

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050093	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/02/2008
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NAME OF PROVIDER OR SUPPLIER SAINT AGNES MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 1303 E. HERNDON AVE., FRESNO, CA 93720 FRESNO COUNTY
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	<p>The following reflects the findings of the California Department of Public Health during a Complaint Investigation conducted on 6/2/08.</p> <p>For Complaint CA00151250 regarding California Code of Regulations, Division 5, Chapter 1, Section 70739(a) Infection Control Program.</p> <p>Inspection was limited to the specific complaint investigated and does not represent a full inspection of the facility.</p> <p>Representing the California Department of Public Health: [REDACTED] /HFEN, [REDACTED] Infection Control Consultant, [REDACTED] MD/Physician Consultant, [REDACTED] /Physician Consultant, [REDACTED] /HFEN and [REDACTED] /HFEN.</p> <p>1280.1(a) HSC Section 1280</p> <p>If a licensee of a health facility licensed under subdivision (a), (b), of (f) of Sections 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation.</p> <p>1280.1 (c) HSC Section 1280</p> <p>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</p>			
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Event ID: J9Y511

8/14/2008

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

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	<p>Continued From page 1</p> <p>injury or death to the patient.</p> <p>California Code of Regulations, Division 5, Chapter 1, Section 70739(a) Infection Control Program</p> <p>(a) A written hospital infection control program for the surveillance, prevention and control of infections shall be adopted and implemented.</p> <p>Based on staff interview, administrative and clinical record review, the hospital failed to ensure a system was developed and implemented to identify, report, investigate, and control surgical site infections for seven of seven patients who had cardiopulmonary bypass surgery (Patient's 1, 2, 3, 4, 5, 6, and 7). The facility failed to protect patients from potential undue adverse surgical site infections which resulted in an Immediate Jeopardy situation.</p> <p>An Immediate Jeopardy was declared on 5/23/08 at 4:40 p.m. The CEO, Infection Control nurse, Senior Administrator Director, Risk Manager, Chief Medical Officer, Infectious Disease/Epidemiologist and Administrative nurse were notified. The facility submitted an acceptable Plan of Action and the Immediate Jeopardy was lifted on 5/29/08 at 1:40 p.m.</p> <p>The facility's failure to protect patients from potential harm including death due to adverse surgical infections consequences is evidenced by the following regulatory deficiency:</p> <p>The hospital failed to ensure a system was developed and implemented to identify, report,</p>			

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	<p>Continued From page 3</p> <p>Surgeon 2 had: 4 instances of sternal and 4 instances of donor site infections.</p> <p>Documentation also disclosed that seven additional cardiovascular surgeons had a total of 15 sternal and donor site infections.</p> <p>During an interview on 5/23/08 at 2:00 p.m., the Infection Control (IC) practitioner could provide no evidence that the hospital had analyzed or acted on the 2007 cardiopulmonary bypass surgical site infection data.</p> <p>On 5/23/08 a request was made for a list of all patients who had cardiopulmonary bypass grafts surgery after 1/1/08. Additional documentation was requested for the same time period listing Surgeon 1's and Surgeon 2's cardiopulmonary bypass patients.</p> <p>The first document showed that nine cardiovascular surgeons performed 153 cardiopulmonary bypass grafts surgeries after 1/1/08.</p> <p>The second document showed that Surgeon 1 and Surgeon 2 had performed 89 of the 153 coronary bypass graft/coronary valve replacement surgeries after 1/1/08.</p> <p>During an interview on 5/23/08 at 2:00 p.m., the IC Practitioner stated the hospital had confirmed four of Surgeon 1's and Surgeon 2's cardiovascular surgery patients had developed surgical site infections since 1/1/08. The IC Practitioner also</p>				

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	<p>Continued From page 4</p> <p>stated the hospital had received information that four additional patients had developed surgical site infections after having coronary artery bypass graft surgery by either Surgeon 1 or Surgeon 2.</p> <p>When asked about the process for receiving data or surgical site infections, the IC Practitioner stated information about the eight patients was received from Hospital B. The IC Practitioner stated Hospital B did not perform coronary artery bypass or coronary valve replacement surgeries. The IC Practitioner stated Hospital B had contracted with the hospital, and Surgeon 1 and Surgeon 2 to provide those services.</p> <p>The IC Practitioner stated the hospital was not aware of any surgical site infections for the nine cardiovascular surgeons. When questioned about the process for collecting surgical site infection data for the cardiovascular surgeons other than Surgeon 1 and Surgeon 2, the IC Practitioner stated the hospital would not have knowledge of surgical site infections unless a patient was readmitted to the hospital for treatment, or had wound cultures done at the hospital.</p> <p>A request was made to review the medical records of the coronary bypass graft patients who developed surgical site infections, or had been identified with possible surgical site infections. The hospital provided the medical records for Patient's 1, 2, 4, 5, 6, and 7. Documentation in the six medical records showed the patients had coronary artery bypass graft surgeries after 1/1/08.</p>				

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	<p>Continued From page 5</p> <p>Included with the medical records for the six patients the hospital had identified with surgical site infections or possible surgical site infections was the medical record for Patient 3. It was noted Patient 3 was not included in the original list of patients who had developed or had been identified with possible surgical site infections.</p> <p>Patient 3's medical record was reviewed, and documentation showed that Patient 3 had coronary artery bypass graft surgery on 2/29/08.</p> <p>Documentation in the seven medical records showed coronary artery bypass graft surgeries were performed by either Surgeon 1 or Surgeon 2. Documentation in the seven medical records showed Surgeon 3 was the assistant surgeon for the seven cases. Documentation in the medical records also showed the veins used for the bypass grafts were harvested (removed for the original site), by an endoscope (flexible lighted tube that is insert through the skin to collect the vein or artery), in place of making a surgical incision to remove the vein or artery.</p> <p>A review of the hospital's first quarter of 2008, surgical site infection data showed the majority of infections were at the donor site. It was also noted that some patients had sternal and donor site infections. The instances of multiple infected surgical sites totaled 11 surgical site infections, caused by different organisms.</p> <p>From the document listing the 89 patients whose coronary artery bypass graft surgeries were</p>			

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	<p>Continued From page 7</p> <p>why their coronary artery bypass graft patients developed surgical site infections more than twice their benchmark goal.</p> <p>The hospital submitted an acceptable Plan of Action on 5/29/08 at 1:40 p.m. and the Immediate Jeopardy was abated.</p>				

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