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

Complaint Intake Number:
CA00491050 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 2309, 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.

Abbreviations used in this document:

CT - Computed Tomography
DED - Director Emergency Department
DIC - Disseminated Intravascular Coagulopathy
ED - Emergency Department
KUB - Kidneys, Ureters, and Bladder (diagnostic medical imaging x-ray)
OR - Operating Room
PA - Physician Assistant

Health and Safety Code Section 1280.3
(a) Commencing on the effective date of the regulations adopted pursuant to this section, the director may assess an administrative penalty

Preparation and execution of this plan of correction does not constitute admission or agreement of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared solely because it is required by state and federal law.

The following constitutes Corona Regional Medical Center’s plan of correction.
against a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 for a deficiency constituting an immediate jeopardy violation as determined by the department up to a maximum of seventy-five thousand dollars ($75,000) for the first administrative penalty, up to one hundred thousand dollars ($100,000) for the second subsequent administrative penalty, and up to one hundred twenty-five thousand dollars ($125,000) for the third and every subsequent violation. An administrative penalty issued after 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. Commencing on the effective date of the regulations adopted pursuant to this section. (g) For the purpose 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 ART6 §70415. Basic Emergency Medical Service, Physician on Duty, Staff.
(a) A physician trained and experienced in emergency medical services shall have overall responsibility for the service. He or his designee shall be responsible for:

1. Implementation of established policies and procedures.

Based on interview and record review, the facility failed to ensure the Emergency Department (ED) Physician implemented the facility policy and procedure for central line insertion when a Physician's Assistant (PA) placed a central line for one patient (Patient 1) and did not obtain a KUB (diagnostic medical imaging x-ray). Due to this failure, the misplaced right femoral central line went undiagnosed for greater than 24 hours, and resulted in the above the knee amputation of Patient 1's right leg.

Findings:

On June 16, 2016, the record for Patient 1 was reviewed. Patient 1 presented to the facility ED, on June 5, 2016, with diagnoses of acute respiratory failure, pneumonia, and sepsis (severe infection).

The "ED Physician Record" dated June 5, 2016, at 2:12 p.m. (addendum to 12:15 p.m.), indicated the ultrasound machine was used to identify the right femoral vein (The femoral vein is located in the upper thigh and pelvic region of the human body), a right femoral vein central line was placed by Physician Assistant (PA) 1, and the procedure was done within accordance to universal protocol. In addition,

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Education and Training

1. Re-educate medical staff, via medical staffing memo, regarding compliance with the Central Line Insertion: Catheter Related Bloodstream Infection Bundle policy. Specifically, to ensure that a diagnostic medical imaging x-ray is immediately performed and read by the line inserter to confirm line placement.

2. Re-educate medical staff, via medical staffing memo, regarding compliance with documenting in the medical record that a diagnostic medical imaging x-ray was obtained, and line placement was confirmed immediately following the central line placement.
the "Patient care was supervised by [name of Physician 1]."

There was no indication in Patient 1's medical record that a KUB was obtained immediately following the procedure to verify correct placement of the right femoral central line.

During an interview with the Director Emergency Department (DED), on November 3, 2016, at 1:35 p.m., DED reviewed the medical record and was unable to find documentation of an x-ray being done after the placement of the femoral central line, on June 5, 2016, to verify placement. The DED stated, per facility policy and procedure, a KUB x-ray should have been done to verify placement of the femoral central line.

During an interview with PA 1, on June 16, 2016, at 12:20 p.m., he stated he placed the right femoral central line for Patient 1 on June 5, 2016, at the request of Physician 1. PA 1 stated Patient 1's head was elevated because he was on a respiratory ventilator, he obtained consent for the procedure from the patient's responsible party, and he used ultrasound guidance to place the right femoral central line. PA 1 stated the vessels were deep, Patient 1 had "difficult anatomy," and dark blood was obtained which indicated venous blood rather than arterial which would be bright red. PA 1 stated for verification of correct placement of a central line placed in the neck or arm a chest x-ray was obtained, "(I) do not get an x-ray (for verification) of a femoral central line." PA 1 stated correct placement was not verified by an x-ray when Patient 1's femoral
central line was placed on June 5, 2016.

Patient 1 was transferred to the Intensive Care Unit on June 5, 2016, at 3:49 p.m., shortly after the placement of the femoral central line.

