CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050093	A. BUILDING _____ B. WING _____	09/12/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SAINT AGNES MEDICAL CENTER	1303 E. HERNDON AVE., FRESNO, CA 93720 FRESNO COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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
	The following reflects the findings of the California Department of Public Health during the investigation of Entity Reported Event Entity Report Event # CA 00161748. Penalty Number #04-2087-0005487-S For Entity Reported Event CA00161748 regarding California Code of Regulations, Division 5, Chapter 1, Article 3-70213(a) written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service and California Code of Regulations, Division 5, Chapter 1, Article 3-70215(a)(b) Planning and Implementing Patient Care. Inspection was limited to the Entity Report Event and does not represent a full inspection of the facility. Representing the California Department of Public Health: [redacted] 1280.1 (a) HSC Section 1280 If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 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. 1280.1 (c) HSC Section 1280		POC ACCEPTABLE YES ☑ NO ☐ Reviewed By: Shirley Campbell Name Facility Notified Name: Amy Schneider Date: 10/6/08 Time: 10:41 Am Notified By: S Campbell Name RECEIVED OCT 15 2008 DEPT OF HEALTH SERVICES LICENSING & CERTIFICATION - FRESNO	

Event ID:TX0V11 10/2/2008 1:23:24PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Amy Schneider TITLE: Patient Safety Officer (X6) DATE: 10/10/08

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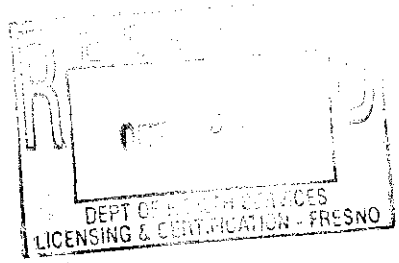
	Continued From page 1 For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY California Code of Regulations Division 5, Chapter 1, Article 3-70213 (a) Nursing Service Policies and Procedures. (a) Written policies and procedures for patient care shall be implemented by the nursing service. California Code of Regulations Division 5, Chapter 1, Article 3-70215 (a)(b) Planning and Implementing Patient Care. (a) A registered nurse shall directly provide: (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. Based on staff interviews, and clinical record and administrative document review the facility failed to ensure written policies and procedures for patient care were implemented by the nursing service and failed to ensure patient care was planned and implemented when: 1. Registered Nurse (RN) 1 failed to assess deterioration in Patient 1's condition for a period of		 1. Staff involved in this case was counseled. • Two staff involved in this case were re-educated about clinical criteria that triggers a Rapid Response Team (RRT) call, SBAR (Situation, Background, Assessment & Recommendation) communication tool for exchange of information during patient care hand-offs, chain of command, role responsibility of a Unit Coordinator, and signs / symptoms of post-op surgical complications. • Staff who were associated with the case and who participated in the Root Cause Analysis were re-educated about communication, documentation, RRT and	9/5/08 9/8/08

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Tammy Schneider TITLE Patient Safety Officer (X6) DATE 10/10/08

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	Continued From page 2 four hours after Patient 1's arrival to a surgical floor from a post-op abdominal hysterectomy (removal of uterus) and bilateral salpingo-oopherectomy (removal of fallopian tubes and ovaries). 2. RN 1 failed to implement policies and procedures that included interventions when Patient 1 exhibited signs and symptoms of a declining condition. The signs and symptoms of the declining condition included the following: persistent low blood pressure, pale, cold and clammy skin, abdominal distention and decreased urine output to less than 50 cc's (a method of liquid measure) in a period of four hours. The cumulative effects of the facility's failure to ensure nursing staff provided care that reflected the nursing process including accurate assessment and implementation by notifying the surgeon and the rapid response team (RRT) allowed a continued deterioration in the condition of Patient 1, who expired during the night following her surgery. An Immediate Jeopardy was declared on 9/9/08 at 2:00 p.m. The CMO, Director of Administrative Services, and the Patient Safety Officer were notified. The facility submitted an acceptable Plan of Action and the Immediate Jeopardy was lifted on 9/11/08 at 12:45 p.m. Findings: 1. On 9/3/08 Patient 1's clinical record was reviewed. It contained the following documentation: Patient 1 was admitted to the facility on 8/22/08 for		Code Blue policy and procedure, and initiation of timely interventions in the care of a post-op patient. 2. A thorough and credible Root Cause Analysis of this case was completed with participation from all relevant units and disciplines and Saint Agnes Medical Center leadership. An action plan for improvement was established that includes the following: • Re-education for Nursing Staff (inpatient, procedural areas & ER) using case study format on hand-off communication and Rapid Response Team criteria. • Difficult airway cart, invasive line supplies and rapid infuser all moved to one location in the central OR core for ease of accessibility *(completed 9/8/08).* • Revise PAT Pre-printed orders to clarify Lovenox orders. 3. Nursing staff on all inpatient units re-educated on use of SBAR hand-off communication tool for patient hand-off and resources available to consult for any patient concerns including criteria for Rapid Response Team call using a case study format. A staff roster is being used to ensure	9/8/08 9/19/08 9/8/08 9/22/08 9/19/08

