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

Complaint Intake Number:
CA00372036 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 22705, 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.

1280.1 (d) Health & Safety Code

This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2008, 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

Event ID: HEBL11 1/21/2014 3:34:15PM

By signing this document, I am acknowledging receipt of the entire citation packet.

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 patient. 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.
administrative penalty, and up to one hundred thousand dollars ($100,000) 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.

1317(a) Health & Safety Code

Emergency services and care shall be provided to any person requesting the services or care, or for whom services or care is requested, for any condition in which the person is in danger of loss of life, or serious injury or illness, at any health facility licensed under this chapter that maintains and operates an emergency department to provide emergency services to the public when the health facility has appropriate facilities and qualified personnel available to provide the services or care.

1317.1 (a) Health & Safety Code

(1) "Emergency services and care" means medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition or active labor exists and, if it does, the care, treatment, and surgery by

Fetal Heart Tones education was created November 8, 2013 and submitted to all nurses for review. A post test was created and mandatory for all nurses to complete by January 10, 2014. To enhance the completed Fetal Heart Tones education All ER nurses will be provided an OB physician’s schedule, which is twice a month, and scheduled to job shadow the OB physicians in their outpatient clinic to improve competency. The ER Manager will be responsible to ensure that the education is completed.

All ED RN’s will have attended a rotation with the OB physicians that have a clinic twice a month at GMC by April 30, 2014. This provides the RN with a hands-on approach to determining Fetal Heart Tones and delineating between mom and baby’s HR. Proof of attendance and competencies completed by the OB physician will be filed in the ED Manager’s records.

Staff RN’s were reminded and will complete a competency on the necessity to document all communications between RN and Physician by April 30, 2014. Staffing changes have occurred in the ED. The ED Manager continues complete chart audits on 100% of all pregnancy related visits to the ED.
a physician necessary to relieve or eliminate the emergency medical condition, within the capability of the facility.

Based on interview and record review, the facility failed to ensure that emergency services and care were provided to Patient 1, a pregnant female and her unborn child (Patient 2), including a complete Medical Screening Examination (MSE) to determine if an emergency condition existed, upon presentation to the Emergency Department (ED). The hospital failed to ensure that Patient 1 and Patient 2 received a uniform standard quality of patient care, treatment and efficiency consistent with generally accepted standards and based on the hospital's Medical Bylaws, as evidenced by:

1. The facility failed to ensure that the signs and symptoms of Preeclampsia (a life-threatening hypertensive disorder of pregnancy), exhibited by Patient 1, were recognized and identified. Preeclampsia is diagnosed when a pregnant patient has blood pressure (BP) that is greater than or equal to 140 mm-Hg (millimeters of Mercury) systolic (maximum pressure) or greater than or equal to 90 mm Hg diastolic (minimum pressure) on two occasions at least 4 hours apart after 20 weeks of gestation (pregnancy) with proteinuria (protein in the urine) in a woman with a previously normal blood pressure. Or in the absence of proteinuria, the patient has new-onset hypertension (high blood pressure) with the new onset of any of the following symptoms: cerebral (brain: headache) or visual symptoms (blurry vision), thrombocytopenia (low platelets), impaired liver

Event ID:HEBL11 1/21/2014 3:34:15PM
function (elevated liver enzymes), impaired kidney function or pulmonary edema (fluid in the lungs).

2. The facility failed to ensure that Patient 1 received a complete MSE, including an examination for facial and hand edema (swelling) and clonus (a cerebral symptom that causes the patient to make large motions after checking the patient's reflexes and is indicative of nervous system irritability) to ensure that Patient 1 did not have Preeclampsia before she was discharged home.

