsible Person(s):
- Quality Improvement Director
- Lab Director
- Blood Bank Supervisor
- Chief Nursing Officer
- ED Director
- Chief Medical Officer
- Risk Manager.
a.m., indicated the patient's red blood cell count was 1.98 mEq/L (milliequivalent per liter), normal is 4.08 to 5.48, and hemoglobin level (part of the red blood cell that carries oxygen to the entire body) was 6.6 mEq/L, normal is 11.5 to 15.0.

According to the Blood Bank (BB) report, Patient 1's BB specimen was drawn on October 18, 2014, at 1:40 a.m. and Patient 1's blood type was identified as A Positive.

A physician's order dated October 18, 2014 at 2:22 a.m., indicated to transfuse two units of blood for a hematocrit level of 21 or less or hemoglobin less 7.0 or less.

The facility form entitled "Transfusion Record," dated October 18, 2014, completed by RN 1, indicated the Unit of blood was A+. The transfusion was started at 4:20 a.m., and completed at 6:00 a.m. The area labeled "Reaction: No__ Yes__ ("Notify Physician and contact the Blood Bank for instructions)" was checked off as "No".

The form indicated the following:
"4:09 a.m. Pre-Transfusion: pulse 95, temperature-36.6 Celsius (97.9 degrees Fahrenheit-normal temperature is 97.7 to 99.5), blood pressure-136/75;

Fifteen minutes after transfusion (no time documented): pulse 123, temperature 36.6 C, blood pressure-99/39 (low blood pressure-normal being 120/80);
Post transfusion (no time documented): pulse 111, temperature 38.1 C (an elevation of 1.5 C or 100.6 Fahrenheit), blood pressure 163/55.

There was no documentation that the physician and the blood bank were notified of the Patient 1's increase in temperature or decrease in blood pressure.

The second unit of blood was started at 6:15 a.m. and completed at 7:50 a.m. No reaction was documented on the Transfusion Record.

Review of the facility policy and procedure titled, "Blood Transfusions," revision dated, September 22, 2014, indicated under "Policy", "It is the policy at Desert Regional Medical Center that patients requiring transfusion will have the procedure performed in a precise and safe manner with proper identification for the recipient as well as the unit to be transfused." Under the section "Adverse or Transfusion Reaction: 1. Signs and symptoms of an adverse reaction are the most common in the first 15 minutes and include:

a. Elevated temperature greater than 1 degree Celsius or 1.8 degree Fahrenheit above baseline.

b. Hypotension (low blood pressure-normal being 120/80)

c. Pain in flank, chest or infusion site

d. Chills, shakes, nausea, vomiting, dyspnea or flushing.
**Summary Statement of Deficiencies**

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<td>e. If urticaria is the only reaction, the blood may be restarted after antihistamines are given, contact physician for orders.</td>
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<td>2. If signs and symptoms of an adverse reaction occur, stop the transfusion.</td>
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<td>4. Notify the physician immediately and obtain orders.</td>
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<td>5. Notify the Blood Bank of the reaction. Laboratory personnel have been instructed to bring the blood bag with any remaining blood to the lab after drawing blood for a transfusion reaction workup.</td>
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During an interview with Patient 1’s family member (FM) on December 4, 2014, at 2:45 p.m., the FM stated, “I was with (patient 1) when the first unit of blood was given...she complained of whole body pain during the administration of blood... (she) kept saying it was freezing cold two to three blankets, up to seven (were placed) on her. Her teeth were chattering...she was shaking like a leaf.” FM stated that when she complained to staff, “They just got another blanket and said that she was cold from the blood transfusion.”

FM stated that she “left and came back on Sunday morning (October 19, 2014) her whole body was swollen...her hand looked like a blown up latex glove...”

Documentation of the physician’s progress notes indicated on October 19, 2014, at 9:30 a.m.,
"Yesterday hemoglobin 10 today 7...must suspect some lab error."

Review of Patient 1's laboratory values dated October 19, 2014, at 6:10 a.m., indicated that her Creatinine level (a blood level that indicates the kidney's ability to get rid of waste in the blood), elevated to 3.9 (normal 0.5-1.0) and Blood Urea Nitrogen (BUN-a blood level that measures the amount of nitrogen in the blood related to the kidneys ability to remove waste) elevated to 41.0 (normal 7.0-15.0).

Documentation of the physician's progress notes on October 19, 2014, at 9:06 p.m., indicated "...There is a possibility of reaction to blood transfusion that the patient got at the time of admission.

The physician progress note dated October 21, 2014, at 1:35 p.m. indicated, "Discussed with Dr....ok for plasmaphoresis. Transfusion incompatibility."