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Amy Schneider TITLE Patient Safety Officer (X6) DATE 10/10/08

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	Continued From page 3 a hysterectomy due to cancer of the uterus. The pre-operative history and physical dated 8/15/08 indicated Patient 1 had no major medical problems. The admission summary indicated Patient 1 had a history of high blood pressure. The blood pressure on admission was documented as 183/74. The intra-operative record dated 8/22/08 indicated surgery began at 3:15 p.m., and ended at 4:57 p.m. Patient 1 was transferred to the Post Anesthesia Care Unit (PACU). The physician's operative report dated 8/22/08 indicated Patient 1 left the operating room in satisfactory condition with all bleeding controlled. The postoperative record dated 8/22/08 documented Patient 1 was admitted to the PACU at 5:01 p.m., and discharged at 6:30 p.m. to the surgical floor. During the time Patient 1 was in PACU her blood pressure (BP) ranged from a high of 155/60 on arrival to the PACU to a low of 110/47 just prior to discharge to the floor (normal BP range 100 to 140 over 60 to 90). The record indicated Patient 1's urinary catheter was emptied of 325 cc's (a cubic centimeter is a unit of liquid measurement) at 6:25 p.m. prior to going to the surgical floor. According to Mosby's Manual of Clinical Nursing Second Edition the symptoms of bodily collapse or near collapse caused by severe blood loss include: hypotension (low blood pressure), cool clammy skin and decreased urine output. The Professional Progress Record (PPR) contained the following entries; On 8/22/08 at 6:30 p.m., it documented Patient 1's arrival on the surgical floor. At 7:00 p.m. Patient 1's blood pressure was documented in the Patient		tracking of staff training each shift at the change of shift. *(Initiated 9/9/08 with a minimum of 95% of staff trained by 9/19/08).* • Posters/flyers placed in all units with the Rapid Response Criteria listed. 9/10/08 • Above case studies utilized in patient hand-off and Rapid Response Team staff training will be included in New Hire Orientation starting immediately & here forward. 9/10/08 4. A message was placed on all AcuDose cabinets regarding the contacting of the Rapid Response Team for all concerns/patient status changes. 9/10/08 *5.* This case and the corrective action plan were reviewed with the Unit Coordinators/RN Supervisors at the Bed Meetings (4 PM, 9 PM, 4 AM & 9 AM) and Nursing Leadership at their regularly scheduled weekly meeting. 9/9/08 9/10/08 6. A new Patient Care Policy and Procedure was developed and implemented regarding Unit Coordinators rounding on all immediate post-operative patients every 6 hours for the first 12 hours post op. *The new policy introduces the following practice patterns that were not in place before this sentinel event:* 9/10/08	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Amy Schneider TITLE: Patient Safety Officer (X6) DATE: 10/10/08

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	Continued From page 4 Graphic Flow sheet as 98/50. At 8:00 p.m., RN 1 documented Patient 1 had a BP of 80/50 and no urine output. It further indicated Patient 1 was pale and complained of being lightheaded. At 9:00 p.m., indicated Patient 1's BP was 80/41. There was no indication Patient 1 had any urine output. At 10:30 p.m. the entry indicated the Surgeon was first notified of Patient 1's declining condition with low blood pressure of 82/50 and no urine output (4 hours after the Patient 1 arrived to the surgical floor). At 10:35 p.m., RN 1 documented the surgeon's order for a 500 cc bolus of intravenous fluid was started and blood for laboratory tests for hemoglobin (Hgb) and hematocrit (Hct) (tests to determine anemia) were drawn. There was no indication Patient 1 had any urine output. At 11:45 p.m., RN 1 documented Patient 1's BP on the left arm was 72/52 and on the right arm it was 74/52. The entry indicated Patient 1's Hct was 27.9% (normal values 37 to 47 %) and the Hgb was 9.3 grams/deciliter (normal values 12 to 16 g/dL). There was no indication Patient 1 had any urine output. At 12:10 a.m., RN 1 documented calling the Surgeon to notify him of Patient 1's declining status. There continued to be no indication Patient 1 had any urine output. On 8/23/08 at 12:35 a.m., RN 1 documented the facility's Rapid Response Team (RRT-a hospital team designed to provide clinical support and intervention for patients needing immediate medical attention) was called (6 hours after Patient 1 arrived on the surgical floor). Patient 1's BP was documented to be 70/30, her abdomen tender and		• *The Unit Coordinator will be notified about a new post op patient at the time of transfer to the patient care unit* • *The Unit Coordinator will confer with the nurse and conduct a formal evaluation of the patient's post-op status and progress against the plan of care* within six hours of arrival to the unit (sooner if indicated) • *The Unit Coordinator will confer with the nurse to conduct a follow up evaluation within the second 6 to 12 hour post-op interval (sooner if indicated)* • *The Unit Coordinator will monitor and evaluate that the nurse has introduced timely interventions to promote patient stability and safety* 7. Unit Coordinator/Supervisor Rounding with any indicated follow up (Communication with MD, Rapid Response Team call per criteria, etc) will be tracked and monitored through the use of a Post operative Patient Rounding log for the next 60 days with results reported to unit managers and cross-referenced with the surgical schedule. The results of this monitoring will also be reported to Nursing Leadership weekly with	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Cindy K Schaudt TITLE: Patient Safety Officer (X6) DATE: 10/10/08