3. The facility failed to ensure that Patient 1 received a necessary, but routine, urine test to check for protein in the urine (proteinuria) as well as basic blood-work and clotting studies (lab test to see if the blood will clot);

4. The facility failed to ensure that Patient 1 and Patient 2 received an Obstetrical (OB) consultation (a review by a physician specializing in the treatment of pregnant patients);

5. The facility failed to ensure that Patient 1 and Patient 2 were effectively monitored;

6. The facility failed to ensure that Patient 1 received other laboratory testing, to determine if she had Preeclampsia;

7. The facility failed to ensure that emergency room policies were in place to address the care and transfer of high risk pregnant patients and;

All Emergency Room staff will be required to read the MSE policy and it will be posted in the Emergency Department, as well as sent to all Emergency Room Physicians. The ER Manager and ER Medical Director will be responsible to ensure that the policy completes the approval process and is read by all ER staff and ER Physicians.

The Emergency Care & Transfer policy and procedure has been updated to reflect the most recent guidelines, referenced in the CHA EMTALA, a guide to patient anti-dumping laws, 2012 edition and EMTALA Answer book, 2014 edition. This policy has been submitted for approval on 12/19/2013. All Emergency Room Staff will be required to read the policy. The ER Manager and ER Medical Director will be responsible to ensure that the policy completes the approval process and is read by all ER staff and ER Physicians.

The Hypertension screening policy and procedure was updated to reflect the American College of Obstetricians and Gynecologists (ACOG) guidelines for 'Management of Preeclampsia and Eclampsia, date January 2002. This policy has been submitted for approval on 12/19/2013. All Emergency Room Staff will be required to read the policy. The ER Manager and ER Medical Director will be responsible to ensure that the policy completes the approval process and is read by all ER staff and ER Physicians.

The ED Care of the Pregnant Patient policy and procedure was submitted for approval on 12/19/2013. The policy addresses the "hallmark" signs and symptoms of an at risk patient, related history to obtain, tools for the assessment, recommended testing, consultation recommendations and transfer. The Emergency Room staff and Physicians will be required to read the policy. The ER Manager and ER Medical Director will be responsible to ensure that the policy completes the approval process and is read by all ER staff and ER Physicians.
8. The facility failed to ensure that Patient 1, who presented to Hospital 1's ED (Emergency Department) with a hypertensive (high blood pressure) emergency and term pregnancy (Patient 2), was given stabilizing treatment. In this case, medications for blood pressure control and seizure prophylaxis (prevention), and delivery of the baby (Patient 2) as necessary or stable transport to a higher level of care at another hospital, before she was discharged from the hospital (Hospital A). These failures resulted in the delayed diagnosis and treatment of Preeclampsia syndrome, a progressive disease, and caused the condition to progress to Eclampsia (seizures in the pregnant patient, a life-threatening condition) which then led to the death of both Patient 1 and her unborn child (Patient 2).

Findings:
During an interview and record review on 10/9/13 at 2:25 pm, ED Physician (MD A), confirmed she was the physician who cared for Patient 1 when she came to the ED on 9/29/13. MD A stated she examined Patient 1 who complained of burning in the epigastric (upper middle abdomen near the liver) area. MD A stated that Patient 1 told her she had eaten hot peppers with a meat sandwich then started having epigastric pain a couple of hours later. Patient 1 denied being in labor and reported no problems with this pregnancy. Patient 1 was non-English speaking and a family member interpreted. Also, MD A confirmed she was board certified in Family Practice Medicine instead of Emergency Medicine. MD A was asked what she knew about the signs of Preeclampsia and she...
stated high BP and edema (swelling). MD A was unable to state the blood pressure range for patients with Preeclampsia. MD A was asked if a urine test to check for protein had been done. MD A explained that there was no lab staff, present in the facility, at the time Patient 1 was in the ED. She stated that there would have been a lab person on call but she would have taken 30 minutes to get to the hospital. MD A confirmed she did not order a urine test although she stated that if a urine dipstick (a test strip that is dipped into a cup of the patient's urine to check for protein) had been available in the ED, she would have used it. MD A was asked if there was a written ED protocol or standard practice for pregnant patients who present to the ED. MD A stated, "not particularly; do a FHT (fetal heart tones) and an exam." MD A was asked if she was aware of any national standards of care and stated, "No," if concerned, she would call Hospital E (trauma center that has high risk OB). MD A stated that she could speak to the charge nurse at Hospital E and they would usually recommend transfer of the patient to their hospital.