The physician's "Progress Note" dated June 5, 2016, at 11:51 p.m. (nine hours and 39 minutes after the line was inserted), indicated "Right lower extremity [the lower extremity refers to the part of the body from the hip to the toes] with decreased pulsation [pulses] and mottling [patches of different colors or shades to the skin/blotchy] possibly arterial insufficiency [slowing blood flow in the arteries]."

The physician's orders included bilateral lower extremity arterial Doppler study (a test to determine adequate blood supply) scheduled for the next morning (June 6, 2016), baseline coagulation studies / DIC panel (multiple lab tests to evaluate the blood's ability to clot), heparin drip (medication used to prevent the formation of blood clots).

A physician's "Progress Note" dated June 6, 2016, at 10:26 a.m., indicated the right lower extremity had decreased pulses and mottling which was possibly due to inadequate blood flow.

The Doppler study titled, "Bilateral Lower Extremity Arterial Duplex Ultrasound" dated June 6, 2016, at 10:54 a.m., indicated blocked blood flow to the femoral artery leading to the right leg.

The CT (Computed Tomography - makes use of
computer-processed combinations of many X-ray images) results dated June 6, 2016, at 2:46 p.m., indicated there was a complete blockage of Patient 1's right superficial femoral artery, popliteal artery (located in the upper thigh extending behind the knee), anterior tibial (the inner bone between the knee and ankle) artery, and posterior tibial arteries (located behind the knee and ankle). The report also indicated there was a catheter positioned in the right femoral artery.

The "Operative Record" dated June 6, 2016, at 3 p.m. (greater than 26 hours after the right femoral central line had been placed), indicated Patient 1 was taken to the Operating Room (OR) for several emergent surgical procedures to remove the catheter and to try to restore blood flow to Patient 1's right leg.

The "Right Lower Extremity Arterial Duplex Ultrasound" dated June 7, 2016, at 2:34 a.m., which was completed following surgery on June 6, 2016, indicated there still was a blockage of blood flow to the arteries in the patient's leg.

The "Operative Record" dated June 7, 2016, at 6:25 a.m., indicated Patient 1 was returned to the OR for a "Thrombectomy [excision of a clot from a blood vessel] right lower extremity with angiogram due to right lower leg ischemia [restriction in blood supply to tissues]."

The physician's "Progress Note" dated June 8, 2016, at 10:15 a.m., indicated "The triple lumen catheter was in the right superficial femoral artery leading to arterial occlusion. Vasopressors [a powerful class of drugs that induce narrowing of
SUMMARY STATEMENT OF DEFICIENCIES

Blood vessels to raise blood pressure were administered via the catheter leading to severe vasoconstriction of runoff arteries leading to severe muscle ischemia and trash foot and leg caused by a blockage of the small blood vessels in the foot that reduces the flow of blood and oxygen to the tissues. Explained to patient's spouse that patient would need a right above the knee amputation."

The physician's "Progress Note" dated June 9, 2016, at 11:55 a.m., indicated a femoral artery occlusion "related to central line, placed in artery instead of vein."

The "Operative Record" dated June 13, 2016, at 1:25 p.m., indicated Patient 1 was returned to the OR a third time, for a right leg above the knee amputation due to an ischemic (inadequate blood supply) right lower leg. The "Operative Report" dated June 13, 2016, at 4:43 p.m., indicated, "The right foot and lower leg was already severely ischemic and trash at time of surgery due to vasopressors [medications used to increase blood pressure] administered via central line in superficial femoral artery... Right lower extremity gangrenous [death of body tissue due to a lack of blood flow] changes."

On July 2, 2016, Patient 1 was transferred to a Long-Term Acute Care Hospital (a type of facility that specializes in the treatment of patients with serious medical conditions that require care on an

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The facility policy and procedure titled "Central Line Insertion: Catheter Related Bloodstream Infection (CR-BSI) Bundle" revised November 2014, revealed "Correct placement is verified by a chest x-ray immediately following the procedure or a KUB if femoral insertion site is used. ... Post insertion X-ray should be immediately performed and read by line inserter, as often a second reader might not notice and/or the inserted catheter might obscure the vision of the wire."

The facility failed to implement their policy and procedure regarding verification of central line placement. This failure contributed to the delay in the identification of a misplaced right femoral central line resulting in the above the knee amputation of Patient 1's right leg.

These failures are deficiencies that have caused, or are likely to cause serious injury and/or death to the patient, and therefore constitute an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.3(g).
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).