The document titled "Transfusion Reaction Evaluation, Pathology Review" dated November 17, 2014, indicated the following information: "On or about 11/17/14 we learned from the (Outside Agency) that this patient experienced a transfusion reaction. Following a very delayed but extensive investigation, we concur - this patient suffered an acute hemolytic transfusion reaction to receiving Group A blood due to mislabeling of recipient blood tubes from the Emergency Department. Further, during the unit's administration, the signs and symptoms of a transfusion reaction were noted but the transfusion reaction protocol was not initiated.

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Event ID: RROL11
6/9/2017 11:15:24AM
Further details are beyond the scope of this report.

Review of Patient 1's clinical record revealed Patient 1 received a total of 93 units of blood products, multiple dialysis treatments, and multiple plasmapheresis treatments after receiving the wrong type of blood.

On 11/12/14, Patient 1, was discharged to a skilled nursing facility, but remained on hemodialysis until 12/3/14. Prior to initial admission to the facility for the recurring bloody nose, Patient 1 lived at home.

Review of a Discharge Summary from the skilled nursing facility, dated 11/21/14, indicated that Patient 1, was transferred to the skilled nursing unit of the facility on 11/9/14. The diagnosis was listed as "Hemolytic uremic syndrome." Hospital course was listed as the patient arriving at the facility with a severe nosebleed and was going to be scheduled for an artery embolization (the blocking of an artery to prevent bleeding), the following morning. "Her labs, which originally had basically been normal, came back showing elevated white count of about 30,000; severe worsening of kidney function with a creatinine having increased..." The Discharge Summary indicated that "her kidney function really had not improved and she was continuing to require hemodialysis 3 times a week; however, gradually, she did resume eating and regaining some strength."

During an interview with the Director of the Emergency Department (DED) on February 3, 2015, at 3 p.m., the DED stated during a laboratory test...
procedure on October 18, 2014, RN 1 labeled a blood sample obtained from another patient with Patient 1's medical information, and sent the sample to the laboratory for testing. The DED stated the testing of the sample was used to determine Patient 1's blood type in order for the patient to receive compatible blood transfusions. The DED stated Patient 1 received two units of A positive blood during the patient's ED admission. The DED stated RN 1 did not label the test tubes according to the facility policy titled, "Blood Bank Collect Specimen Collection and Handling," dated with revision on May 16, 2011, the nurse must label the specimen with information obtained from the patient's hospital ID armband before leaving the patient's bedside. The DED acknowledged the nurse did not follow facility blood collection policy and procedure.

An interview was conducted with the Director of Clinical Quality Improvement (DCQI), on February 4, 2014, at 10:30 a.m. regarding the first transfusion. The DCQI stated the nurse who transfused the first unit of blood should have stopped the blood based on the blood pressure of 99/39 (hypotension). The DCQI stated the post transfusion temperature went up more than one degree from 36.6 to 38.1 a 1.5 degree change. The DCQI stated the change in vital signs should have been reported to the physician and the facility laboratory immediately.

A review was conducted of the facility policy titled, "Blood Bank Collect Specimen Collection and Handling," dated with revision on May 16, 2011. The policy indicated under Principle, "Inadequate or
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<td>incorrect identification of the recipient is the most common cause of serious complications of transfusion. THE IMPORTANCE OF PROPER PATIENT IDENTIFICATION CANNOT BE OVEREMPHASIZED. The patient must be positively identified upon collection of a blood bank specimen, and again prior to the administration of donor unit(s).</td>
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The policy further indicated under section E, "The phlebotomist [or RN per their licensure as an RN may draw blood] completes the Blood Bank "Specimen Tube" label with information obtained from the patient's hospital ID (Identification) armband:

1. Patient's first and last names
2. Reference and if available medical record number
3. Date of birth
4. Doctor's name
5. Room number or location
6. Date and time specimen is drawn and identification of the person drawing the specimen.

Alternatively, a computer-generated label including the patient information (1-5 above) may be placed on the "Specimen Tube" label, and the printed information verified against the patient's hospital armband.

The "Specimen Tube" label is affixed to the blood bank collect specimen before leaving the patient's bedside. The phlebotomist [RN] also labels the corresponding Blood Bank recipient band with the patient's name and date of specimen collection, and
inserts it into the pink blood bank armband prior to placing it on the patient."

During an interview with the Director of Clinical Laboratory (DCL), on February 3, 2015, at 1:30 p.m., the DCL stated after retesting the blood specimens labeled as Patient 1's, it was determined the first tube drawn in the ED was labeled with Patient 1's name, but the sample was not Patient 1's blood. The DCL stated Patient 1 was not A positive.

The RN failed to follow the facility's policy and procedure regarding blood sample labeling, failed to identify signs and symptoms of a blood transfusion reaction, and failed to follow the facility policy and procedure for transfusion reactions.

This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).