During an interview on 10/10/13 at 11:35 am, the Chief of Staff/ED Medical Director (MD B) stated that an average of 450-550 patients come to the ED each year and 5% are pregnant, including all stages of pregnancy. MD B was asked about the lack of policies for care of the pregnant patient while in the ED. MD B stated that the policies were "well intended, but not something we use." He stated that Patient 1 had been discharged with an unacceptably high BP. MD B confirmed that the MSE for Patient 1 was done at 9:42 pm on
9/29/13 and Patient 1 was discharged at 10:40 pm, so there would have been time for the lab tech to have been called in and have the urinalysis done to check for proteinuria, had it been ordered, before Patient 1 was discharged home. MD B was asked about the lack of policies pertaining to treatment of Obstetrical patients in the ED. MD B stated that he sees the policies when they are updated, but he does not review all of them. He stated that a policy was not something that they would look up frequently. MD B confirmed that a plan of action to prevent similar incidents from happening again had not yet been formulated.

Review of the Emergency Room/Outpatient Record, dated 9/29/13 and timed 9:12 pm, indicated that Patient 1 was a "29-year-old female, Chief Complaint (reason patient came to the ED) of Upper stomach/ back pain, 9 months pregnant." The initial vital signs included "blood pressure 172/110 (normal is less than 120/80)." The Physical Exam section indicated that Patient 1 was in "moderate distress." Abdominal physical exam findings were indicated as, "Tender, right, upper epigastric, FHT (fetal heart tones) 132." The Psych Affect (psychiatric or psychological emotional state) portion of the physical exam form indicated Patient 1 was "Very Anxious." The Physical Exam section "Extremities," which allowed a practitioner to circle if the Patient's hands or feet were tender, swollen or had edema, was left blank. There was no evidence that Patient 1's reflexes were checked, which could have detected clonus (a sign of Preeclampsia). The section of the record that indicated X-ray and laboratory test
results was blank. There was no evidence that the fetus (Patient 2) was monitored for well-being after the initial vital signs (blood pressure, pulse, FHT) were taken. Under "Diagnosis" Hypertension of any kind, was not mentioned.

After Patient 1 returned home on 9/29/13, an ambulance was called at 11:11 pm and arrived at her home at 11:20 pm. Patient 1 was taken to another facility (Hospital E). Upon arrival, Patient 1 began having seizures and her baby (Patient 2) was found to be without a heartbeat and was delivered stillborn. Patient 1 was diagnosed with a catastrophic brain bleed, pronounced brain dead and taken off life support on 10/1/2013 at Hospital E.

A review of Hospital 1's policy and procedure titled "Medical Screening Examination", last revised 6/06, read that any unscheduled patient...receives a Medical Screening Examination (MSE) sufficient to determine if an emergency medical condition exists". A review of Hospital 1's ED policy and procedure manual disclosed there were no policies that dealt with the care and treatment of Obstetrical patients who presented to the ED. During an interview on 10/9/13 at 11:30 am, the Chief Nursing Officer confirmed that they had no such policies and procedures.

A review of Hospital 1's Medical Staff Bylaws, revised and adopted on 11/29/12, indicated, "These Bylaws are adopted in recognition of the mutual accountability, interdependence and responsibility of the Medical Staff and the

<table>
<thead>
<tr>
<th>(X4) ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>(PREFIX TAG)</td>
<td>(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
<td>(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
</tr>
</tbody>
</table>

1317(a) 1-8 continued from page 7

The Standing Orders policy and procedure was updated to include the protocol for OB patients equal to or greater than 20 weeks gestation. The Standing Orders policy and procedure was submitted for approval on 1/19/2013. The ER Manager and ER Medical Director will be responsible to ensure that the policy completes the approval process and is read by all ER staff and ER physicians. The Chief Nursing Officer and Administrator will ensure compliance.