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	Continued From page 5 distended, and her appearance pale. The Rapid Response Team Record dated 8/23/08 was reviewed. It documented the RRT arrived at Patient 1's bedside at 12:34 a.m. The patient was pale, dizzy, cold and clammy, BP was 70/30 and urine output was less than 50cc in the prior six hours. The post operative note dated 8/23/08 at 3:00 a.m. indicated the surgeon saw Patient 1 at 12:30 a.m. He documented the patient was anemic, cold and clammy, and her abdomen was distended. The Surgeon decided to return Patient 1 to the operating room (OR). Prior to beginning surgery the Patient 1 became unresponsive and resuscitation measures were initiated. The Code Blue/Pre-crisis Intervention Documentation Record dated 8/23/08 indicated resuscitation efforts started at 1:45 a.m., and continued until 3:11 a.m. According to the record, Patient 1 expired at 3:13 a.m. 2. In an interview on 9/4/08 at 9:20 a.m., the Chief Medical Officer (CMO) stated, in reference to Patient 1, "the nursing staff delayed in calling the Rapid Response Team "(RRT) and the surgeon. The CMO stated "by the time they got her to the OR it was too late." In an interview on 9/4/08 at 10:13 a.m., the Chief Nursing Officer (CNO) stated the nurses at the bedside were able to and should call the unit coordinator, the crisis nurse or the RRT any time		actions and continued monitoring implemented as needed. *(initiated 9/10/08)* • Monitoring will be accomplished through Unit Coordinator/RN Supervisor concurrent critique of primary RN initial post-op assessment and timely intervention with results reported to Nursing Leadership weekly and the Crisis Assessment Team (Rapid Response and Code Blue Performance Improvement Committee) monthly. The Crisis Assessment Team reports results to the Critical Care Committee, the Quality Council and the Board of Trustees. Corrective actions will be initiated based upon results of monitoring. Monitoring and reporting will be implemented for 60 days and then re-evaluated to determine if additional monitoring is required. Responsible: Chief Nursing Officer RECEIVED OCT 15 DEPT OF PUBLIC HEALTH LICENSING & CERTIFICATION FRESNO	

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	Continued From page 6 there was a significant change in a patient's condition. The CNO stated the nurses "should notify the unit coordinator" as their first line of support when there was a change of condition in a patient. In an interview on 9/9/08 at 8:45 a.m., RN 1 stated the unit coordinator and the Surgeon were not contacted regarding Patient 1 until sometime after 10:00 p.m. on 8/22/08. (RN 1 contacted the surgeon at 10:30 p.m.). The RRT was not called for Patient 1 until 12:30 a.m. When asked why, RN 1 stated "I felt my interventions were enough". RN 1 stated "I probably should have called sooner" referring to the Surgeon, the RRT and the unit coordinator. In an interview on 9/9/08 at 9:15 a.m., the Unit Coordinator (UC) stated "RN 1 called at 10:15 or 10:30 p.m. and told me Patient 1 had a low BP and the Surgeon was called and gave orders". Unit Coordinator 1 stated "I received another call from RN 1 at 12:25 a.m., to report the patient had been dizzy, was pale with a distended abdomen, a low BP and no urine output. "The UC stated that based on Patient 1's low BP at 8:00 p.m., "I would have notified the surgeon at that time". The UC stated she felt RN 1 "should have notified me earlier and intervened sooner." In an interview on 9/9/08 at 9:30 a.m., the Surgeon stated he was first notified of Patient 1's low BP and lack of urine output after 10:00 p.m., on 8/22/08. The Surgeon stated "I should have been notified after two hours with no urine output". The			

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	Continued From page 7 Surgeon stated "it might have made a difference if Patient 1 had been taken to the operating room earlier". On 9/4/08 the facility's policy and Procedure for the Rapid Response Team and Emergency Care contained documentation that the RRT was to be called to prevent an actual or potential deterioration in a patient's condition. The policy contained the following documentation regarding the procedure "1. The person at the bedside determines that the patient was clinically unstable, at high risk of deterioration, or has an acute change in one of the following: ... C. Systolic BP less than 90 mmHg ... F. Urine output less than 50 ml in 4 hours ... 2. The person calls the Rapid Response Team ". The death certificate dated 8/28/08 listed the immediate cause of death as cardio-respiratory arrest with the underlying causes as Hemovascular shock, Intra-abdominal Hemorrhage and Post Operative Bleeding. RN 1 failed to notify the UC or surgeon for four hours, and the RRT for six hours, regarding the deteriorating condition of Patient 1 following her arrival on the surgical floor. The failures of RN 1 to timely assess the deterioration in Patient 1's condition and to timely implement interventions in accordance with the facility's policies and procedures constituted a noncompliance with one or more requirements of licensure that caused, or was likely to cause, serious injury or death to Patient 1.			

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Denyse Schneider Patient Safety Officer 10/10/08

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