An education series "Key Elements for the Management of Hypertensive Crisis In Pregnancy" published by ACOG in 2013. The education will provide criteria for diagnosis of chronic hypertension in pregnancy, criteria for diagnosis of preeclampsia or eclampsia in the emergency room, criteria to treat, medications, warning signs of deterioration in patient status, patient education, and transfer or consult criteria.

The education will be mandatory for all ER nursing staff and ER physicians. The first education series is scheduled for the first Thursday in January 2014. Post test will be completed by all ER nursing staff and ER physicians. The ER Manager will keep the post test records for the ER nursing staff and will ensure that all nursing staff complete the education. The ER Medical Director will ensure that all ER Physicians complete the education. All ER Physician post tests will be kept in the Medical Staff office.

The education series will be implemented and made part of the ER nursing staff and ER Physicians' orientation. The education will be completed on an annual basis by all ER nursing staff and ER Physicians.

The ER Manager and the ER Medical Director will monitor the compliance of all staff in completing the education. The Chief Nursing Officer and Administrator will ensure compliance.
Governing Body of (name of facility) in protecting the quality of medical care provided in the hospital and assuring the competency of the hospital's Medical staff. "1.3-1a. The Medical Staff's purposes are: To assure that all patients admitted or treated in any of the hospital services receive a uniform standard of quality patient care, treatment and efficiency consistent with generally accepted standards attainable within the Hospital's means and circumstances." "1.3-2d. The Medical Staff's responsibilities are to establish and enforce, subject to the Governing Body approval, professional standards related to the delivery of health care within the Hospital."

Review of the American College of Emergency Physicians (ACEP) article published in 3/2009, entitled "Focus On: Preeclampsia" indicated, "Preeclampsia is defined as hypertension and proteinuria (protein in the urine) that occur after 20 weeks gestation. " Diagnostic criteria for preeclampsia include a systolic blood pressure greater than 140 mm-Hg or a diastolic blood pressure greater than 90 mm Hg in a woman who was normotensive (normal BP) prior to 20 weeks gestation." "Severe preeclampsia is diagnosed by a systolic blood pressure greater than 160mm Hg or diastolic blood pressure greater than 110 mm Hg, excess proteinuria, severe oliguria (low urine output), cerebral or visual disturbances, pulmonary edema (excess fluid in the lungs), impaired liver function, epigastric or right upper quadrant pain, thrombocytopenia (low platelet count), or fetal growth retardation (poor fetal growth). Additional studies include serum
creatinine (kidney function test), platelet count, serum alanine and aspartate aminotransferase concentrations (ALT and AST - Liver function tests) ... The HELLP syndrome (hemolysis, elevated liver enzymes and low platelets) is a sign of severe preeclampsia. Every patient should have fetal heart sounds checked to confirm viability as part of the patient's vital signs. "A non-stress test (electronic fetal heart monitoring) or biophysical profile (test to monitor the fetus) is used to evaluate fetal well-being. Visual disturbances, severe headaches and liver tenderness in patient with severe preeclampsia should be treated aggressively to prevent progression to seizures and maternal organ damage." "Management should focus on blood pressure control, seizure prophylaxis (prevention) and treatment, and delivery when necessary. Although obstetric consultation is warranted in every case of Preeclampsia, emergency physicians should be comfortable with the initial management."

The facility failed to ensure that Patient 1's signs (severe high blood pressure and tender right upper epigastric-liver area) and symptoms (epigastric pain, headache) of Preeclampsia were recognized and failed to ensure that she received a complete and adequate MSE, including a routine urine dipstick test for proteinuria, and an OB consult. The facility also failed to ensure that Patient 1 and Patient 2 were closely monitored during the 1 1/2 hours she remained in the ED despite presenting with severe high blood pressure (hypertension) that did not return to normal, and epigastric pain that was not fully relieved. The facility failed to ensure...
that Patient 1's emergency medical condition was identified, due to failure to perform an adequate MSE, did not ensure that Patient 1 was treated for severe HTN and allowed Patient 1 and Patient 2 to be discharged home without adequate treatment and stabilization.

The failure of the facility to provide emergency services and care caused or likely caused serious injury or death of Patients A and B.

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).